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Chapter 17

The Evolution of Patient-Based Outcome Assessment Instruments in Acupuncture Research: Choosing Patient-Based Outcomes

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1. Introduction

In this chapter, we present the patient-based outcome assessment (PBOA) instruments that have been used to determine outcomes in acupuncture clinical research, and highlight measures that are feasible, practical, economical, reliable, valid, and responsive to clinical change. The material in this chapter has been previously published in the Journal of Alternative and Complementary Medicine (See Footnote[*1]). This chapter has been edited to reflect and enhance, in particular, recent discussions on measures that cover issues of specific concern to the patient (i.e. health and wellbeing). It must be noted that often patient reported outcomes are measured by questionnaires that cover issues of specific concern to the patient. However, patient reported outcomes should be distinguished from PBOAs. Patient reported outcomes connotes patient-provided (rather than clinician observed) information; however, the information sought may or may not be focused on what the patients consider the most important health-related outcomes. An example of a patient-reported outcome is a sleep diary, in which patients track and report hours of sleep during a trial of a sleep medication. On the other hand, patient based outcomes explore the patient's health from her own perspective, and include

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measures of health that may lie outside of traditional medical surveys. An example of a PBOA related to a sleep medication trial is a self-report sleep diary in which the patient rates how refreshed she feels following medication-induced sleep. For the purposes of this chapter we define PBOA as any questionnaire, interview schedule and other related method or that assesses the *patient's* health, illness and benefits of health care interventions from the *patient's* perspective.

As health care costs continue to escalate in the U.S, especially in the military, there is renewed pressure on both payers and providers to demonstrate that the services provided by all clinicians are cost effective. There is also an emphasis on quality of patient care, manifested through an increasing demand for evidence based medicine demonstrated through performance measurement. Health care clinicians, patient advocates, regulatory authorities, administrators and policy makers are increasingly recognizing that patient focused outcome research, as captured by PBOA, is an important component of current quality based initiatives, and the evaluation of health care services.

Outcome instruments can provide information on the effectiveness of interventions and inform "real life" clinical practice. There is a range of outcome instruments available for acupuncture research and clinical practice, yet choosing the best outcome instrument is difficult due to numerous factors. [1,2]. Some of the important features of outcome measurements include that the instrument should: "(1) be valid, i.e. must measure what it sets out to test; (2) be reliable and consistent, i.e. it should give reproducible results on different occasions or with comparable groups; [3] (3) be responsive to clinical change; (4) be economical, (5) be feasible to administer; and (6) make it possible to compare findings to other studies, populations, or standard norms, etc. (p.356) [4] In addition to these considerations, the patient health status must also be considered, and it should be particularly suited to measure those aspects of health that the intervention of interest is likely to affect. Selecting suitable outcome instruments can be time consuming and challenging. There are hundreds of outcome measure and instruments available. Instruments can be patient-completed (self- administered) questionnaires, physiological tests, clinician-completed observation scales, task-specific activities/tests and impairment tests.

Assessing health outcomes associated with acupuncture is particularly challenging. [5] Acupuncture has been claimed as an effective treatment for certain chronic pain conditions. [6,7] According to the National Institutes of Health (NIH) Consensus Development Conference Statement there is "clear evidence for acupuncture's efficacy for treating postoperative and chemotherapy nausea and vomiting, [8,9] the nausea of pregnancy, [10] and postoperative dental pain." [11] Acupuncture has also been claimed effective for other various pain conditions such as migraines, [12-14] back pain, [14] tennis elbow, [15,16] menstrual cramps, [17] fibromyalgia, [18] and carpal tunnel syndrome. [19]

However, acupuncture, like many Complementary and Alternative Medicine (CAM) therapies, often does not involve a standardized protocol but rather is tailored to meet the patient's unique clinical presentation, needs or desires. In addition, previous studies have found that

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acupuncture may result in subtle improvements in a general sense of well-being in ways that may not be measured by standardized instruments. [5] Therefore using PBOAs to assess the benefits of acupuncture can be particularly meaningful, since they are customized to address patients' unique clinical needs and therapeutic goals. There still remains the challenge "to define *a priori* a single set of clinical outcomes to assess." [5]

1.1. The review

The objectives of the original review were to: 1) assess the available literature and identify the most common pain, disability, and quality-of-life PBOA instruments used in acupuncture research; 2) describe a framework for identifying appropriate sets of instruments; and 3) address the challenges associated with these instruments that are relevant to acupuncture. This chapter reassesses the available literature and identifies the most common PBOA instruments used in the original review. Also, this chapter enhances and builds on the discussion concerning the frameworks, in identifying appropriate sets of instruments and some of the challenges associated with the use of these instruments to measure acupuncture's effects.

2. Methods

We conducted our original search in 2009. At that time, our search included all published clinical trial abstracts in the PubMed database from inception to Feb 2009. We performed another search in August 2012. This secondary search included all abstracts for clinical studies published in PubMed from Feb 2009 to August 2012.

Our original search in 2009 was conducted in two phases. Initially, a broad systematic search was performed to identify existing instruments for measuring pain, disability, general health status and well-being found in acupuncture therapy studies. To be included in this phase of the review, an instrument had to be used in at least 3 separate studies that met our search criteria. Patient outcome instruments were included if they were found cited in the abstract of a paper reporting research related to acupuncture. We used the same methodology for our search from Feb 2009 to August 2012.

We categorized the type of patient outcome instruments into two categories: physiological or patient-based. We used our definition of PBOA to sort and review those articles in full that included PBOA and acupuncture. Because of time limitations, we did not pull the full text articles for our secondary search from Feb 2009 to August 2012. Therefore we cannot discuss whether a recent study (Feb 2009-August 2012) has a PBOA instrument as a primary or secondary measure (See table 1).

For each instrument that was included, a second search was conducted to identify papers reporting research on its psychometric properties. This second phase of searching was not confined to studies of acupuncture. Data on the psychometric properties of identified instruments were subsequently extracted and compared (See table 2).

	Included studies (Inception - April 2009)		Studies with No PBOA (Inception - April 2009)		Included studies (April 2009 - Aug 2012)	
	n	%	n	%	n	%
Total number of studies	258		112		206	
Study design						
RCT	182	70.543%	39	34.821%	203	98.544%
CCT	28	10.853%	23	20.536%	38	18.447%
CO	8	3.101%	0	0.000%	9	4.369%
Mixed Design	2	0.775%	11	9.821%	9	4.369%
Pilot	25	9.690%	9	8.036%	40	19.417%
CT	8	3.101%	0	0.000%	0	0.000%
SR	5	1.938%	11	9.821%	7	3.398%
Other	0	0.000%	19	16.964%	0	0.000%
General Topic						
musculoskeletal	86	33.333%	24	21.429%	1	0.485%
women's Health	25	9.689%	10	8.929%	6	2.913%
headache	24	9.302%	7	6.250%	1	0.485%
other type of conditions	21	8.139%	23	20.536%	18	8.738%
neurologic condition	20	7.751%	7	6.250%	7	3.398%
mental health	18	6.976%	5	4.464%	5	2.427%
gastrointestinal disorders	14	5.426%	3	2.679%	12	5.825%
addiction	11	4.263%	3	2.679%	7	3.398%
autoimmune condition	8	3.1%	11	9.821%	27	13.107%
cardiovascular condition	8	3.1%	8	7.143%	2	0.971%
cancer and treatment related symptoms	7	2.713%	3	2.679%	91	44.175%
pulmonary disorder	5	1.937%	2	1.786%	3	1.456%
allergy	4	1.55%	1	0.893%	16	7.767%
urological disorder	4	1.55%	5	4.464%	1	0.485%
sleep disorder	3	1.162%	0	0.000%	45	21.845%
PBOA Instrument is primary	192	74.418	NA	NA	U	U
PBOA Instrument is secondary	21	8.139	NA	NA	U	U
PBOA Instrument is valid and reliable	223		NA		U	U

PBOA, patient-based outcome assessment; CO, cohort study; CCT, controlled clinical trial; CT=other clinical trial; Pilot, pilot study; RCT, randomized control trial; SR, systematic review.

Table 1. Study Characteristics

	Assessing	*Validity*	*Reliability*	*Clinical Responsiveness*	*Cost*	*Feasibility*	*Comparability*
Visual Analog Scale (VAS)	General Pain Intensity (Acute or Chronic)	X	X	X	Training: None Equipment: None Cost: Copying Permission: U	Self-administered, 1 min	X
Numerical Pain Rating Scale (NRS)	General Pain Intensity (Acute or Chronic)	X	X	X	Training: None Equipment: None Cost: Copying Permission: U	Self-administered, 1 min	X
McGill Present Pain Index (MPI or MPQ) (Including: the McGill Short Form Pain Questionnaire)	General Pain Intensity (Acute or Chronic)	X	X	X	Training: None Equipment: None Cost: Copying Permission: U	Self-administered, 5-10min	X
Oswestry Pain Disability Index (ODI) (Including: revised versions 1.0, 2.0, AAOS/MODEMS, "revised ODI")	Functional Disability & Back Pain (Acute or Chronic)	X	X	X	Training: None Equipment: None Cost: Copying Permission: Needed[a]	Self-administered, 5 min	X
Roland Morris Disability/Activity Questionnaire (Including: revised versions RM-23, RM-18)	Functional Disability & Back Pain (Acute & Subacute)	X	X	X	Training: None Equipment: None Cost: Copying Permission: None[a]	Self-administered, 5 min	X
SF-36 (Including modified versions)	Health Related Quality of Life	X	X	X	Training: None Equipment: Possibly Cost: Varies Permission: Needed, co-copyright holders[b]	Self-administered, 5 min	X
Nottingham Health Profile (NHP)	Health Related Quality of Life	X	X	X	Training: None Equipment: None Cost: Copying Permission: None	Self-administered, 7-10 min	X
Western Ontario and McMaster Universites (WOMAC) Osteoarthritis Index	Functional Disability & Arthritis Pain (Acute or Chronic)	X	X	X	Training: None Equipment: None Cost: Copying Permission: U	Self-administered, 5-10min	X

	Assessing	*Validity*	*Reliability*	*Clinical Responsiveness*	*Cost*	*Feasibility*	*Comparability*
Pain Disability Index	Functional Disability & Pain (Acute & Subacute)	X	X	X	Training: None Equipment: None Cost: Copying Permission: U	Self-administered, 5-10min	X
Beck Depression Inventory (BDI)	Depression	X	X	X	Training: None Equipment: None Cost: Copying Permission: U	Self-administered, 5-10min	X
Hamilton depression scale (HAMD)	Depression	X	X	X	Training: None Equipment: None Cost: Copying Permission: U	Self-administered, 5-10min	X
Measure Yourself Medical Outcome Profile (MYMOP)	Primary Care Setting	X	X	X	Training: None Equipment: None Cost: Copying Permission: Needed: Register as a user[c]	Self-administered, 7-10min	X
Hospital Anxiety & Depression Scale (HADS)	Hospital General Medical Outpatient	X	X	X	Training: None Equipment: None Cost: Copying Permission: Needed[d]	Self-administered, 5-10min	X

[a] The instruments (RM-24 & ODI version 2.0) are include in Roland and Fairbank (2000) appendixes (Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability

Questionnaire. Spine 2000; 25: 3115–3124). When used in the forms reproduced in the appendixes (Roland and Fairbank 2000), no permission is required from the authors or from Spine.

[b] RAND Health, a research division of the RAND corporation, the Medical Outcomes Trust (MOT), Health Assessment Lab (HAL), and QualityMetric Incorporated are co-copyright holders of the

Short Form Health Surveys.

[c] User registration is required at www.pms.ac.uk=mymop=index.php?c¼contact&s¼register.

[d] For purchase of questionnaire contact GL Assessments.

X, Available; U, unavailable.

Table 2. Common Pain, Disability, Depression, Health Status, and Well Being Measures use in clinical acupuncture research (Total n= 464)

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2.1. Inclusion and exclusion criteria

Originally the studies eligible for inclusion in the review included peer reviewed clinical trials, case reports, and randomized controlled trials for which a full abstract was available. A sensitive search was originally conducted for key search terms for ‘acupuncture’, 'pain', ‘disability’, ‘well-being’ and 'outcome measures'. Search terms for ‘acupuncture’ and 'pain' were limited to the title or abstract to constrain the magnitude of the review yield to a manageable size. For example search terms included: Acupuncture, Acupuncture Therapy, Acupuncture, Ear, Acupuncture Points, Acupuncture Analgesia, patient, outcome, measure, assessment and derivatives of each.

Acupuncture was defined according to the National Institutes of Health (NIH) National Center for Complementary and Alternative Medicine (NCCAM). [11]
The search restrictions were human, clinical trial, editorial, letter, meta-analysis, practice guideline, randomized controlled trial, and review for which a full abstract was available. Full length manuscripts were pulled whenever possible. This review also obtained full length manuscripts that reported the psychometric properties of the PBOA instruments. Hard copies were obtained of the instruments of interest that were reported in included papers. All abstract reviewed were in English. The search was restricted to instruments targeted towards adults (i.e. 16 years or older). No upper age limit was set.

Of the 520 abstracts reviewed 111 abstracts were case reports. Nearly always, a case report is written after the fact (after something of interest was noted in a given person). Therefore, a research-oriented outcome measure would not be expected to have been administered in a case report. For the purposes of this review, we exclude case reports from the final analysis.

We instead expanded our search to include all acupuncture clinical studies including but not limited to pain (see figure 2). This systematic review excluded studies on laser acupuncture, TENS, dry needling, audits, surveys, literature reviews, commentaries and proceedings.

The complete search strategy is illustrated in Figures 1 and 2. The database searched was PubMed. All papers were screened for pain, disability, general health status and well-being instruments that were reported in the title, abstract, and full article.

3. Results

The original search initially identified 582 articles. After screening of title/abstract, 212 articles were excluded. From the remaining 370 citations, 258 manuscripts identified explicit PBOA, while 112 abstracts did not include any PBOA (Fig. 1). A total of 258 manuscripts were extracted and reviewed (Table 1). When we conducted our secondary search for new papers (2009-2012) we found an additional 242 abstracts. Of the 242 article abstracts, 206 manuscript abstracts identified explicit PBOA, while 12 abstracts did not include any PBOA (Fig. 2). We excluded the 12 articles that did not include any PBOA from our discussion section and tables; therefore, this chapter discusses the results of an aggregate total 464 articles with PBOA instruments.

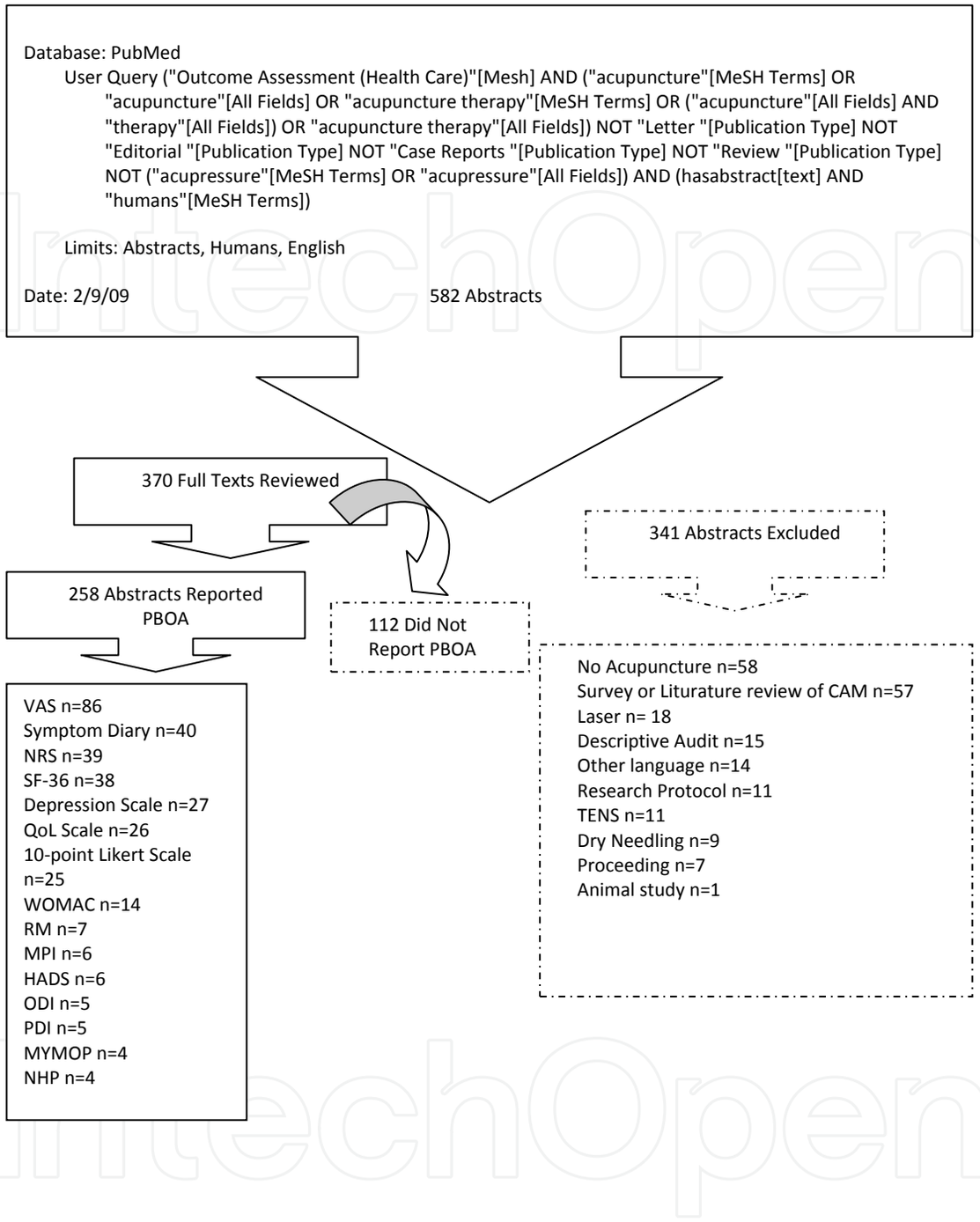

Figure 1. Primary search inclusion / exclusion flow chart

The original (inception) and secondary searches (2009-2012) both found that randomized control trials (RCTs) were the most common design for clinical acupuncture studies that met the criteria for inclusion in this discussion. In addition, musculoskeletal disorders were the most the most common condition researched in the included acupuncture studies. Of those instruments reviewed, the Visual Analog Scale (VAS) was

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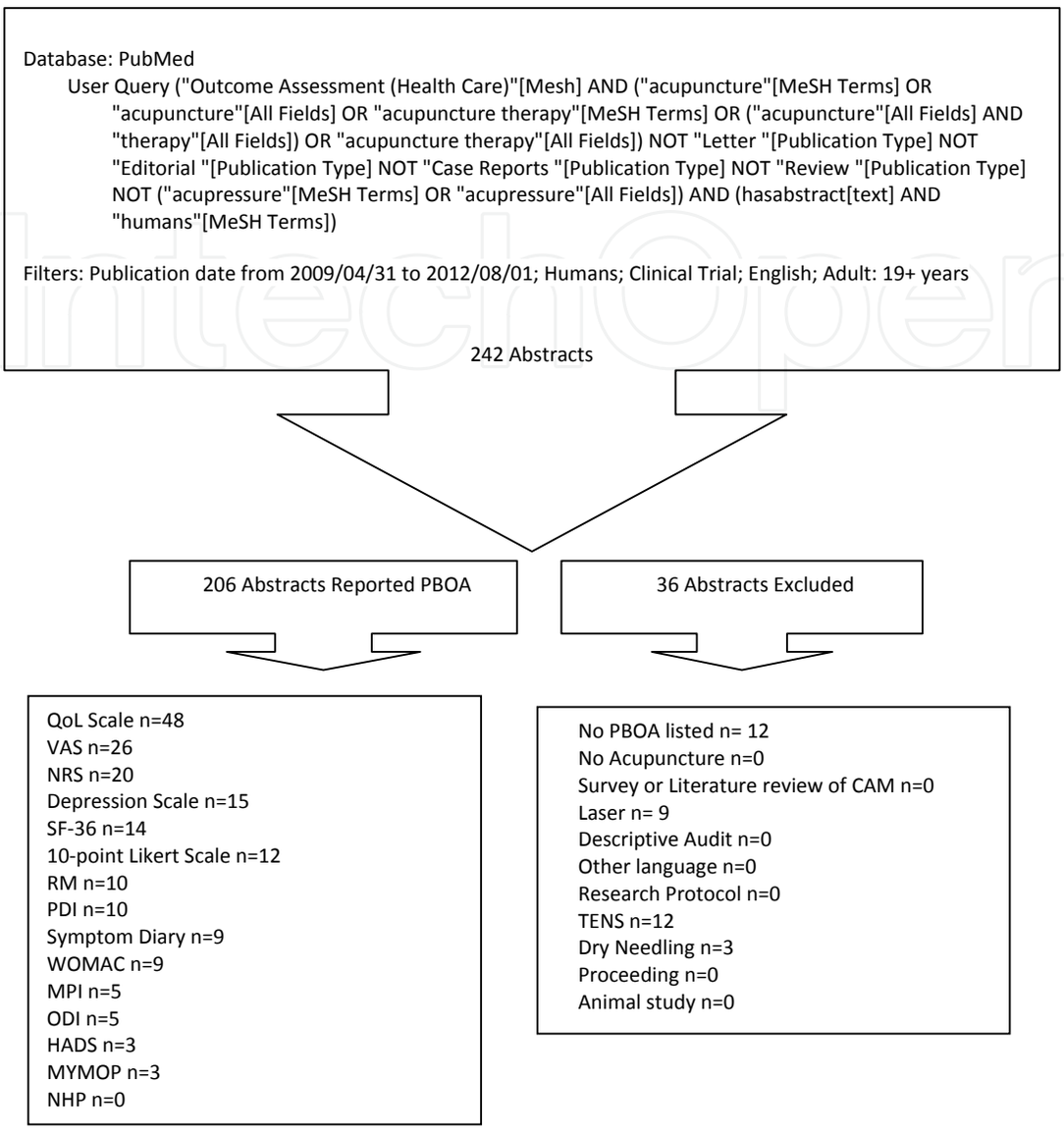

Figure 2. Secondary search inclusion / exclusion flow chart

the most common PBOA measure identified. Furthermore, we found that the VAS and the Numerical Pain Rating Scales (NRS) are the most common scales used to measure pain intensity. [20] The most commonly used health status and well being instrument was the SF-36. The vast majority of studies included PBOA instruments as their primary measure (~70%).

When we conducted our search in 2009, we found that the most common instruments used in acupuncture studies were single dimensional pain scales such as the VAS (n=86) and NRS

(n=39). Also in 2009, we found that about 60% of all acupuncture studies in this review used some sort of Quality-of-Life (QoL) measure.

In 2012, of those instruments reviewed during our secondary search, the Quality of Life Scale (QoL) was the most common PBOA measure identified. The Medical Outcomes Study Short Form-36 (SF-36) was the most common QoL instrument used across all study designs and conditions. Similar to our original search in 2009, the VAS and the Numerical Pain Rating Scales (NRS) were the most common scales used to measure pain intensity.

The most common multi-dimensional pain scales used in acupuncture pain studies were the McGill pain questionnaire (MPQ), the Oswestry Pain Disability Index (ODI), the Roland Morris Disability/Activity Questionnaire (RM), and the Western Ontario and McMaster Universites (WOMAC) Osteoarthritis Index. Table 1 provides a summary and characteristics of the studies included. Data on the psychometric properties of identified instruments were subsequently extracted and compared (See Table 2).

The number of study participants in the original search included studies ranged from 5 to 14,161 subjects. There were 11 studies that included 1,000 or more subject participants. The vast majority of the studies identified in this review employed a battery of instruments rather than a single instrument. Most study abstracts included a number of different PBOA instruments as well as including both patient and clinician reported instruments.

Our review found that identifying the main outcome of interest, i.e. pain as the primary outcome measure, was common is acupuncture studies. This was especially true for our most recent review of the literature (2009-2012). However, we also found that the types of existing PBOA instruments used in acupuncture clinical studies varied widely in their length and content from study to study. Some studies lacked standardized protocols for choosing PBOA instrument (~20%).

4. Discussion

There seems to be an increase in studies from Feb 2009 to Aug 2012 that incorporate PBOA. In 2009 we found that 582 clinical trial abstracts for acupuncture that reported PBOA. On Aug 1, 2012 we found 242 clinical trial abstracts that incorporate PBOA. This large increase, in a short time span, in clinical acupuncture studies that incorporate PBOA may reveal the considerable maturation of the field of acupuncture research. Langevin et al. [21] published white paper, identifies gaps in knowledge underlying the paradoxes and proposes strategies for their resolution through translational research. The authors recommend that acupuncture treatments should be studied (1) “top down” as multi-component “whole-system” interventions and (2) “bottom up” as mechanistic studies that focus on understanding how individual treatment components interact and translate into clinical and physiological outcomes. They

state that, "the complexity of acupuncture interventions makes it unlikely that even a battery of standardized outcomes will adequately capture the richness of practitioners' experiences, which may inform optimal study design." Langevin et al. recommend that, qualitative methods be used "to explore the meaning that patients ascribe to an intervention, the process and context by which healing occurs, outcomes that are relevant and meaningful to patients, and how interventions fit within everyday lives [22]." [21] We discuss these challenges in more detail in below sections.

4.1. Challenges and psychometric properties associated with PBOA instruments and acupuncture

The goal of this section is to provide the reader with a rich outline of the important aspects of the PBOA instruments examined in this review, rather than to discuss all the published works relating to the PBOA instruments. Toward that effort, we will briefly discuss some of the studies that highlight important aspects of a PBOA instrument (i.e., validity) that are significant when considering its use as an outcome measure in acupuncture research or clinical care.

The VAS is a patient completed analogue instrument that evaluates pain intensity and function, typically on a 100-mm-long horizontal or vertical line anchored at each end with a statement representing the extremes of the dimension being measured. The patient places a mark on the appropriate position on the line to represent his pain level. Generally, the NRS styles also include a horizontal line, but unlike the VAS, the NRS uses whole numbers (typically 0-10) to measure pain severity.

Both instruments provide pain intensity estimates relatively quickly, are highly patient-centered, have the most value when looking at change within individuals and are of less value for comparing across a group of individuals at one time point. Also both instruments are quick and simple to administer, [23] easy to translate into other languages, inexpensive, [24] and readily available. [25]

The single dimensional pain intensity scales (i.e. the VAS and NRS) have been criticized for their lack of sensitivity, oversimplifying the patient's experience of pain, and their single dimension of pain (e.g. intensity). [26] Also the VAS and NRS may not be an effective PBOA instrument for patients who have cognitive or motor problems, and in young children and elderly patients. [27]

Both in 2009 and 2012, we found that many (~60% or more) of all acupuncture studies in this review used some sort of Quality-of-Life (QoL) measure. QOL is a broad multidimensional concept that usually includes subjective evaluations of both positive and negative aspects of life. [28]

As stated, the Medical Outcomes Study Short Form-36 (SF-36) was the most common QoL instrument used across all study designs and conditions. The SF-36, often referred to as the MOS SF-36 [29], and the RAND 36-Item Health Survey 1.0 (distributed by RAND Corporation) are identical scales with 36-item general health. In 2012, we found that the majority of acupuncture clinical studies included QoL measures. For acupuncture and other CAM studies, QoL instruments such as the Centers for Disease Control and Prevention's (CDC) health-

related quality of life (HRQOL) defines health as a multidimensional construct that includes physical, mental, and social domains. This broad multidimensional aspect of QoL measure may also be presented as a challenge since the term "quality of life" has meaning for nearly everyone and every academic discipline, individuals and groups can define it differently. Although health is one of the important domains of overall quality of life, there are other domains as well—for instance, jobs, housing, schools, the neighborhood. Aspects of Culture, values, and spirituality are also key aspects of overall quality of life that add to the complexity of its measurement." [30] Nevertheless, it seems that a many acupuncture studies use QoL as a measure of health surveillance and intervention outcome. There are substantial reliability and validity data for Qol measures such as the SF-36. [31-34] Other QoL measures used were the NIH-Chronic Prostatitis Symptom Index (NIH-CPSI), the Nottingham Health Profile (NHP), and the EuroQol 5-Dimension form (EQ-5D).

For pain related studies such as headache, musculoskeletal, cancer,and treatment related symptoms the most common scales used in acupuncture clinical research included the VAS, NRS, 10-point Likert scale on subjective experience and global wellbeing (n=25), and symptom diary (n=40). However, most studies did not include citations for the use of the 10-point Likert scale on subjective experience and global wellbeing and symptom diary. Therefore it is unknown if there are any validity or reliability issues associated with these instruments. The Symptom Diary was also commonly used among acupuncture studies of pulmonary, sleep, and urological disorders. We were unable to determine whether the Symptom Diaries used in acupuncture research were structured, meaning that the research participants recorded particular information related to a specific health event or a particular research question; or unstructured (i.e., journals, used to explore a patient's spontaneous thoughts and feelings in relationship to a particular event). [35] No study in this review cited a standardized and validated Symptom Diary. While there are validated Symptom Diaries available (i.e., the Diagnostic Headache Diary), [36] it may be that most researchers are unable to find in the published literature a specific diary that meets their particular research question and therefore each research team devises its own diary. [37]

Aside from brief or predictable procedure related pain, more comprehensive pain assessment requires the determination of other characteristics of the pain, such as location and quality, and its effect on mood and function. Multidimensional pain assessment tools have been developed to quantitate these aspects of pain.

Our results found that the most common multi-dimensional pain scales used in acupuncture pain studies were the McGill pain questionnaire (MPQ), the Oswestry Pain Disability Index (ODI), the Roland Morris Disability/Activity Questionnaire (RM), and the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index.

McGill pain questionnaire (MPQ), also known as the Melzack pain questionnaire, was developed by Ronald Melzack of McGill University in 1975. This original questionnaire attempted to specify pain experience using 78 pain descriptors on 4 dimensions; I) sensory (items 1-10), II) affective (items 11-15), III) evaluative (items 16) and; IV) an additional miscellaneous descriptor (items 17–20). [38] In 1980, Melzack noted that the MPQ was too long and

complex for use in most clinical trials, and a short form of the MPQ (SF-MPQ) was derived from commonly used sensory and affective descriptors in the clinical studies Melzack conducted up to that time.

The ODI, like the MPQ, is a self-report questionnaire designed for assessing the degree of functional limitation in patients seeking secondary care for low-back pain, while the RM is designed for assessing the degree of functional limitation in patients with low-back pain in primary care. [39] The development, testing, and properties of both measures have been extensively examined and adequately reviewed (Table 2). Both instruments have been translated into many languages and used to evaluate outcome in a range of populations, settings, and interventions.

The WOMAC is a disease specific, self administered questionnaire that evaluates three dimensions: pain (5 questions), stiffness (2 questions), and physical function (17 questions). [40] The WOMAC was constructed to evaluate patients' experience of osteoarthritis (OA) of the knee and hip. It was designed in the late eighties in response to the lack of a multidimensional instrument that could measure clinically important, patient-relevant symptoms of OA in the knee and hip. [41]

The reliability and validity of the WOMAC has been demonstrated in a number of studies. [40-45] Overall the WOMAC has been compared to many instruments [46-55] with mixed results depending on which subscales (physical function, pain, and stiffness) were being evaluated or on what specific condition was being evaluated (total hip arthroplasty, total knee arthroplasty, OA of knee, OA of hip, rheumatoid).

Disability and depression scales were mainly used in acupuncture studies on mental health, neurologic conditions, addiction, autoimmune condition and musculoskeletal disorders. The most common disability and depression scales were the Pain Disability Index (PDI), and Beck Depression Inventory (BDI).

The PDI is a patient-completed, condition-specific functional status questionnaire. [56] The PDI rates the level of disability on a numerical rating scale (0=no disability and 10=maximum disability) assessing 7 broad categories of activity including items on recreation, personal care, activities related to home and family, work, frequency and quality of sex life, social activity and general life-support functions (e.g. eating, sleeping, and breathing). [57-59]

The BDI [60-62] is a multiple-choice self-report inventory among the most widely used instruments for measuring the severity of depression and related mental health. Both instruments were created to measure the intensity, severity, and depth of depression. There are several versions of both instruments.

The PDI and the BDI have been translated into many languages and used to evaluate outcome in a range of populations, settings, and interventions.

4.2. Measures for acupuncture in primary care settings and hospitals

The Measure Yourself Medical Outcome Profile (MYMOP), and the Hospital Anxiety and Depression Scale (HADS) [63,64] were used in several acupuncture clinical studies, including

acupuncture for chronic pain management and in the elderly (Fig. 1). MYMOP is an outcome measure originally developed to measure aspects and symptoms that a patient determines are most important to her or him, and their effects. It is a sensitive measure of within-person change over time, is applicable to the whole spectrum of illness seen in primary care, is capable of measuring the effects of a wide variety of care, and enables the patient to score the chosen variables. [65] The HADS consists of 14 questions, 7 for anxiety and 7 for depression. Although it was originally designed for hospital general medical outpatients, it has been extensively used for other populations such as in primary care. [63, 64]

The psychometric properties for the HADS have been extensively evaluated and validated across a range of populations, settings, and interventions.

4.3. PBOA instruments in acupuncture versus conventional therapy research

In 2006, Hull et al., [5] researched the various methods of assessing clinically meaningful change associated with a course of acupuncture treatments. They reported that assessing outcomes associated with acupuncture is particularly challenging compared to other therapies because ''acupuncture may result in subtle improvements in a general sense of well-being in ways that may not be measured by standardized instruments, and acupuncture treatments often are customized to meet individual patients' unique clinical needs and therapeutic goals, thereby making it difficult to define a priori a single set of clinical outcomes to assess'' (p. 247). [5] We believe that Hull et al. correctly assert that the effects of acupuncture cannot be easily quantified by commonly examined clinical outcomes due to its whole systems construct.

CAM therapies are often based on whole medical systems that are built upon complete systems of theory and practice, as is true for acupuncture. [66] Most research on acupuncture effects and application remains inconclusive among contemporary biomedical researchers and clinicians because the acupuncture research does not generally involve a standardized protocol. Acupuncturists generally tailor the treatments and therapeutic objectives to meet the individual patient's unique clinical presentation, needs, or desires. In addition, Hull et al. state that, "such individualized treatment approaches and therapeutic objectives may limit the ability of standardized instruments to assess meaningful clinical change among groups of patients'' (p. 248). [5]

4.4. Next steps: The need for more comparative research

The allopathic medical model limits treatment modalities to medications alone or in combination with, procedures, surgery and physical therapy. A more whole person integrative approach opens the therapeutic window to other options that can provide healing benefits.

The gold standard double blind placebo controlled drug trial has an honored place in modern science-based medicine but this method of study does not provide information about the patient as a person across the full spectrum of their health goals, expectations and needs. Regardless of the mechanisms by which acupuncture might provide benefit or harm patient-

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based outcome assessments must be developed that can be trusted, provide meaning and point the way toward their impacts.

Many patients suffer from chronic conditions for which standard diagnostics and treatments do not result in understanding, cure or satisfactory strategies to achieve better health with disease. In these cases other systems of medicine suggest approaches that may offer hope, relief, facilitate healing, and result in a greater degree of health. Additionally, for some people a surgical, molecular and biological cure may result in unnecessary disability because the barriers to whole-person healing and thriving were not removed. Each person can be responsible for some determinants of their own health and well-being and some whole-person alternative medical models better assure personal involvement and activation in the promotion of health and healing. Maturing our understanding of patient-based outcomes assessments can facilitate personalized, precision and participatory health behaviors and activities. Acupuncture and other non-pharmacological means to address acute, chronic and syndromic conditions should be addressed by comparative research to reveal optimal healing effective and safe strategies.

4.5. Finding more information on PBOA instruments

There are electronic databases established as sources of information on PBOA instruments for clinical and research use. Some can be accessed free of charge, whereas others require membership or fees. Khorsan *et al* discuss many common electronic databases and translated version of PBOA instruments available for researchers and clinicians [4]. One such source is the Patient-Reported Outcomes Measurement Information System (PROMIS). [67] PROMIS was originally developed as an NIH Roadmap network project intended to develop, validate, and standardize item banks to measure patient-reported outcomes relevant across common medical conditions. [68]The PROMIS is a publicly available system that can be added to and modified periodically, and which allows clinical researchers to access a common repository of items and computerized adaptive tests. The PROMIS is also a network for researchers and clinicians to collaborate on the collection of self-reported data from diverse populations with a variety of chronic diseases, using agreed-upon methods, models, and questionnaires.

4.6. Limitation

This study does not review all the measures found. It reviews the most frequently used measures. It therefore isn't a review of all the 'pain disability' measures. The aims of this review are to assess the common measures available and used, to identify the PBOA, and to describe a framework for identifying appropriate sets of measures, while addressing the unique challenges associated with use of these measures to assess acupuncture. A limitation of our review was that the outcome instrument had to appear in at least 3 publications in order to be included.

5. Conclusion

In conclusion, acupuncture researchers, like all clinical researchers, should assess the appropriateness of their treatment approach defined and measured by clinically significant change and determine patient satisfaction with the intervention. We found in this review that acupuncture research includes a combination of validated instruments, such as common standardized questionnaires that assess functional status or health-related QoL before and after the administration of a therapeutic intervention for a specific condition. Examples include the VAS, NRS, and SF-36 and disease specific QoL instrument such as the WOMAC, BDI, and RM used to quantify change over time. However, acupuncture research also included a wide variety of unvalidated instruments like the 10-point Likert scale on subjective experience and global well-being and Symptom Diary. Both types of measures were used to capture particular health and wellbeing information from the study participants in relationship to a specific health event or an experience based on a particular research question that no single instrument and no combination of validated scales alone could achieve. The large number of unvalidated PBOA instruments in acupuncture research may be associated with the paradigm of whole systems medicine [5]. Therefore, instruments such as MYMOP may be most useful for assessing clinical change in patients who present for acupuncture treatment with a variety of symptoms, clinical conditions, and therapeutic objectives.[5] Further research is needed to determine whether these results apply across other whole medical system therapies compared more so than to conventional therapy research.

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