

THE PROCAIM NETWORK

www.procaim.org

*Patient Reported Outcomes
from
Complementary, Alternative
& Integrative Medicine
Network*



From the Schools of Medicine and Public Health, University of California – Los Angeles.

Developed under grant #AT002681 from the National Center for Complementary and Alternative Medicine to the UCLA Center for Neurovisceral Sciences and Women's Health.

PROCAIM, which stands for Patient-Reported Outcomes from Complementary, Alternative, and Integrative Medicine, is a Web-based data collection and information system. PROCAIM collects a wide range of data using standardized questionnaires that address changes over time in symptom severity, mood, stress and coping skills, and quality of life. Access is through the PROCAIM web site, www.procaim.org.

The **PROCAIM Network** is a multi-clinic research project linking patients, treatment providers, and researchers interested in improving health and well-being through the various integrative therapies, including mind/body approaches and complementary and alternative medicine. The PROCAIM Network facilitates study of the effects of various therapies on patient self-reported outcomes and symptoms.



PROCAIM is supported by grant AT002681 from the National Center for Complementary and Alternative Medicine (NCCAM) to the UCLA Center for Neurovisceral Sciences and Women's Health (CNS/WH). The central and overarching theme of the CNS/WH is to study the interface between stress, pain, and emotion in health and chronic disease.

The PROCAIM Network facilitates research into the interactions among stress, coping, symptoms, and treatments by collecting data from a large and varied patient population.

The PROCAIM database serves as a research resource for effectiveness research and hypothesis-driven collaborative studies on the pathophysiological mechanisms involved in symptom presentation and treatment response.

A Brief Background

The practice of medicine continues to evolve at an ever-accelerating pace. Correspondingly, patients are becoming more involved in their own health care and decision-making. Their expectations for their care are dramatically changing and their satisfaction is driving treatment decisions.

The Internet is accelerating this evolution in the practice of medicine. Patients are using the Internet to get information about their medical conditions. Clinical practice groups are also using the Internet to share and coordinate their activities. Researchers are using the Internet to conduct multi-site clinical trials involving large numbers of patients in diverse locations.

Believing that new technologies can only serve to make patients more active and satisfied participants in their care, we have created an Internet-based practice network of treatment providers, patients, and researchers. PROCAIM uses reliable and valid instruments to collect information directly from patients about their symptoms and satisfaction with treatment and provides them the opportunity to track their outcomes and communicate with their care givers.

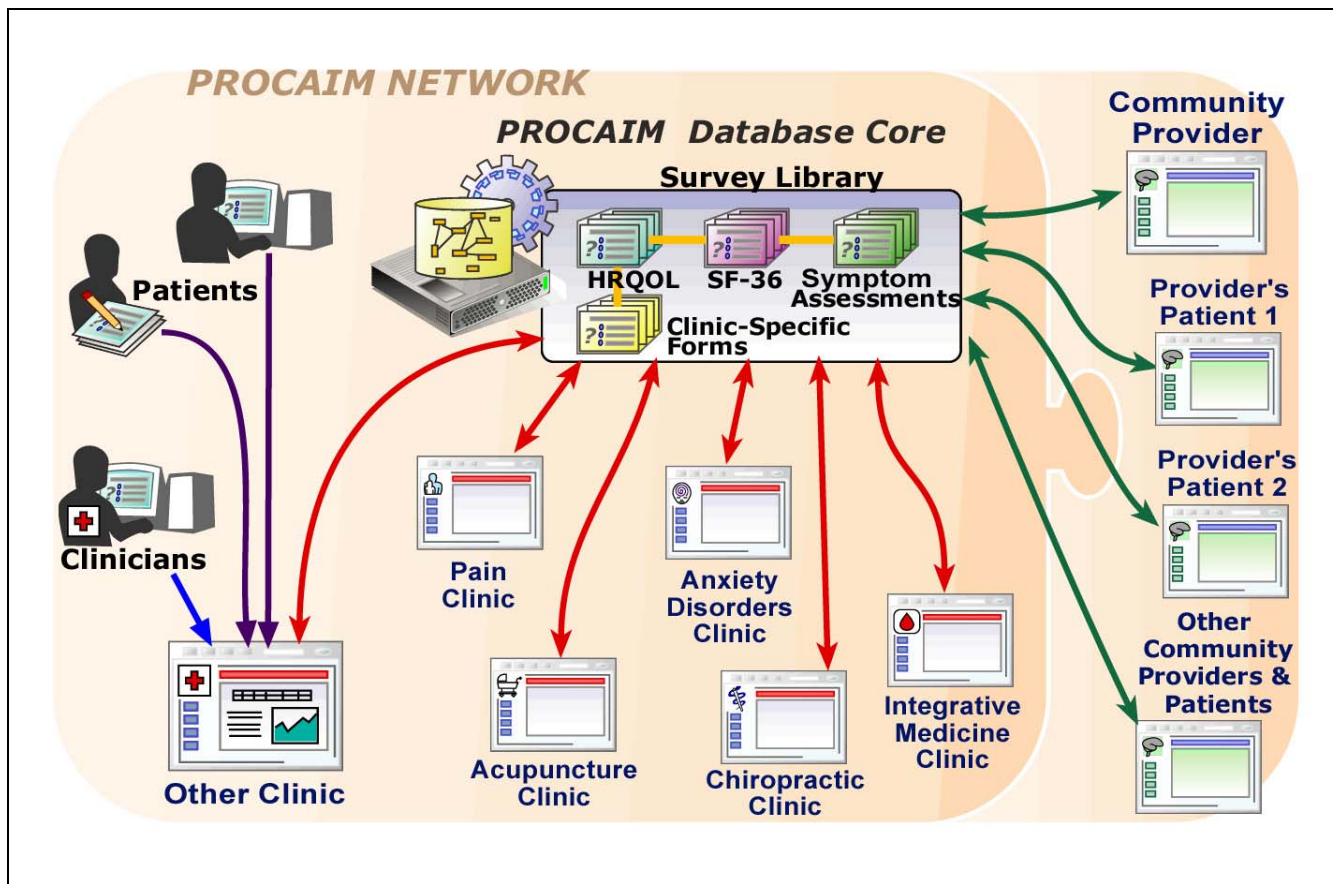
How does PROCAIM work?

Patient recruitment and consent. Patients learn about PROCAIM through fliers placed in participating and affiliated clinics. Patients may be recruited through participating clinics or they may self refer after reading our brochures. Clinic patients are consented by either a coordinator at participating clinics or by PROCAIM staff. Consented patients receive instructions for logging on to the web site through a computer at the clinic or on their own personal computers. Upon their first visit to the site, patients log in using their email address as their username and then are prompted to create a password.

On-line consent. Alternatively, patients may now access PROCAIM directly, read the on-line consent form, and agree to participate by entering their email address and username.

Consented patients then begin to complete a series of scheduled questionnaires on the PROCAIM web site. The initial (baseline) set of surveys takes approximately 30-45 minutes and can be completed at two sessions in the first week. Thereafter, patients are sent e-mail reminders to complete additional assessments at intervals over the next 12 months. Patients are participants for either the duration of their clinic treatment, until consent is withdrawn, or at the end of one year (whichever comes first).

Provider reporting. Providers may be asked for their patients' diagnoses and recommended treatments. When patients are recruited through clinics or if patients who self-enroll agree to share their questionnaire information, the treatment providers will be asked for the primary and secondary diagnoses, and if the patients have any functional disorders.



Data Collection

The PROCAIM core consists of a library of self-report questionnaires. The questionnaires were selected on the basis of available evidence of validity, standardization, commonness of use, public domain access, and instrument length. These instruments include assessments of quality of life, somatic symptom severity, depression and anxiety, coping skills, early life trauma, current stress, and specific symptoms including pain, sleep problems and fatigue.

The resulting data represent a Common Data Set across all participating clinics and patient populations. This data set contains general demographic information including age, gender, education, ethnicity; a brief review of current symptoms, a brief description of treatment history, and longitudinal information obtained from the self-report questionnaires at baseline and at intervals over one year.

Clinicians or clinic coordinators can log in to review patients' information and to provide diagnoses, clinical judgment of treatment outcome, and primary treatment modality (e.g., acupuncture, medication type and dose, biofeedback, cognitive-behavioral psychotherapy).

Participating clinics can choose to utilize either the full PROCAIM Library or - under certain conditions with some treatments and patient populations - to a pared-down PROCAIM-lite version. The "lite" version does not utilize the full battery of questionnaires and requires less frequent responses on the part of the patient. See below for a comparison of the two data sets, the questionnaires and schedules for each.

PROCAIM COMMON DATA SET: Questionnaires and Schedule

Questionnaire	Baseline	1 month	2 month	3 month	6 month	9 month	12 month
Demographics	x						
Early Trauma Inventory	x						
Treatment History				x	x	x	x
SF36	x			x	x	x	x
Patient Health Questionnaire-15	x			x	x	x	x
Hospital Anxiety and Depression	x			x	x	x	x
Life Orientation Test-R	x			x	x	x	x
Perceived Stress Scale	x			x	x	x	x
Catastrophizing (Coping Strategies)	x			x	x	x	x
Daily Stress Inventory	x				x		x
Spirituality	x				x		x
Mindful Awareness Assessment Scale	x	x	x	x	x	x	x
Brief Pain Inventory	x	x	x	x	x	x	x
HAM-D sleep	x	x	x	x	x	x	x
Recent Life Changes		x			x		x
Global Improvement	x	x	x	x	x	x	x
Satisfaction with Care			x	x	x	x	x
System Assessment	x	x	x	x	x	x	x

- Questionnaires and frequencies in red represent the “lite” version.
- The complete data set includes both black and red questionnaires.

In addition to the above protocol, participating clinics can work with the PROCAIM research team to include their own instrumentation and protocols.

Data Storage and Confidentiality.

The PROCAIM system was developed by the UCLA Computing Technology Research Labs (CTRL). All data are maintained by CTRL, which provides a HIPAA-compliant, secure hosting environment with multiple data backups.

Digital access to data is limited to individual patients, the clinical providers, and the research team by storage into secured computer accounts. Data security is insured through the use of level-specific passwords and SSL encryption technology.

Data confidentiality is controlled through different levels of access. For example, *patient-level* access, which requires patients’ email address and self-generated password, permits patients to view their own information. *Therapist-level* access, which requires clinical staff’s email address, a self-generated password and administrative approval, permits viewing and entry of treatment and diagnosis for their own patients

What is the significance of PROCAIM?

The PROCAIM database facilitates large scale, multi-site studies in the following areas.

- Effectiveness research, to evaluate the effectiveness of the various modes of mind/body interventions and to identify characteristics of patients who may be most likely to improve with each type of treatment.
- Hypothesis-driven research, to enhance understanding of the complex pathophysiology underlying some of the most common chronic stress-related diseases (such as visceral and somatic pain syndromes, disorders of mood and affect, and addictive behaviors).
- Clinical management, to assist participating clinics that treat patients with various mind/body therapies and other forms of complementary and alternative medicine
- Clinical trials to evaluate competing treatments or treatments vs. placebo

The PROCAIM Network's goal is to foster collaborative research among treatment providers and clinical researchers for research questions best addressed both by analysis of new or existing data and by hypothesis-driven data collection. Members of the CNS/WH faculty are available to provide statistical and epidemiologic consulting for research questions, study designs and analytic methods relevant to the PROCAIM database.

What does PROCAIM look like?

To view a version of the PROCAIM system and try a few functions as either a patient or a care provider, please log on to the demo version.

PROCAIM DEMO INSTRUCTIONS for PATIENTS AND PROVIDERS

To begin taking the patient surveys, log in at <http://demo.procaim.org>.

Click "Integrative Medicine Clinic" on the left side of the screen

Click "New User"

Enter first and last name, email address, and password. Click "OK"

Select "Questionnaires" link on the left.

To view the system as a care provider, log in at <http://demo.procaim.org>.

Click "Integrative Medicine Clinic" on the left side of the screen

Enter email address: firstprovider@ucla.edu

Enter the password: [temp](#)

Click "Log In"

To enroll a new patient

Select "Enroll New Patient Under "Patient Administration" heading," link.

Enter patient name and email address, and verify patient consented (Approved).

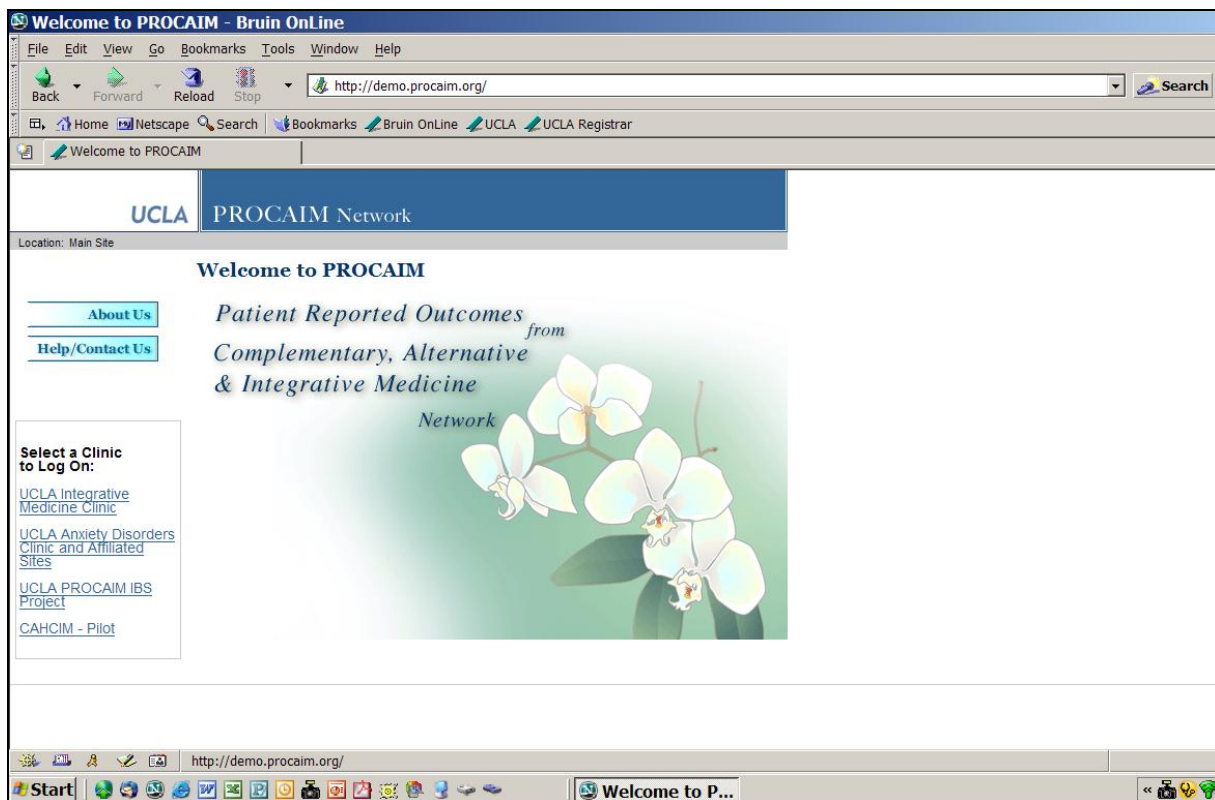
The system is designed to automatically generate a password "temp" and send an email to the patient. The e-mail contains instructions to log in as a returning user using the "temp" password, change the password, explore the site, and begin completing the questionnaires.

To add diagnosis and treatment information on an existing patient

Select "Patients Approved Report" link under "Patient Administration" heading,

Select "Diagnosis" link to the right of the patient's name and email address.

Complete the questionnaire, which includes questions regarding the patient's primary diagnosis, secondary diagnoses, other functional disorders, treatments, and prediction of progress.



How can PROCAIM be utilized?

Clinics can join the PROCAIM Network to help track their patients' outcomes. Clinical researchers can utilize any of the questionnaires in PROCAIM's survey library and its Internet accessibility to collect longitudinal data from patients in clinical trials or to conduct health outcomes studies. Other researchers can use PROCAIM's database and questionnaires to address specific hypotheses, add other instruments, and develop and test new questionnaires.

For more information about PROCAIM, please contact Dr. Deborah Ackerman or any of the following:

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