

THE ROLE AND IMPORTANCE OF DEFINITIONS AND STANDARDS IN HEALING RESEARCH

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This supplement has been produced with funding from the Samuelli Institute for Information Biology. It contains 7 peer-reviewed papers presented at the First American Samuelli Symposium held in January 2003. These papers contain information on the definitions of healing energy, healing intention, and healing relationships, and recommendations for research protocols and methodologies that can serve as guidelines for basic and clinical research in these fields of inquiry. After the conference, one additional paper providing an example of healing research evaluation with quality guidelines, authored by Crawford, Sparber, and Jonas, was sent to the 7 senior authors of the presented papers for their peer-review and approval for inclusion.

The purpose of this introduction is to describe the process whereby the papers were created for this supplement, and our view of the purposes these guidelines can serve for the research and practice community.

BACKGROUND

People have a remarkable capacity to heal. Before the era of scientific medicine, most efforts were directed toward the support and simulation of the person's healing capacity. Thus, an emphasis on healing and healing relationships has been integral to all cultures since the dawn of mankind.

Also remarkable are the diversity of healing methods that "work" in indigenous practices, and for that matter current clinical practice, to relieve symptoms and improve function. These diverse healing systems have some core common components. Consciousness and perception play a crucial role in healing no matter what modality is used. This includes perception of the etiology and meaning of the illness, the intention to change and improve, belief in the therapy and the practitioner, and an expect-

ation for recovery. Most traditions also point to the occurrence of a process of deepening insight and awareness during effective encounters, called mindfulness or "presence," which is accompanied sometimes by an altered sense of time and space.

Many healing traditions describe a palpable sense of both emotional and physical healing "energy" and connectivity. Emotionally, this arises from empathy and manifests as compassion. Physically, this energy arises from bodily presence, and can be enhanced and concentrated by movement, breath, and focused attention. In many cultures, this is sometimes called "bioenergy" or vital energy.

There are also healing relationships and rituals. The former create a feeling of belonging and safety, and the latter create an environment of right social and cultural order or coherence. Out of these relationships and rituals comes a sense of control or empowerment in the ill person. When maximized, these common factors are said to induce meaning or context responses, and are the main factors underlying improvements reported with placebo.

Optimizing these common components of healing may improve health and well-being across a variety of conditions and treatments. We currently believe that certain healing modalities can enhance the above core components. A health-promoting lifestyle is on this list. This includes clean air and water, a balanced diet, adequate exercise, relaxation and stress management practices, and a sense of social connectivity and support. Health and healing also require management of exposure to toxins and addictions. These include drugs, alcohol, smoking, and food or other behavioral and social addictions.

Treatment modalities that stimulate inherent healing capacities usually involve targeted stresses that reactively induce recovery and repair mechanisms. These interventions can be physical (surgery, acupuncture, biological toxins [vaccinations], chemical toxins and drugs, exercise and manipulation); psychological (counseling, altruistic service, psychotherapy, meditation); or energetic (t'ai chi, qigong, yoga, homeopathy, energy healing, exposure to nature, music, and singing). While discovering which of these interventions is generally effective is the purview of science, properly selecting, maximizing, and managing the effects of these interventions in individual situations is

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the art of medicine. Both science and art are needed for the creation of optimal healing environments.

Opportunities in Healing Research

Today we have an unprecedented opportunity to investigate the impact of healing on persons and healthcare. There is an increased openness to the concept of holistic healing as a companion to curative therapies. However, little research has been done on the mechanisms of healing. We have sophisticated measurement technologies on the cellular, physiological, and neuroscience levels. Research designs and methodologies are improved, thereby allowing for more precise control of bias and more accurate description, measurement, and analysis of outcomes. There is now an acceptance that a plurality of research approaches is needed to fully understand a phenomenon. Most notable are the complementary nature of laboratory studies, randomized and observational clinical trials, and qualitative research for investigating the effects in medicine. Using all of these tools through rigorous research will help us enhance our understanding of how healing happens.

It was our belief that there were 2 major difficulties in moving forward in these fields of scientific inquiry: (1) the lack of standard definitions of terms such as healing, healing energy, intention, and healing relationships, and (2) the generally poor quality of current research with inadequate design, measurement, and analysis. We further believed that the creation of clear, standardized, working definitions and research guidelines would create a foundation of consistency, completeness, and uniformity, allowing a rational and systematic research agenda to be put in place.

Therefore, in this meeting, we focused on developing definitions for 3 core components of healing:

1. Laboratory research on consciousness and bioenergy,
2. Clinical research on consciousness and bioenergy,
3. Assessment of the clinical impact of healing relationships during care by nurses and physicians.

Similarly, we opined that research standards and guidelines would be needed for the conduct of healing research in at least 6 areas:

1. Laboratory research,
2. Randomized controlled trials,
3. Systematic review and meta-analyses,
4. Qualitative research,
5. Outcome, observational and epidemiological investigations, and
6. Health services research and technology assessment.

A dominant purpose of performing research is to derive data that can be promulgated and thereby shared with the scientific community. Similar to the concept of standardized definitions and protocols is the concept of uniformity in reporting data. A pertinent precedent in the conventional medical literature is the requirements surrounding the reporting of randomized trials (CONSORT),^{1,2} meta-analyses and systematic reviews of randomized trials (QUOROM),³ and meta-analyses and sys-

tematic reviews of observational trials (MOOSE).⁴ The requirement that these 3 standards for reporting always be used by investigators if the submission is to be accepted for publication in a peer-reviewed journal has been an important improvement and advance in the medical literature. In the same fashion, we believe there is considerable merit in investigators' planning, conducting, and reporting their work with respect to the definitions and guidelines described in this supplement.

PRECONFERENCE ACTIVITY

Seven writing committees were formed. Six committees had the responsibility for preparing draft working papers related to either basic or clinical research protocols for studies on healing energy, healing intention, or healing relationships. A committee composed of the 6 chairs with its own chair had the responsibility for preparing a paper containing the definitions of terms. Each writing committee was composed of up to 4 additional members. These working paper drafts were sent for review to all invited committee members before the meeting.

Two documents pertinent to the content of the research protocol draft papers were provided to the writing committees as background information. Created by one of us (WBJ), the documents, "Research Goals-Design Match," and "The Likelihood of Validity Evaluation Guidelines," are appended to this paper (Appendix 1 and 2, respectively).

CONFERENCE

The meeting took place in Newport Beach, Calif, January 10-12, 2003. The individual draft papers were presented at a plenary session composed of all of the attendees, a group of 35 distinguished research scientists. Recommendations made at that time as to content and meaning subsequently were integrated by each committee into their individual manuscripts. The final version of each paper is contained in this supplement.

COMMENT

The Samuelli Institute of Information Biology (SIIB) is a nonprofit, nonaffiliated medical research organization supporting the scientific investigation of healing processes with information biology and its application in health and disease. The Institute conducts and supports creative and rigorous scientific research through a network of laboratory programs around the world. More detailed information is available at <http://www.siib.org>.

SIIB offers this supplement with the full recognition that further modification and editing will be necessary as the science in these fields matures and continues to grow. We recognize there is controversy about some of the definitions used in these papers, and also which methodologies from conventional science can be applied to areas of inquiry in healing or to complementary and alternative medicine (CAM) in general. There also is a debate over whether the standardized protocols now extant in conventional science can be translated and therefore should be applied to CAM research.⁵

Understanding all of this, we are pleased to provide the information in this supplement to our colleagues. We sincerely hope that these definitions, guidelines, and recommendations will serve as the foundation and basis for future thought, inquiry, and studies in these fields of inquiry.

References

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2. Rennie D. CONSORT revised: improving the reporting of randomized trials. *JAMA*. 2001;285(15):2006-2007.
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APPENDIX 1. RESEARCH GOALS—QUALITY CRITERIA MATCH

The definition of quality research depends on the goals of that research. Therefore, a clear selection of research goals and questions is required before deciding on quality guidelines.¹ Quality guidelines for research should accomplish both general and specific goals oriented around the following domains of research:

1. *Proof of causality*: Sometimes also called “proof of principle” research, this requires careful control of all parameters that might influence the outcome other than the purported causal influence. It also usually requires exact, independent replication and may require systematic negative controls. Examples of this include research on mind-matter interactions (MMI) with random event generators and Direct Mental Interaction with Living Systems (DMILS) experiments with electrodermal augmentation (EDA) outcome parameters.

2. *Demonstration of theory/mechanism*: This involves the selection of specific and sometimes multiple control situations to test a theory or mechanism. Examples include testing of the data augmentation theory (DAT) in MMI research, or the mechanism of intracellular calcium rise from bioenergy, or the point location theory in acupuncture. Appropriate controls will vary as a function of theory.

3. *Clinical efficacy*: This research is directed at whether causal principles apply to a healing intervention for a specific clinical outcome. This usually requires a double blind, randomized controlled trial with a detailed specification of both the intervention and the primary outcome to be changed. The CONSORT criteria for reporting clinical research (especially the internal validity criteria) are a good starting point for this.²

4. *Clinical effectiveness*: These studies are designed to examine the contribution of a healing intervention to outcomes in nonexperimental clinical settings. Also known as observational or outcomes studies, they are often part of health services research. External validity criteria are useful guidelines for determining quality research on clinical effectiveness.

5. *Impact studies*: Sometimes termed “pragmatic trials,” these are designed to assess the impact (in terms of feasibility,

quality of life, clinical outcomes, economic burden and human relationship parameters) of interventions by whole systems, usually in an unblinded, but often randomized fashion, using standard care as the baseline control. In terms of quality criteria, they attempt to maximize external validity and fall midway between efficacy and effectiveness studies on internal validity.³

References

1. Jonas WB, Linde K. Conducting and evaluating clinical research in complementary and alternative medicine. In: Gallin J, ed. *Principles and Practice of Clinical Research*. New York: Academic Press; 2002:401-426.
2. Rennie D. CONSORT revised: improving the reporting of randomized trials. *JAMA*. 2001;285(15):2006-2007.
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Likelihood of Validity Evaluation (LOVE) Guidelines

Dimension	Criteria
<p>Internal validity</p> <ul style="list-style-type: none"> How likely is it that the effects reported are due to the independent variable (the treatment)? 	<p>Randomization</p> <ul style="list-style-type: none"> Were subjects assigned to treatment groups randomly and in a concealed manner? <p>Baseline comparability</p> <ul style="list-style-type: none"> Were gender, age, and prognostic factors balanced? <p>Change of intervention</p> <ul style="list-style-type: none"> Was there loss to follow-up, contamination, poor compliance? <p>Blinding</p> <ul style="list-style-type: none"> Did the patients, practitioners, evaluators, analysts know who got the treatment? <p>Outcomes</p> <ul style="list-style-type: none"> Were the objectivity, reliability, and sensitivity of the outcomes assessed? <p>Analysis</p> <ul style="list-style-type: none"> Was the number treated large? Were <i>P</i> values significant? Were multiple outcomes measured and properly analyzed?
<p>External validity</p> <ul style="list-style-type: none"> How likely is it that the observed effects would occur outside the study and in different settings? 	<p>Generalizability</p> <ul style="list-style-type: none"> Was there a range of patients as would be seen in practice or were there multiple or narrow inclusions and exclusions? <p>Reproducibility</p> <ul style="list-style-type: none"> Was what was done clear? Were confidence intervals reported? Was the treatment transferable to other practitioners? <p>Clinical significance</p> <ul style="list-style-type: none"> Was the effect size large enough to make a difference? Is the condition in need of this type of treatment? Were any preferences determined? Was adherence high? <p>Therapeutic interference</p> <ul style="list-style-type: none"> Was there flexibility in varying the treatment? Was feedback on the outcomes available? Is the treatment feasible in most (or your) practice settings? <p>Outcomes</p> <ul style="list-style-type: none"> Were the outcomes clinically relevant? Were the outcomes checked for importance with the patients? Were any important outcomes missing?

APPENDIX 2: THE LIKELIHOOD-OF-VALIDITY-EVALUATION GUIDELINES

The following set of research quality items, with an acronym of LOVE, have been validated and are used in evaluating a number of publication sets in complementary medicine and healing research.^{1,2}

References

- Jonas WB, Linde K. Conducting and evaluating clinical research in complementary and alternative medicine. In: Gallin J, ed. *Principles and Practice of Clinical Research*. New York: Academic Press; 2002:401-426.
- Jonas WB, Crawford C. *Healing, Intention, and Energy Medicine: Research, Methods and Clinical Implications*. London, UK: Churchill Livingstone; 2003.

Likelihood of Validity Evaluation (LOVE) Guidelines (cont'd)

Dimension	Criteria
<p>Model validity</p> <ul style="list-style-type: none"> • How likely is it that the study accurately reflects the system under investigation? 	<p>Representativeness/accuracy</p> <ul style="list-style-type: none"> • Were the therapists well trained and experienced? • Was the treatment strategy adequate? • Was the treatment clearly described? <p>Informed consent</p> <ul style="list-style-type: none"> • Was the informed consent comprehensive? • Was the informed consent effective—did patients understand it? • Did the informed consent generate expectations different from practice? <p>Methodology matching</p> <ul style="list-style-type: none"> • Were the goals of the study clear and limited? • Did the investigators select the correct research method to achieve the goals? <p>Model congruity</p> <ul style="list-style-type: none"> • Were the patients classified, was the treatment determined, and were the outcomes assessed according to the system of practice studied? <p>Context and meaning</p> <ul style="list-style-type: none"> • Did the patients and practitioners believe in the therapy? • How well was the intervention adapted to the culture, family, and meaning of the patient?
<p>Reporting quality</p> <ul style="list-style-type: none"> • How likely is it that the report accurately reflects what was found in the study? • How clear and accurate is the information presented? 	<p>Comprehensive</p> <ul style="list-style-type: none"> • Can you address the above criteria? <p>Clarity</p> <ul style="list-style-type: none"> • Could you reproduce this study? <p>Conclusions</p> <ul style="list-style-type: none"> • Were the conclusions and reporting format (eg, relative versus absolute improvement rates, strength of wording) appropriate to the data collected?