



# PAIN

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## Outcomes and Effective Pain Treatment

### Will This Treatment Help?

Patients and their families have always been concerned with the likely success or failure of proposed or actual care. Osler, in his essay on medical practice in ancient Greece, described a system in which state physicians were appointed annually.<sup>1</sup> Reappointment depended on the outcome of a public hearing in which the community could voice its pleasure or displeasure with the physician's clinical outcomes during the prior year. As cited by Osler, Socrates (c. 400 B.C.E.) asked, "If you and I were physicians, and were advising one another that we were competent to practice, should I not ask you, and would you not ask me, Well, what about Socrates himself, has he not good health? And has anyone else ever been known to be cured by him, whether slave or freeman?"<sup>2</sup> Ongoing skepticism over subsequent millennia as to the benefits of actual or proposed medical treatments is evident in historical letters, books, plays, and poems. As observed by the character Beralde in Molière's comic drama *Le Malade Imaginaire* (1673), "medicine is only for those who are fit enough to survive the treatment as well as the illness."

*Well, what about Socrates himself, has he not good health? And has anyone else ever been known to be cured by him, whether slave or freeman?  
(Plato, 400 B.C.E.)*

Today, formal assessment of health and the evaluation of health care rely upon measurement. Yesterday's passive, obedient patient has been replaced by an educated consumer, empowered through access to information on the Internet, including statistics on providers' outcomes, and in some areas, legal judgments against them. Megatrends such as the increasing emphasis upon quality of care, a declining proportion of care rendered for acute illness versus chronic disease, the advance of technology, rising health care costs, and adoption of an evidence-based approach to health care<sup>3-5</sup> have reinforced the need to change from a provider-centered health care culture to a patient-centered culture.<sup>6</sup> These trends favor the use of patient-centered outcomes: outcome measures that are important from the patient's point of view. Patient satisfaction with care is increased when clinicians take the patient's view into account<sup>7</sup>, as are patient compliance with treatment programs<sup>8</sup> and the likelihood that the patient will maintain a continuous relationship with the health care provider.<sup>9</sup> Equally important to practitioners and patients is the effectiveness of treatment, i.e., the outcome of treatment as carried out in typical practice settings, measured over the course of the condition using measures that matter most to patients.<sup>10</sup> The hypotheses of outcomes research may be identical to those of clinical trials, and both types of trials may measure the same parameters and endpoints. However, outcomes research—also referred to

### UPCOMING ISSUES

**Opioid Abuse Potential**

**Opioid Refractoriness**

**What Does Pain Hurt?**

as “effectiveness research”—is more likely to be generalizable to typical medical practice than are controlled clinical trials (“efficacy research”). What outcomes research lacks in clinical trials’ potential methodological rigor, it seeks to compensate for in the size of the population under study, the duration of observation, and reliance upon statistical techniques to control for confounding variables.<sup>11</sup>

***Societal and medical trends favor the use of patient-centered outcomes***

**Outcome Instruments**

The pressing need to know which treatments reduce pain, which improve health-related quality of life (HRQOL), and in particular which treatments are worth paying for, has spurred the development of a number of outcome instruments. These instruments seek to capture in simple, speedy, and robust fashion the health status of patients.<sup>12</sup> During the 1990s, published descriptions of the development and evaluation of patient-assessed measures rose from 144 to 650 annually, of which 30% were related to cancer. Reports of disease-specific measures rose exponentially.<sup>13</sup> Unfortunately, there is little standardization in the use of such measures within clinical trials.

***During the 1990s, published descriptions of patient-assessed measures rose from 144 to 650 annually, but with little standardization***

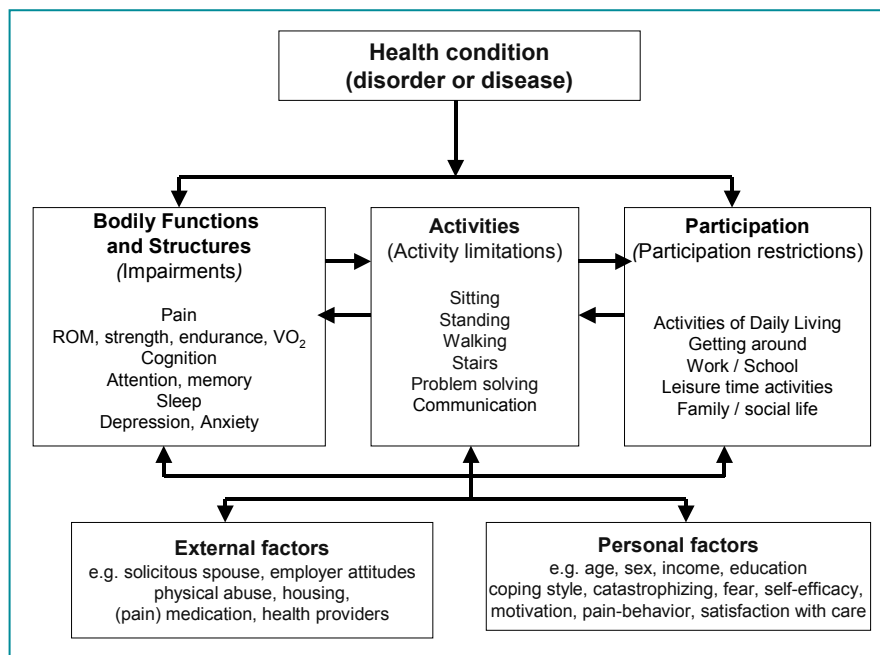
For example, 125 distinct tools to assess pain were applied in the 218 randomized controlled trials (of over 18,000 titles screened) reviewed in the U.S. Agency for Healthcare Research and Quality evidence report on management of cancer-related pain, depression, and fatigue.<sup>14</sup> In a review on tools used in prostate cancer outcomes research between 1990 and 2000, 149 primary data papers were found that contained patient

outcome data. Forty-two standard instruments were used, accounting for 44% (179 of 410) of the measures overall.<sup>15</sup> Meta-analyses and systematic reviews in all areas of health care have been more concerned with the quality of the studies and the types of interventions used than with the heterogeneity of the outcome measures employed.<sup>16</sup> Thus, at present an ironic situation exists, in which standardized outcomes instruments that individually encourage uniformity of data gathering have proliferated, increasing the aggregate complexity of the field.

Clearly we need to find consensus on the conceptual framework and structure of measurement tools to increase consistency and comparability across studies and patients. The World Health Organization’s International Classification of Functioning, Disability and Health (ICF) offers such a framework.<sup>17</sup> The ICF conceptualizes functioning as a complex interplay of so-called health components: body functions, body structures, activities and participation, and environmental and personal factors. These health components are linked to each other in the model of the ICF (Fig. 1). The ICF encompasses outcomes relevant to all patients as it provides a common language and framework for the description of health conditions and health-related states.<sup>18</sup>

***A European group has gathered large amounts of data on HRQOL in cancer; pain researchers and clinicians should follow a similar strategy***

Pain, especially chronic pain, presents a unique challenge to outcomes research due to the central importance of patient-centered and patient-reported information. Unlike most other medical conditions, chronic pain may involve multiple organ systems, pathophysiological processes, and biomedical disciplines. Although pain is widely viewed merely as a symptom, it is in fact a subjective experience and perception.<sup>19</sup> This perception



**Fig. 1.** The World Health Organization’s International Classification of Functioning, Disability and Health (ICF) model for patients with pain.

not only depends on nociceptive transmission and modulation within the CNS, but it is integrated with psychological, social, and/or other environmental factors.<sup>20</sup> Physical functioning, work, family, and social relationships are usually impaired by chronic pain. Comorbid conditions such as depression or anxiety often accompany chronic pain.<sup>21-23</sup> For these reasons, comprehensive assessment of patients with chronic pain should occur within a multidimensional framework.<sup>24</sup>

***Unlike most other medical conditions, chronic pain may involve multiple organ systems, pathophysiological processes, and biomedical disciplines***

Many instruments have been applied to assess the impact of pain on patients' lives. According to Kirshner et al.<sup>25</sup> and Guyatt et al.,<sup>26</sup> health status measures have three broad applications: (1) discrimination between individuals or groups, (2) prediction of outcomes, and (3) evaluation of change over time. Generic HRQOL instruments are mostly epidemiological tools and as such are intended to measure change in large populations of patients. By design they are not meant, nor in general are they sufficiently sensitive, to measure changes in a single person.

***The WHO's ICF offers a uniform framework to measure function, health, and disability***

Furthermore, generic HRQOL instruments do not provide information on items frequently assessed in pain management such as solicitous responses,<sup>27,28</sup> coping ability,<sup>29,30</sup> fear avoidance,<sup>31-33</sup> and the extent of disablement from pain. It is therefore recommended to augment a generic HRQOL instrument with a disease-specific instrument. Ideally the instrument should provide relevant information to all clinicians within an inter- or multidisciplinary team to formulate a treatment plan, allow for measurement of the outcome of treatment interventions, have a low respondent burden, and be sensitive enough to detect changes at both group and individual levels.

***Generic HRQOL instruments are not meant, nor are they sufficiently sensitive, to measure changes in a single person***

International standardization of outcome measures has taken place for a number of disorders. Core data sets have been agreed upon for low back pain<sup>34,35</sup>; chronic widespread pain<sup>36</sup>; knee, hip, and hand osteoarthritis<sup>37</sup>; chronic pain<sup>38</sup>; and rheumatoid arthritis.<sup>39</sup> Recommendations from diverse working groups range from which domains to measure (e.g., pain, physical function, patient satisfaction) to endorsement of specific tools. Clinical pain research needs to adopt a common core measure to be used by all to facilitate collaboration, as well as comparison and pooling of data, among researchers and clinicians. A good example of such an effort is that of the European Organization for Research and Treatment of Cancer Quality of Life (EORTC) group, which has developed a cancer core measure for HRQOL (EORTC QLQ-C30). Intended

for all researchers and clinicians to use, this instrument can be supplemented by a condition-specific questionnaire. The EORTC group has gathered large amounts of data using this core measure; pain researchers and clinicians should follow a similar strategy.

***We need international consensus on core outcomes measures appropriate to the multidimensional complexity of pain***

**Standards for Outcomes Measurement**

Outcomes instruments should be applied serially over time to monitor health status, and the results should be linked to health care interventions and any mediating factors. A prerequisite to doing so is that the measurement tool be reliable, valid, precise, specific, sensitive, and responsive to change.<sup>40</sup>

A review on reporting on reliability and validity of outcomes measures in rehabilitation medicine research identified 171 papers that employed 651 outcome measures. However, reliability data was provided for only 20.1% of these measures and validity data for only 6.9%.<sup>41</sup> Physical impairments were the most common class of outcomes (60%), while functional assessment comprised 12% of the outcome measures. The WHO report on the burden of musculoskeletal conditions at the start of a new millennium<sup>42</sup> identified 147 instruments for the measurement of musculoskeletal pain that are supported by reliability and validity data. Recently, quality criteria for measurement properties of health status questionnaires were proposed<sup>43</sup> so that clinicians and researchers can now explicitly and precisely discuss how to meet these criteria. We also need to discard those measures that do not meet the quality criteria.

In proposing core data sets to assess patients with pain and their responses to treatment, we must keep in mind the issue of cross-cultural adaptation. Cross-cultural adaptations of low back pain (LBP) self-report questionnaires were recently found to frequently lack sound psychometric evaluation.<sup>44</sup> Guidelines for cross-cultural adaptations exist and should be followed<sup>45,46</sup> so that we can be assured of comparability of the content of the questionnaires used in different countries.

***Treatment effectiveness is assessed in typical practice settings over the course of the condition***

**Conclusion: Getting to Work**

Not only should care itself be evidence-based, but so should the measurement tools used to evaluate its practical results.<sup>47</sup> Systematic reviews of the psychometric properties of health status measurement tools are appearing more frequently. We now have quality criteria for health status questionnaires and an international consensus framework to assess the impact of pain on health. We need international consensus on core outcomes measures that do justice to the multidimensional complexity of pain. If we want to advance our own field, we need to get to work!

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