

# Is this working? The importance of outcome measures in herbal & naturopathic practice

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## Abstract

An acknowledged strength of herbal and naturopathic medicine is its patient-centred focus, yet critics often state that these disciplines lack evidence of efficacy. Assessing efficacy of the individualised care practices of herbalists and naturopaths is not always an easy process, for clinicians or for researchers. The incorporation of outcome measures, especially patient-reported outcome measures (PROMs) in clinical practice has the potential to improve the assessment of efficacy at the individual patient level. Additionally, increased use of outcome measures in published case studies may assist in evidence generation which is consistent with the individualised care philosophies inherent to naturopathic and herbal medicine. This commentary piece will introduce the reader to the concept of outcome measures, discuss their nature, and point out some of the benefits as well as barriers to their widespread use.

## Introduction

The American Institute of Medicine, in 1990, defined quality in health care as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”<sup>1</sup> Few would argue that this is a useful definition, especially with its focus on the patient. However, with debate around the quantity, quality, relevance and utility of some research in herbal and naturopathic medicine, how does a clinician know whether or not they are providing quality care? The answer may lay in the use of outcome measures.

## The nature of outcome measures

Outcome measures can take many forms, such as blood tests, patient questionnaires, or physical examination methods such as blood pressure monitoring or joint mobility tests. Haemoglobin A1c, blood inflammatory markers, or cardiac output, are classic examples of objective and disease specific measures, which often come to mind when considering how to measure the efficacy of treatment in diabetics, patients with lupus, or heart disease patients respectively. All are useful and valid tools; however, their limitations must also be recognised. A test's sensitivity and specificity must be understood for effective clinical interpretation. Additionally, the relevance of results to the patient and their perception of their own health status must also be considered, especially in complex and chronic conditions.

For example, using positive changes in HbA1c results in a diabetic patient as an indicator of treatment efficacy, whilst valuable and important, may not provide the total picture of the patient's health. Perhaps the positive result is due to regular hypoglycaemic episodes every week.

It also ignores the impact that dietary restriction or hypoglycaemic treatment may be having on the physical, psychological and social wellbeing of the patient.<sup>2</sup>

In recognition of these limitations, broader and sometimes more subjective measures have increasingly been used in research. These broader measures often take the form of quality of life questionnaires such as the well known 36-item Short Form Health Survey (SF-36; mostly a research tool) and the more clinically useful, but somewhat similar, 20-item Short Form Health Survey (SF-20). These tools can assist clinicians and researchers in evaluating the broader wellbeing of an individual or group of individuals, but again have their limitations. They are not disease specific, and are often designed from the perspective of population-level research. Thus on their own, these measures may lack individual relevance in the one-on-one clinical care situations found most commonly in naturopathic and herbal practice.

## Patient reported outcome measures (PROMs)

In a number of areas of health care, a new paradigm for measuring patient outcomes is emerging. This paradigm acknowledges that there is a need for patient-centred tools for evaluating disease severity and the progress (if any) obtained from treatment. Such measures should require patient interaction and reflection to be deemed clinically relevant and patient-centred. These newer measures (Table 1) are being collectively referred to as Patient Reported Outcome Measures (PROMs).<sup>2,3</sup>

PROMs are, by their very nature, subjective. This, in fact, is the strength and value of PROMs – they represent the patient's perception and experience of health and disease, unencumbered by the clinician's opinion, or

highly technical but sometimes alienating pathology reports. Thus, they are truly patient-centred methods of evaluating efficacy of treatment. Generally speaking, PROMs tend to examine one of six different constructs:<sup>2</sup>

- health status
- quality of life (QoL)
- health-related quality of life (HRQoL)
- wellbeing (often psychological)
- treatment satisfaction
- symptoms and functioning

It is important to remember that health status is not the same as quality of life. Indicators of health status can be measures such as the ability of a patient with chronic joint disease to climb four flights of stairs. Quality of life is a broader measure encompassing the patient's subjective evaluation of the quality of their physical, psychological and social aspects of their life. Both types of measures have their value in practice. Health-related quality of life becomes more specific and evaluates the degree to which the disease, and any associated treatment, impacts on the patient's quality of life.<sup>2</sup>

## Relevance of outcome measures in clinical practice

In the publication *Crossing the Quality Chasm: A New Health System for the 21st Century*, the Committee on Quality of Health Care in America in 2001 stated: "The health care delivery system is in need of fundamental change. Many patients, doctors, nurses, and health care leaders are concerned that the care delivered is not, essentially, the care we should receive. The frustration levels of both patients and clinicians have probably never been higher. Yet the problems remain. Health care today harms too frequently and routinely fails to deliver its potential benefits."<sup>4</sup>

In response to this realisation, they detail six aims for quality health care:<sup>5</sup>

- Safe
- Effective
- Patient-centred
- Timely
- Efficient

- Equitable

The use of outcome measures, especially PROMs, can directly help clinicians achieve three of these six aims – specifically safe, effective and patient-centred care. Outcome measures give us a way of measuring effectiveness, and a way of being alerted to issues around safety. PROMs in particular, due to the fact that they are examining the patient's perception of their illness and treatment, help encourage a strong patient-centred focus in the delivery of our care.

## Barriers to the use of outcome measures

Despite the potential value of employing outcome measures in practice, research in allied health indicates only about 20-30% of clinicians routinely measure outcomes in practice.<sup>6</sup> Of course this raises the question as to why.

A number of publications have outlined some key barriers to the routine usage of outcome measures. Some of these barriers include:

- Lack of time<sup>6,7</sup>
- Fear of adding to workload<sup>3,7</sup>
- Belief that the clinician understands the patient's problems and doesn't need additional information<sup>3</sup>
- Fear of change<sup>7</sup>
- Concerns around being assessed and criticised<sup>7</sup>
- Lack of knowledge, skill and training<sup>6,7</sup>
- Lack of support from health care management<sup>6</sup>
- Tools being burdensome<sup>7</sup>
- Cost constraints<sup>7</sup>

## Overcoming barriers to the use of outcome measures

A study of Australian occupational therapists (OTs) published in 2006 demonstrates ways that some of these barriers can be overcome, resulting in increased use of outcome measures. This study employed an educational intervention consisting of a one-day workshop, with an accompanying information package, which included nine outcome measurement tools for use with chronic pain patients. Whilst the number of OTs enrolled in this study was low (n=36), 65.7% of OTs in the study

**Table 1: A sample of selected Patient Reported Outcome Measures**

Name	Type	Application	Comments
Diabetes Health Profile (DHP-18)	HRQoL	Monitoring impact of diabetes on patient's life	License required (but free for clinical use). Useful in clinical practice.
Headache Impact Test™ (HIT™)	Symptoms and functioning	Headache severity and impact of treatment evaluation	License required. Useful in clinical practice.
Measure Yourself Medical Outcome Profile (MYMOP-2)	Symptoms and functioning	Any condition involving symptoms	Public domain access. Useful in clinical practice.
Patient Health Questionnaire-9 (PHQ-9)	Wellbeing (psychological)	Severity of depression	Public domain access. Useful in clinical practice and research settings.

reported using outcome measures prior to the workshop intervention, which increased to 91.4% four months after the workshop. Furthermore, this study gathered data from participants around the factors which they perceived as helping to affect change, revealing that 86% rated the workshop presentations as important, 89% rated the workshop discussion as important, 74% rated the workshop practical sessions as important, and 86% rated the resource package as important.<sup>6</sup>

However, an important question to consider is whether the implementation of outcome measures in naturopathic and herbal practice is possible, and if so, is it valuable? To date there is very little evidence available to answer this question. However, Secor et al in 2004 showed that not only is it possible, but that there is perceived benefit.<sup>8</sup> This study, conducted in a complementary and alternative medicine outpatient clinic in Connecticut, utilised the SF-12v2® Health Survey with 94 patients with pain of various causes, who were receiving acupuncture, chiropractic or naturopathic treatment. The study demonstrated positive changes in physical health scores within the SF-12v2® from baseline, with the authors stating that the data collection system was well received by staff and patients within the clinic.<sup>8</sup>

### Traps to avoid

Nelson and colleagues discuss the fact that patients generally welcome the routine use of PROMs, but that they “must be used well and not misdirect the focus of the clinical encounter, burden patients, or focus only on factors that have value to clinicians.”<sup>3</sup>

Additionally, reliability and validity of the outcome measure is essential for it to be successfully incorporated into patient management.<sup>2,3</sup> This is particularly important in naturopathic medicine, where in recent years there has been an explosion in the use of alternative testing procedures. For example, the zinc taste test (ZTT) has been used diagnostically to evaluate zinc status (due to zinc deficiency being linked to diminished taste acuity in humans and animals), as well as a way of evaluating the effectiveness of supplementation. However, an Australian review focusing on the correlation between ZTT and zinc status published in the *Journal of Alternative & Complementary Medicine* in 2012, found only three studies that could be included in the review. Two of these showed some degree of correlation between zinc status and ZTT result but suffered from serious methodological flaws, and the largest of the three studies showed no correlation between three different measures of zinc status and the ZTT result.<sup>9</sup> Thus, it is imperative that herbal and naturopathic clinicians consider the validity and reliability of any outcome measure tool before implementing it in their practice.

### Conclusion

The use of outcome measures, especially Patient Reported Outcome Measures (PROMs) has the potential

to provide greater insight to herbal and naturopathic clinicians regarding the nature and severity of the patient’s health complaint, and the impact of treatment. However, evidence from medical and allied health research indicates relatively low usage of outcome measures and identifies a number of legitimate barriers to implementation. Tailored educational interventions may assist in overcoming some of these barriers and increasing the utilisation of outcome measures in practice.

Additionally, the potential for evidence-generation offered by the routine use of outcome measures should not be ignored. It is important to note that evidence-based medicine is more than treating patients based on research evidence alone. According to Straus et al, “evidence-based medicine (EBM) requires integration of the best research evidence with our clinical expertise and our patient’s unique values and circumstances.”<sup>10</sup>

By incorporating PROMs into practice, and subsequently publishing case studies and case series, we can all contribute to the growing evidence-base of naturopathic and herbal medicine. At the same time we continue to adhere to our patient-centred philosophy and bypass some of the methodological criticisms of more controlled research designs such as the randomised controlled trial.

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