

CPAIN Overview

The Chronic Pain Impact Network™ (CPAIN) www.cpain.org is a national program designed and developed by REGISTRAT-MAPI to improve the lives of patients and support clinicians dealing with chronic pain. CPAIN uses innovative technology to capture data on pain treatments and associated patient reported outcomes. The program has two parts, the Patient Profiler and the Research Study. The CPAIN Patient Profiler provides clinicians with longitudinal patient profile reports containing comprehensive assessments that guide pain management and monitor treatment effectiveness over time. The Research Study provides network-wide data that allow for global assessments of pain management such as comparative effectiveness research (CER) analyses, enhanced postmarketing safety surveillance, and execution and assessment of risk evaluation and mitigation strategies (REMS).

Chronic pain is common, affecting an estimated 33% of the US population and accounting for an estimated 100 billion dollars in costs related to health care, lost productivity, and litigation. Unfortunately, chronic pain is often under-treated and not well managed and is considered to be a major public health problem. Chronic pain is therefore a logical focus for comparative effectiveness research that has become a national priority as the US struggles with the world's highest health care costs and questions being raised about the quality of health care delivered. Another public health problem is the abuse of prescription medications, particularly with opioids.

CPAIN uses a validated database to capture information on pharmacologic and non-pharmacologic treatments. Patient reported outcomes data are also collected to measure the comparative effectiveness and safety of different therapies. Patient descriptive data allows for a better understanding of how different types of chronic pain are being managed and clinician descriptive data allows for a better understanding of who is managing chronic pain and whether this affects patient outcomes. Additional safety information will be collected on the misuse, abuse and diversion of medications. The network of pain clinicians and chronic pain patients that are part of the program provides an important resource for pharmaceutical and medical device companies designing product specific clinical studies. CPAIN can be utilized for study feasibility, investigator and patient recruitment, and conduct of sub-studies and surveys.

CPAIN provides value to multiple groups. The self-assessment tools in the Patient Profiler help patients communicate with their managing clinicians allowing them to more succinctly describe their continuum of care and the impact that chronic pain has on their daily lives. CPAIN data help clinicians document the comprehensiveness and quality of patient care and help guide

treatment decisions. The ease of use of the Patient Profiler and the degree to which it can be efficiently incorporated into routine clinical practice is a key determinant in ensuring the early adoption of CPAIN.

Comparative effectiveness, safety, and economic impact data from the CPAIN Research Study help pharmaceutical and medical device companies justify the cost of their products. The epidemiology of chronic pain and product utilization data help these companies design clinical development programs and develop marketing strategies. Payers, private and federal and state governments, can use outcomes data to guide reimbursement decisions. Regulators need safety data to monitor marketed products and to guide decisions on risk mitigation strategies. Medical societies need these types of data to develop evidence based treatment guidelines.

The use of CPAIN outcome data to develop “measurement based pain management” practices has been validated at the University of Washington (UW) and was used as the basis for the Washington State Legislature Engrossed Substitute House Bill 2896 passed 11-Mar-2010 (attached). Additionally, the US Department of Defense (DoD) conducted a nationwide search of pain outcome programs and selected CPAIN as the best choice. The American Academy of Pain Medicine (AAPM) also conducted a similar search and is now in discussions with REGISTRAT-MAPI for an alliance with CPAIN.

Competitive Analysis

No other databases currently exist that combine patient reported outcomes, patient demographics, clinician demographics, prescription data, non-pharmacologic treatment data and misuse, abuse and diversion data. The largest provider of prescription information is IMS Health, treatment information and patient demographics can be obtained from claims and other electronic health record (EHR) databases, and several companies are developing various practice management tools that collect patient reported outcomes.

The natural history of chronic pain may be difficult to study using a claims or EHR database because of lack of specific patient symptom information. Practice management tools do not collect detailed treatment data. CPAIN is the most comprehensive chronic pain database that uniquely captures patient reported outcome data and provides clinicians with effective practice management tools.

Value to Payers

As new pain therapies are introduced payers are often faced with tough decisions about levels of coverage. They often question how data from controlled

clinical trials relate to “real world” product use. Data on comparative effectiveness and economic impact should provide payers with much needed evidence to support their decisions about treatment reimbursement. CPAIN may make it possible to identify a small subset of chronic pain patients responsible for a disproportionate percent of costs. Identifying this subset early and referring them to more efficient specialty care as the potential to decrease overall costs.