



# The challenges and opportunities of using patient reported outcome measures (PROMs) in clinical practice

Michael Fleischmann<sup>\*</sup>, Brett Vaughan

College of Health and Biomedicine, Victoria University, Melbourne, Australia

## ARTICLE INFO

### Article history:

Received 4 January 2018

Received in revised form

12 March 2018

Accepted 29 March 2018

## ABSTRACT

From the standpoint of the healthcare provider, multiple contributors to a patients' clinical presentation, difficulty with translating research trials into one's practice, conflicting clinical practice guidelines, and an ever-increasing volume of literature compounds the difficulty for clinicians to determine best care, which addresses the biological, psychological and sociological health domains. If clinicians are adopting a patient centred model of care – routine use of validated patient reported outcome measures (PROMs) which elicit patients' views of their symptoms, their functional status, their health-related quality of life (HRQoL), all of which encompass several domains – are paramount. This commentary advocates for the use of PROMs on a wider scale than is currently described in the literature. Background information on PROMs is provided along with suggesting important questions to ask as a clinician when implementing these in practice. The current commentary addresses these questions and describes the implementation of PROMs using published case studies that describe osteopathy management for a variety of conditions.

Crown Copyright © 2018 Published by Elsevier Ltd. All rights reserved.

## Background

Substantial advances in the biological, social and psychological sciences shape the current healthcare provider era, bringing with it greater awareness of public health issues, readily accessible health information and treatments that aim to positively influence quality of life. This advancement has increased uncertainty in many aspects of healthcare delivery at the level that matters most to patients and clinicians: patient care. For many health professions, routine measurements such as radiographic imaging (magnetic resonance imaging) and/or clinical chemistry measurement in blood samples, physical tests such as muscle strength and joint range of motion, contribute to clinical decision-making however, research has shown that the relationship between clinical examination findings and patient symptoms is somewhat limited. Several research reports have demonstrated that clinical examination of the musculoskeletal system including the shoulder [1,2], hands [3] and lumbar spine [4] are limited, as they do not measure multiple domains of health. Furthermore, numerous studies have highlighted the dilemma of incidental findings reported in diagnostic imaging and whether they have a clinical impact [5,6].

The use of patient reported outcome measures (PROMs) may help bridge this gap as their use ensures the patients' values and expectations are present in all aspects of care ensuring management remains patient-centred [7], rather than tissue focussed or 'biomedical'. PROMs are defined as any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else [7–12].

### Patient reported outcome measures

PROMs were originally developed for comparing groups of individuals in clinical trials and population studies with the results used to develop treatment recommendations and inform health policy [7]. As the experience in the development and use of these measures increased, it became obvious that there was clinical value in using individual patient PROMs profiles in routine practice to provide clinicians with a standardised approach to monitor patient symptoms, evaluate treatment outcomes and support shared decision-making [7,9].

There is growing interest internationally in the routine integration of data from PROMs into the evaluation and decision-making activities at all levels of the health system, beyond just the clinical consultation. This has potential advantages for clinicians as it provides evidence based outcomes that stakeholders

<sup>\*</sup> Corresponding author. College of Health & Biomedicine, City Flinders Lane Campus, Victoria University, PO Box 14428, Melbourne, Victoria 3000 Australia.

E-mail address: [michael.fleischmann@vu.edu.au](mailto:michael.fleischmann@vu.edu.au) (M. Fleischmann).

understand, efficiently builds large-scale or national datasets, and ultimately improves patient care. There is however, a need for further theoretical development around the use and expected impact of PROMs to guide implementation and evaluation at all levels. As such osteopathy is caught in the middle of needing to validate their healthcare provision with evidence from PROMs.

Internationally, routine use and consistent exploration of the measurement properties of PROMs is being encouraged, or are already embedded in the health systems of several Organisation for Economic Co-operation and Development (OECD) countries. For example in 1975, the medical profession in Sweden established the nation-wide use of PROMs using disease-specific clinical databases known as quality registers [10]. By 2000, PROMs were introduced into some parts of the United States with the aim of extending PROMs as a reimbursement mechanism for accountability within care organisations [10].

In Australia, PROMs are an emerging method of assessing the quality of health care [13]. They yet to be embedded in routine measurement at a regional or national level, but they are routinely emerging in clinical trial work [14–16] and in healthcare policy advocacy. Government clearly shares the push for their use as evidenced by the Australian Commission of Safety and Quality in Healthcare commissioning research groups such as the University of Wollongong, New South Wales, to investigate their utility.

Since 2009, it has become mandatory in the United Kingdom to use PROMs to report outcomes for certain elective surgical patients as a method of collecting information on the effectiveness of patient care within the National Health Service (NHS) from the patient perspective [10]. This mandatory adoption of PROMs has been driven by the United Kingdom government to enable comparison of health service PROMs that can be used for various forms of individual-level feedback to improve treatment decisions made by patients and clinicians [10]. The broader emphasis on PROMs however, has led to the need for guidance on the development, use, measurement, and analysis and the establishment of a conceptual foundation for PROM assessment to overcome issues with PROMs.

PROMs are being used to evaluate healthcare effectiveness at different levels of the health system, from the individual to the service and system levels [13]. Research has demonstrated that their use during the clinical consultation and in multidisciplinary team discussions is thought to contribute to shared clinical decision-making and patient-centred care [7,10].

PROMs are in the form of questionnaires, which are usually designed to focus on one or more specific domains of a patient's health. Some PROMs specifically measure a combination of physical, mental and social domains, collectively known as health-related quality of life (HRQoL), while others evaluate single dimensions of health (i.e. physical activity, function), service aspects (i.e. patient satisfaction), or are disease specific.

Using condition-specific instruments has great potential for evaluating domains of physical functioning and health-related quality of life commonly affected by a specific pathology or body region dysfunction [17]. Condition-specific instruments include questions focused on issues or aspects of health that are commonly affected by the specific condition or body region dysfunction that is under consideration [18]. In the context of wrist osteoarthritis, condition-specific patient-reported outcome measures can be used to evaluate the impact of osteoarthritis on the upper limb, wrist and hand functioning [19]. Although the content of condition-specific instruments may vary somewhat depending on whether they focus on pathological symptoms or body region functioning (or both), they share a common goal of evaluating key elements of disability or health-related quality of life relevant to wrist arthritis sufferers [20].

Research has shown that systematically collecting patient

perspectives avoids the problem of observer bias [21]. In the context of spinal surgery, McCormick and colleagues [22] stated that clinicians' reports were biased and therefore may not reflect the impacts of treatment on the ultimate goals of improving function and quality of life and reducing pain. Of course, PROMs can be subject to bias and error, but this problem also affects so-called 'objective' measures such as blood tests, interpretation of diagnostic imaging and physical examinations. When looking at outcomes for individual providers or services, PROMs can be useful because they focus on what matters most to patients. Furthermore, patient involvement in outcomes reporting may also be health-promoting; for example, by improving adherence and allowing patients to monitor changes in their own condition [21,23].

Without the use of PROMs which provide valid measurement of many domains of a patient's health, and routine osteopathic examination, it is hard to make a verifiable case for the effectiveness of a treatment. Widespread adoption of PROMs in osteopathic practice is something for the profession to embrace as it has the potential to empower patients, support clinical decision-making, drive quality improvement and improve the evidence-base for osteopathy care.

Implementing routine PROMs involves many practical decisions, including (1) identifying the goals for collecting PROMs in practice, (2) selecting the patients, setting and method of assessment, (3) evaluating the impact of the PROMs intervention on clinical practice, and (4) identifying barriers and opportunities of using PROMs. This commentary will discuss these 4 points and provide a case study, which is aimed to assist the clinician in the use of PROMs.

#### *Identifying the goals for collecting PROMs in practice*

When searching for appropriate PROM to use with a patient, it is important to ask the following questions:

- (1) 'What do I want to measure?'
- (2) 'How do PROMs impact my clinical practice?'
- (3) 'What PROMs are recommended and being used by others?'
- (4) 'What domains/items are important for patients?'

The first question will help determine which health domains should be utilised, e.g., pain, mobility, social functioning and/or other. The second and third questions will aid selection of the appropriate tool.

PROMs have the potential to play a key role in bringing the patient's voice to evidence-based healthcare. However, to realize this potential, it is pertinent to interpret the relevance of PROMs in making decisions about treatment [24]. Such decisions are made at both the individual level, when a patient chooses among treatment options or decides to cease or reduce treatment, and at the group level, when clinical research is conducted to test the relative effectiveness of treatments, often testing a promising new treatment against current best practice. At both of these levels, it is imperative to know how much of a difference in PROM or HRQoL scores matters. The difficulty is working out to whom it should matter, and in what sense it should matter.

If one wished to measure the changes in a single patient with shoulder pain, to inform decisions about ongoing treatment, a condition-specific measure may be the best option [7]. It may even be optimal to use a generic, and condition-specific PROM and/or a patient generated scale in combination [7,9,25]. Whatever the final selection, the intended purpose of the outcome measurement should be clear – to ensure the right tool is selected for what is to be measured. PROMs selection should be based on the strength of their measurement properties which should be established in the population of interest, and on other key aspects including acceptability and interpretability. Table 1 provides definitions of

**Table 1**  
Common measurement properties.

|                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reliability                  | Reliability is the consistency between the score of a health outcome measure applied in different circumstances. The principle of reliability is that applying the PROM on separate occasions or by different observers produces similar results [26].<br>Encompasses: Test-retest reliability (degree to which results are replicated over time in stable patients); internal consistency (how well items that are grouped in a domain correlate); and, in interviewer administered PROMs, inter-rater reliability, i.e., agreement between two independent interviewers.                                                                     |
| Validity                     | Validity is the ability of the test to measure what is intended to measure. Validity can be broadly divided into three types (referred to as the 3 Cs), content validity, construct validity and criterion validity [26]<br>Encompasses:<br>> content validity (degree to which the PROM evaluates all important aspects of the disease/disorder;<br>> construct validity, whether behaviour of the measure is consistent with hypotheses regarding: (a) probable relationships with other instruments and/or (b) performance of the tool in different subgroups; and,<br>> criterion validity, i.e., correlation with a 'gold standard' [27]. |
| Responsiveness               | Responsiveness is the ability of the PROM tool to detect a change in patients' clinical condition. This is estimated by applying the health outcome measure to a group of patients whose clinical condition has changed [26].                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Acceptability                | Acceptability is the extent to which an instrument is acceptable to patients. Indicators of acceptability include administration time, response rates, and levels of missing data [28].<br>There are many factors that can influence acceptability including the mode of administration, questionnaire design, and the health status of respondents. The format of patient-reported instruments can also influence acceptability.                                                                                                                                                                                                              |
| Minimal important difference | MID is defined as the smallest difference in score in the domain of interest that patients perceive as important. The difference in score could be negative or positive, so either beneficial or harmful, and which would lead the healthcare provider to consider a change in the patient's management' [29].                                                                                                                                                                                                                                                                                                                                 |

commonly used measurement properties in questionnaires.

PROMs should be fit-for-purpose with respect to the above psychometric properties, scoring system, mode of administration, cost per administration [13]; Sansoni [30] reports that a battery of PROMs (with minimal overlap) will be required if PROMs data are to be put to many purposes. Further, for the purposes of patient monitoring and practice improvement, PROMs should be responsive to changes in the condition or disease that would mandate changes in patient management [13];

For the purposes of comparisons within conditions or diseases, PROMs should be sensitive to important changes in the condition or disease, provide a summary measure of changes in the condition or disease, and be able to differentiate between important subgroups within the condition- or disease-population [31].

For the purposes of comparisons across conditions (such as subacromial impingement) or diseases (rheumatoid arthritis), PROMs can be used to capture important changes in the relevant outcome for a broad range of conditions/diseases [31].

For performance measurement and benchmarking at provider- and system-levels, PROMs should be relevant to stakeholders and responsive (ACI, 2016 p19 citing NQF, 2013).

For the purposes of informing patient choice and facilitating shared care, PROMs should be meaningful to the target population [13]. Asking patients what matters to them (such as which domain to measure) when administering PROMs is recommended.

#### *Selecting the patients, setting and method of assessment*

The main advantage of generic instruments (i.e. SF-12) is that they are suitable for use across a broad range of health problems. They can be used for comparisons of treatments for different patient groups and are suitable for use with healthy populations to generate normative data [32]. Their broad scope means that they have potential to capture the influence of co-morbidity on quality of life, as well as unexpected positive or negative effects of an intervention. The flip side is that their broad applicability means that some level of detail or sensitivity is sacrificed, which may limit the relevance of generic instruments when applied to a specific patient population. Some measures are better than others in their ability to discriminate between individuals with different levels of severity at a single point in time [33], and some are better than others in their interpretability, which is their ability to detect change in minimal important difference (MID).

There are several resources available to aid location and

selection of validated PROMs. The Patient Reported Outcome and Quality of life Instruments Database (PROQOLID; [www.proqolid.org](http://www.proqolid.org)) can be searched for specific instruments (e.g., 'Neck Disability Index') or by disease/disorder (e.g., 'osteoarthritis'), or domain (e.g., 'pain') [34]. The International Society for Quality of Life Research (ISOQOL) has published recommendations on the agreed minimum measurement property standards for PROMs [35]. Finally, the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) group have produced a critical appraisal checklist (available at [www.cosmin.nl](http://www.cosmin.nl)) for the evaluation of PROM measurement properties [12,26,27,33,36,37].

Ruta et al. describe that the task faced by respondents completing individualised instruments is usually more difficult than that for instruments based on summated rating scales [38], such as a visual analogue score for pain. General features of layout, appearance, and legibility are thought to be important influences on acceptability.

PROMs should also be acceptable to their target population, both in terms of the questions asked (e.g., are they appropriately worded? easily understood?) and their overall patient burden (e.g., is the completion time for the PROM agreeable?). Ideally, PROMs are completed by patient self-report, as this provides a direct assessment of the patient's outcomes, but in some instances, patients are not capable of responding for themselves such as young children or the cognitively impaired [39,40], or potentially those with English as a second language (where a PROM has not been translated).

*Evaluating the impact of the PROMs intervention.* When evaluating the use of PROMs, clinicians ought to evaluate minimal important difference (MID) by comparing findings from the literature. Some PROMs that have been developed for use at the group level in research settings (especially generic tools) may be less reliable at the individual patient level [41–44], therefore, PROM measurement should always be used as an adjunct to clinical judgement [25,45] and adjusted for depending on case mix. In practice, this means standardising for the impact of patient characteristics and other factors to isolate the remaining effects of treatment efficacy and quality of care (which are within the reasonable control of the provider).

The use of PROMs data for performance measurement provides methodological challenges. First, the PROM itself should be valid and reliable for measuring treatment results at individual patient

level. Second, the performance measure as derived from the PROM data should be valid and reliable to identify practice variation and quality of healthcare providers. Third, data should be reported and presented in a clear manner to support clinicians and patients in making informed choices. Advanced methodology is needed to enhance interpretation of data in comparing the quality of providers to inform patients and purchasers. Based on emerging evidence, guidance and research efforts to improve the interpretability of patient-reported outcomes is likely to enhance decision-making and the impact from using PROMs in practice.

#### *Identifying barriers and opportunities of using PROMs in clinical practice*

**Barriers.** Reports have detailed that clinicians tend to be both sceptical of and possibly irritated by pressures to use patient reported outcome measures (PROMs) in practice [8]. The scepticism pertains, in part, to whether standardised instruments provide any added value in eliciting information about their patients when clinicians do thorough examinations already, especially when patient populations reflect such diversity i.e. sociodemographic differences and complex pain syndromes. Secondly, clinicians have been worried about the technical aspects of implementing them, such as the resources needed to make PROMs routine practice in the management of patients – possibly decreasing time doing manual therapy.

The number of available PROMs has dramatically increased over the past few decades; consequently, the choice of which PROM to use is becoming more difficult. There are often multiple instruments available for measuring the same health construct in the same patient population. For example, a systematic review published in 2005 identified 36 PROMs for measuring back-specific functional status in patients with LBP [46], all with varying measurement properties.

**Opportunities.** The routine use of PROMs provides an opportunity to help drive change in healthcare which is organised and delivered. There are four priorities for maximising the positive contribution PROMs provide patients (and family members), clinicians, 3rd party payers:

- Firstly, the osteopathic profession needs to combine initiatives to use PROMs for clinical management and for provider comparisons. Its routine practice now that 3rd party payers (such as workers compensation and private health insurers, and general practitioners on behalf of their referred patients) request completed PROMs to justify subsidised treatment for patient injuries and conditions.
- Secondly, we need to encourage the adoption of new data collection technologies such that PROMs become part of everyday care.
- Thirdly, we need to tackle the methodological challenges which pertain to the patient and clinician that remain unresolved to ensure PROMs are used appropriately.
- And finally, we must make use of the opportunity that PROMs present to develop value based care in which our osteopathic health service can be driven by health outcomes per dollar spent.

Holt et al. describe holism as, 'a philosophy or model of health care which involves providers and patients in a cooperative effort to establish and maintain optimal health and wellbeing of the whole person in his or her environment by using any activity modality of diagnosis, prevention and/or therapy capable of fulfilling the particular health needs of the patient' [47]. Osteopaths posit that they value being holistic healthcare providers, who employ the biopsychosocial model of care when managing patients however,

reports suggest that healthcare providers are not using validated outcome measures to ensure that all health domains are routinely examined [48–51]. Numerous authors have argued that clinical outcomes alone, even if thorough, cannot capture all relevant information about the patient and that there are some things only a patient can report [21,52]. Several authors have advocated for the use of PROMs to facilitate shared decision making and patient-centred care [7,10,45,53]. For example, Bitton et al. suggest that PROMs may help clinicians develop tailored recommendations for screening and prevention and promote a more personalised health system [54] – a holistic healthcare system.

#### **Practical examples**

There are numerous examples within the osteopathy literature demonstrating the selection and use of PROMs in patient care. Feehan et al. published a case report on the use of osteopathy care to manage an acute traumatic knee meniscus injury in a 25-year-old patient [55]. A multimodal approach was utilised including manual therapy and exercise rehabilitation. Although range of motion and pain was evaluated, the primary outcome measures selected were the Knee Injury and Osteoarthritis Outcome Score (KOOS) [56,57] and the Lower Extremity Functional Scale [58,59]. The case report provides an example of the use of two PROMs and in this case, the use of a PROM (KOOS) that captures HRQoL, activities of daily life (ADL) and sport related function impairment. Further, the measurement properties of these measures are well described in the literature [58,60] providing additional support for their use. Another case report by Ross et al. described the use of a condition-specific PROM to evaluate the outcomes of osteopathy care for an Achilles tendinopathy [61]. The selection of PROMs in the case report by Bennett et al. [62] was guided by the literature describing the responsiveness of the measure for the specific condition being managed, in this case subacromial impingement. These case report examples demonstrate that a range of readily available PROMs assessing multiple domains, are suitable for routine use in osteopathy practice. A previous commentary by Vaughan and DiVenuto [63] provided an overview of common PROMs that could be readily used in daily clinical practice and although this was published over 10 years ago, many of these PROMs still have utility in practice.

#### **Conclusion**

If clinicians truly are adopting a patient-centred, holistic model of care routine use of validated PROMs which elicit patients' views of their symptoms, their functional status, and their health-related quality of life (HRQoL) is paramount. Routinely collecting data via PROMs may increase the accountability of osteopathic service and provision and provide more evidence of positive outcomes, which is the lifeblood in the century of evidence-based medicine.

The use of PROMs to measure health status in routine practice has some distinct advantages over traditional clinical examination and outcome measures (i.e. range of motion), as they may directly facilitate change behaviour for patients, clinicians, and policy-makers [7,9,64–66]. Further benefits are highlighted by Sprangers et al. [67] who found that PROMs can assist in the identification of patients who may be susceptible to poor quality of life, which in turn can enable better targeting of specific support, such as psychological, social and/or referral for pharmacological treatment. In addition, these authors note the importance of administering PROMs through the continuum of care, as they can provide information about patient preferences, behaviours and baseline HRQoL at the initial visit, and can help in evaluating disease progression or regression and treatment effects at subsequent visits. Practitioners

are encouraged to seek out PROMs that could be suitable for their own practice and patient population given the considerations described previously (i.e. validity, reliability, responsiveness, acceptability and interpretability). Further, we would encourage practitioners to consider developing case studies with the use of PROMs for publication in the journal to develop the evidence-base for osteopathy and inform future research.

### Statement of competing interests

#### Conflict of interest

MF states that there are no competing interests.

BV declares that he is an associate editor for the International Journal of Osteopathic Medicine but did not take part in the peer review process.

#### Funding sources

Not applicable.

#### Ethical approval details

Not applicable.

### Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.ijosm.2018.03.003>.

### References

- [1] Gismervik SØ, Drogset JO, Granviken F, Rø M, Leivseth G. Physical examination tests of the shoulder: a systematic review and meta-analysis of diagnostic test performance. *BMC Musculoskel Disord* 2017;01/25;18:41. <https://doi.org/10.1186/s12891-017-1400-0>.
- [2] Hegedus EJ, Goode A, Campbell S, Morin A, Tamaddon M, Moorman 3rd CT, et al. Physical examination tests of the shoulder: a systematic review with meta-analysis of individual tests. *Br J Sports Med* Feb 2008;42:80–92. <https://doi.org/10.1136/bjsm.2007.038406>. discussion.
- [3] Almoallim H, Attar S, Jannoudi N, Al-Nakshabandi N, Eldeek B, Fathaddien O, et al. Sensitivity of standardised musculoskeletal examination of the hand and wrist joints in detecting arthritis in comparison to ultrasound findings in patients attending rheumatology clinics. *Clin Rheumatol* Sep 2012;31:1309–17. <https://doi.org/10.1007/s10067-012-013-5>.
- [4] Iversen T, Solberg TK, Romner B, Wilsgaard T, Nygaard Ø, Waterloo K, et al. Accuracy of physical examination for chronic lumbar radiculopathy. *BMC Musculoskel Disord* 2013;07/09;14:206. <https://doi.org/10.1186/1471-2474-14-206>.
- [5] Lumberras B, Donat L, Hernandez-Aguado I. Incidental findings in imaging diagnostic tests: a systematic review. *Br J Radiol* Apr 2010;83:276–89. <https://doi.org/10.1259/bjr/98067945>.
- [6] Guerazzi A, Niu J, Hayashi D, Roemer FW, Englund M, Neogi T, et al. Prevalence of abnormalities in knees detected by MRI in adults without knee osteoarthritis: population based observational study (Framingham Osteoarthritis Study). *BMJ Br Med J (Clin Res Ed)* 2012;345.
- [7] Kyte DG, Calvert M, van der Wees PJ, ten Hove R, Tolan S, Hill JC. An introduction to patient-reported outcome measures (PROMs) in physiotherapy. *Physiotherapy* 2015;06/01;101:119–25. <https://doi.org/10.1016/j.physio.2014.11.003>.
- [8] Kendrick T, El-Gohary M, Stuart B, Gilbody S, Churchill R, Aiken L, et al. Routine use of patient reported outcome measures (PROMs) for improving treatment of common mental health disorders in adults. *Cochrane Libr* 2016 Jul 13:7.
- [9] Santana MJ, Haverman L, Absalom K, Takeuchi E, Feeny D, Grootenhuys M, et al. Training clinicians in how to use patient-reported outcome measures in routine clinical practice. *Qual Life Res* Jul 2015;24:1707–18. <https://doi.org/10.1007/s11136-014-0903-5>.
- [10] Weldring T, Smith SMS. Patient-reported outcomes (PROs) and patient-reported outcome measures (PROMs). *Health Serv Insights* 08/04 2013;6: 61–8. <https://doi.org/10.4137/HSI.S11093>.
- [11] Steven L. Realizing the PROMise of PROMs. *HealthcarePapers* 2012;11:20–3.
- [12] van Vliet LM, Harding R, Bausewein C, Payne S, Higginson IJ. Creating guidance for the use of patient reported outcome measures (proms) in clinical palliative care. *BMJ Support Palliat Care* 2014;4:113.
- [13] ACI. Patient reported outcome measures and patient reported experience measures – a rapid scoping review. [www.aci.health.nsw.gov.au/\\_data/assets/pdf\\_file/0009/281979/ACI\\_PROMs\\_Premis\\_Report.pdf](http://www.aci.health.nsw.gov.au/_data/assets/pdf_file/0009/281979/ACI_PROMs_Premis_Report.pdf). [Accessed 5 March 2018].
- [14] Kyte D, Ives J, Draper H, Calvert M. Current practices in patient-reported outcome (PRO) data collection in clinical trials: a cross-sectional survey of UK trial staff and management. *BMJ Open* 2016;6: e012281.
- [15] Holmes MM, Lewith G, Newell D, Field J, Bishop FL. The impact of patient-reported outcome measures in clinical practice for pain: a systematic review. *Qual Life Res* 2017;26:245–57.
- [16] de Jong MJ, Huibregtse R, Masclee A, Jonkers D, Pierik M. Patient-reported outcome measures for use in clinical trials and clinical practice in inflammatory bowel diseases—a systematic review. *Clin Gastroenterol Hepatol* 2017 Oct 23. pii: S1542-3565(17)31244-2.
- [17] Patrick DL, Deyo RA. Generic and disease-specific measures in assessing health status and quality of life. *Med Care* 1989;S217–32.
- [18] Wells GA, Russell AS, Haraoui B, Bissonnette R, Ware CF. Validity of quality of life measurement tools—from generic to disease-specific. *J Rheumatol Suppl* 2011;88:2–6.
- [19] Bachmeier CJ, March L, Cross M, Lapsley H, Tribe K, Courtenay B, et al. A comparison of outcomes in osteoarthritis patients undergoing total hip and knee replacement surgery. *Osteoarthritis Cartilage* 2001;9:137–46.
- [20] McPhail SM, Bagraith KS, Schippers M, Wells PJ, Hutton A. Use of condition-specific patient-reported outcome measures in clinical trials among patients with wrist osteoarthritis: a systematic review. *Adv Orthoped* 2012;2012.
- [21] Black N. Patient reported outcome measures could help transform healthcare. *BMJ Br Med J (Clin Res Ed)* 2013;346. <https://doi.org/10.1136/bmj.f167>.
- [22] McCormick JD, Werner BC, Shimer AL. Patient-reported outcome measures in spine surgery. *J Am Acad Orthop Surg* Feb 2013;21:99–107. <https://doi.org/10.5435/jaaos-21-02-99>.
- [23] El Miedany Y. PROMs in inflammatory arthritis: moving from static to dynamic. *Clin Rheumatol* 2013;06/01;32:735–42. <https://doi.org/10.1007/s10067-013-2228-0>.
- [24] King MT. A point of minimal important difference (MID): a critique of terminology and methods. *Expert Rev Pharmacoecon Outcomes Res* 2011;11: 171–84.
- [25] Snyder CF, Aaronson NK, Choucair AK, Elliott TE, Greenhalgh J, Halyard MY, et al. Implementing patient-reported outcomes assessment in clinical practice: a review of the options and considerations. *Qual Life Res* Oct 2012;21: 1305–14. <https://doi.org/10.1007/s11136-011-0054-x>.
- [26] Alrubaiy L, Hutchings HA, Williams JG. Assessing patient reported outcome measures: a practical guide for gastroenterologists. *United Eur J Gastroenterol* 2014;2:463–70. <https://doi.org/10.1177/2050640614558345>. 08/18/received 10/10/accepted.
- [27] Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual Life Res* 2010;19. <https://doi.org/10.1007/s11136-010-9606-8>.
- [28] Fitzpatrick R, Davey C, Buxton MJ, Jones DR. Evaluating patient-based outcome measures for use in clinical trials. *Health Technol Assess* 1998;2: 1–74. i-iv.
- [29] Guyatt GH, Osoba D, Wu AW, Wyrwich KW, Norman GR. Methods to explain the clinical significance of health status measures. In: *Mayo clinic proceedings*, vol. 77. Elsevier; 2002. p. 371–83.
- [30] Sansoni JE. Health outcomes: an overview from an Australian perspective. 2016.
- [31] Greenhalgh J. The applications of PROs in clinical practice: what are they, do they work, and why? *Qual Life Res* Feb 2009;18:115–23. <https://doi.org/10.1007/s11136-008-9430-6>.
- [32] Bryan S, Broesch J, Dalzell K, Davis J, Dawes M, Doyle-Waters MM, et al. What are the most effective ways to measure patient health outcomes of primary health care integration through PROM (Patient Reported Outcome Measurement) instruments. *Vanc Cent Clin Epidemiol Eval* 2013.
- [33] Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *J Clin Epidemiol* 2010;63. <https://doi.org/10.1016/j.jclinepi.2010.02.006>.
- [34] Emery MP, Perrier LL, Acquadro C. Patient-reported outcome and quality of life instruments database (PROQOLID): frequently asked questions. *Health Qual Life Outcome* Mar 8 2005;3:12. <https://doi.org/10.1186/1477-7525-3-12>.
- [35] Reeve BB, Wyrwich KW, Wu AW, Velikova G, Terwee CB, Snyder CF, et al. ISOQOL recommends minimum standards for patient-reported outcome measures used in patient-centered outcomes and comparative effectiveness research. *Qual Life Res* 2013;10/01;22:1889–905. <https://doi.org/10.1007/s11136-012-0344-y>.
- [36] Omoumi P, Vande Berg B. Hip imaging: normal variants and asymptomatic findings. *Semin Musculoskel Radiol* 2017;21:507–17. <https://doi.org/10.1055/s-0037-1606136>.
- [37] Dean Deyle G. The role of MRI in musculoskeletal practice: a clinical perspective. *J Man Manip Ther* 2011;19:152–61. <https://doi.org/10.1179/2042618611Y.0000000009>.
- [38] Ruta DA, Garratt AM, Russell IT. Patient centred assessment of quality of life for patients with four common conditions. *Qual Health Care* 1999;8:22.

- [39] Naglie G, Tomlinson G, Tansey C, Irvine J, Ritvo P, Black SE, et al. Utility-based quality of life measures in Alzheimer's disease. *Qual Life Res* May 2006;15: 631–43. <https://doi.org/10.1007/s11136-005-4364-8>.
- [40] Seid M, Limbers CA, Driscoll KA, Oipari-Arrigan LA, Gelhard LR, Varni JW. Reliability, validity, and responsiveness of the pediatric quality of life inventory (PedsQL) generic core scales and asthma symptoms scale in vulnerable children with asthma. *J Asthma* Mar 2010;47:170–7. <https://doi.org/10.3109/02770900903533966>.
- [41] Beaton DE, Boers M, Wells GA. Many faces of the minimal clinically important difference (MCID): a literature review and directions for future research. *Curr Opin Rheumatol* 2002;14:109–14.
- [42] Cook CE. Clinimetrics corner: the minimal clinically important change score (MCID): a necessary pretense. *J Man Manip Ther* 2008;16: 82E–3E.
- [43] Lauridsen HH, Hartvigsen J, Manniche C, Korsholm L, Grunnet-Nilsson N. Responsiveness and minimal clinically important difference for pain and disability instruments in low back pain patients. *BMC Musculoskel Disord* 2006;7:82. <https://doi.org/10.1186/1471-2474-7-82>.
- [44] Wright A, Hannon J, Hegedus EJ, Kavchak AE. Clinimetrics corner: a closer look at the minimal clinically important difference (MCID). *J Man Manip Ther* 2012;20:160–6. <https://doi.org/10.1179/2042618612Y.0000000001>.
- [45] Snyder CF, Jensen RE, Segal JB, Wu AW. Patient-reported outcomes (PROs): putting the patient perspective in patient-centered outcomes research. *Med Care* Aug 2013;51:S73–9. <https://doi.org/10.1097/MLR.0b013e31829b1d84>.
- [46] Grotle M, Brox JL, Vøllestad NK. Functional status and disability questionnaires: what do they assess?: a systematic review of back-specific outcome questionnaires. *Spine* 2005;30:130–40.
- [47] Holt GA, Hall EL. Potentials for HOLISM in pharmacy. *Am Pharm* 1983/01/01;23:38–41. [https://doi.org/10.1016/S0160-3450\(16\)31851-7](https://doi.org/10.1016/S0160-3450(16)31851-7).
- [48] Hanbury A. Identifying barriers to the implementation of patient-reported outcome measures using a theory-based approach. *Eur J Person Cent Healthc* 2017;5:35–44.
- [49] Jensen RE, Snyder CF, Abernethy AP, Basch E, Potosky AL, Roberts AC, et al. Review of electronic patient-reported outcomes systems used in cancer clinical care. *J Oncol Pract* Jul 2014;10:e215–22. <https://doi.org/10.1200/jop.2013.001067>.
- [50] Kramer JM, Schwartz A. Reducing barriers to patient-reported outcome measures for people with cognitive impairments. *Arch Phys Med Rehabil* Aug 2017;98:1705–15. <https://doi.org/10.1016/j.apmr.2017.03.011>.
- [51] Valier ARS, Jennings AL, Parsons JT, Vela LI. Benefits of and barriers to using patient-rated outcome measures in athletic training. *J Athl Train* Sep-Oct 2014;49:674–83. <https://doi.org/10.4085/1062-6050-49.3.15>.
- [52] Timmins N. NHS goes to the PROMS. *BMJ* 2008;336:1464.
- [53] Secord AA, Coleman RL, Havrilesky LJ, Abernethy AP, Samsa GP, Cella D. Patient-reported outcomes as end points and outcome indicators in solid tumours. *Nat Rev Clin Oncol* Jun 2015;12:358–70. <https://doi.org/10.1038/nrclinonc.2015.29>.
- [54] Bittton A, Onega T, Tosteson AN, Haas JS. Toward a better understanding of patient-reported outcomes in clinical practice. *Am J Manag Care* Apr 2014;20: 281–3.
- [55] Feehan J, Macfarlane C, Vaughan B. Conservative management of a traumatic meniscal injury utilising osteopathy and exercise rehabilitation: a case report. *Compl Ther Med* Aug 2017;33:27–31. <https://doi.org/10.1016/j.ctim.2017.05.007>.
- [56] Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee injury and osteoarthritis outcome score (KOOS)—development of a self-administered outcome measure. *J Orthop Sports Phys Ther* 1998;28:88–96. <https://doi.org/10.2519/jospt.1998.28.2.88>.
- [57] Ingelsrud LH, Terwee CB, Goncalves RS, Roos EM. Minimal important change for the knee injury and osteoarthritis outcome score (KOOS) in patients with knee osteoarthritis. *Osteoarthritis Cartilage* 2014;22:S179–80. <https://doi.org/10.1016/j.joca.2014.02.338>.
- [58] Binkley JM, Stratford PW, Lott SA, Riddle DL. The Lower Extremity Functional Scale (LEFS): scale development, measurement properties, and clinical application. *Phys Ther* 1999;79:371–83.
- [59] Mehta S, Fulton A, Quach C, Thistle M, Toledo C, Evans N. Measurement properties of the lower extremity functional scale: a systematic review. *Physiotherapy* 2015;101:e992–3. <https://doi.org/10.2519/jospt.2016.6165>.
- [60] Collins NJ, Misra D, Felson DT, Crossley KM, Roos EM. Measures of knee function: international knee documentation committee (IKDC) subjective knee evaluation form, knee injury and osteoarthritis outcome score (KOOS), knee injury and osteoarthritis outcome score physical function short form (KOOS-PS), knee outcome survey activities of daily living scale (KOS-ADL), lysholm knee scoring scale, oxford knee score (OKS), western ontario and McMaster universities osteoarthritis Index (WOMAC), activity rating scale (ARS), and tegner activity score (TAS). *Arthritis Care Res Nov* 2011;63(Suppl 11):S208–28. <https://doi.org/10.1002/acr.20632>.
- [61] Ross G, Macfarlane C, Vaughan B. Combined osteopathy and exercise management of Achilles tendinopathy in an athlete. *J Sports Med Phys Fit* Jan-Feb 2018;58:106–12. <https://doi.org/10.23736/s0022-4707.17.06817-7>.
- [62] Bennett S, Macfarlane C, Vaughan B. The use of osteopathic manual therapy and rehabilitation for subacromial impingement syndrome: a case report. *Explore* Sep - Oct 2017;13:339–43. <https://doi.org/10.1016/j.explore.2017.01.002>.
- [63] Vaughan B, DiVenuto G. An introduction to the use of outcomes questionnaires in osteopathic practice. *J Osteopath Med* 2004/10/01;7:85–95. [https://doi.org/10.1016/S1443-8461\(04\)80017-0](https://doi.org/10.1016/S1443-8461(04)80017-0).
- [64] Prinsen CAC, Vohra S, Rose MR, Boers M, Tugwell P, Clarke M, et al. How to select outcome measurement instruments for outcomes included in a "Core Outcome Set" — a practical guideline. *Trials* September 13 2016;17:449. <https://doi.org/10.1186/s13063-016-1555-2>.
- [65] Cella D, Hahn EA, Jensen SE, Butt Z, Nowinski CJ, Rothrock N, et al. Patient-reported outcomes in performance measurement. Patient-Reported Outcomes in Performance Measurement. Research Triangle Park (NC): RTI Press; 2015 (c) 2015 Research Triangle Institute. All rights reserved. This book is protected by copyright. Credit must be provided to the author and source of the book when the content is quoted. No part of this book may be reproduced in any form by any electronic or mechanical means (including photocopying, recording, or information storage and retrieval) without permission in writing from the publisher..
- [66] Bryan S, Davis J, Broes J, Doyle-Waters MM, Lewis S, McGrail K, et al. Choosing your partner for the PROM: a review of evidence on patient-reported outcome measures for use in primary and community care. *Healthc Policy* 2014;10:38–51.
- [67] Sprangers MA, Cull A, Groenvold M, Bjordal K, Blazeby J, Aaronson NK. The european organization for research and treatment of cancer approach to developing questionnaire modules: an update and overview. *EORTC quality of life study group. Qual Life Res* May 1998;7:291–300.