



Measurement of Pain
Behavioral, Social
and Biological Factors

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Executive Summary
National Institutes of Health
Office of the Director
Office of Behavioral and Social Sciences Research

Meeting Description

The Office of Behavioral and Social Sciences convened a panel of experts on *Measurement of Pain: Behavioral, Social, and Biological Factors* on February 13-14, 2020 in Rockville, MD. The primary goal of the meeting was to inform the behavioral and social sciences research community, stakeholders, and NIH Institutes and Centers about cutting-edge ways to measure chronic pain and what research is needed to develop, test, and validate the next generation of pain measures.

Meeting Objectives

The objectives and goals of the meeting were to:

- 1) Describe major influences on current pain measurement instruments.
- 2) Inform researchers in the field about existing technologies and encourage discussion about unmet needs.
- 3) Identify steps to move toward more accurate and comprehensive measurement of pain experiences.

Background

An estimated 11 to 40 percent of US adults report chronic pain, with considerable population subgroup variation. The condition has been linked to restrictions in mobility and daily activities, dependence on opioids, anxiety and depression, and poor perceived health or reduced quality of life (<https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6736a2-H.pdf>). In the context of chronic pain, the consensus is psychosocial and emotional factors play major roles in severity and impact on daily functioning. Consequently, rating of chronic pain should be understood from a framework of multiple factors, including, but not limited to the situation, patient demographics, reports of function and quality of life.

Comprehensive measurement is needed to address the complex, interconnected experience of chronic pain, which can vary throughout the day or with a person's experiences. Because pain is a subjective and individually variable experience, providers are unable to verify how much pain a person is experiencing. They often also ask questions that people experiencing pain are

unable to answer specifically—for example, a person’s “average” pain level may vary dramatically throughout the day, between days, or depending on activities. Science does not currently have a good understanding of how interactions between various factors influence a person’s pain level. Many people who experience pain say that current pain measurements are somewhat useful but do not capture the full pain experience; a paradigm shift is necessary to transition pain care to match what people experience.

Although many innovations have been developed, the zero-to-10 pain scale remains the most commonly used measure. It lacks precision, does not account for the subjectivity of the pain experience nor the factors that may affect how people self-report their pain. Item response theory tests and environmental momentary assessments (EMAs) both can capture more complexity than the standard pain scale, but further innovation is needed. Wearable devices and sensors in mobile phones are beginning to be used for innovative tests and monitoring, and their use is likely to expand. Currently there are no validated biomarkers of pain and this area of research remains in its early stages.

Meeting Highlights

There were a series of scientific presentations that highlighted:

- 1) Current advances and challenges in chronic pain measurement
 - Current models fail to capture the heterogeneity of pain and its temporally dynamic changes.
 - Pain is the most common reason people resort to legal action, but the legal system has a long-standing tradition of seeking verification and quantification that does not correlate with the heterogeneity of pain. In legal and cultural spheres, terms such “psychological” and “subjective” can be used negatively; thus, researchers and clinicians should be aware that these terms are used and understood differently outside their own field.
- 2) Moving beyond the visual analog scale
 - Single item visual analog scales are inadequate to measure the multi-factorial nature of the pain experience. Current scales ask respondents to rely on memory, which is often affected by mood and the pain experience itself.
 - More recent advances in pain reporting have standardized stimuli and allow self-reports in natural settings, allowing the development of a moving average and collection of other factors affecting the pain experience.
- 3) Multiple factors (co-morbidities, social, cultural factors, age) contributing to the chronic pain experience
 - Depression and anxiety are common features in the pain experience, both as precipitators of pain and outcomes of unrelieved pain.
 - Sleep disturbances, which is often reported in the chronic pain setting, can be considered pain outcomes, and the consequences of disturbance can be measured and are less likely to be influenced by environmental factors.
 - Within the pediatric setting, children experience chronic pain at similar rates to adults. Children live in the context of their families’ experiences of depression, anxiety, financial burden and are important considerations in pain assessment and treatment.

- Pain catastrophizing involves multiple primary sensory and associative brain networks, which in normal functioning activate and deactivate as distinct assemblies. Individuals with greater connectivity between networks are more likely to engage in pain catastrophizing, which may reduce the brain's ability to switch between active networks and blur the networks that are normally distinct.
- 4) Use of technologies to inform pain outcomes and their role in clinical trials and measurement development
- Current wearable devices provide more granular data on functional measures, allowing researchers to identify some impairments that might be missed in visual assessment.
 - The increasing use of apps is allowing for data collection outside the clinic setting and is adding to the growing body of evidence that African Americans are disproportionately burdened by chronic pain, regardless of their activity levels.
 - Quantitative sensory testing (QST) operates under the hypothesis that the clinical phenotype of pain reflects the underlying mechanism; however, this needs further testing. Additionally, it is time consuming and cost prohibitive in large phase III trials.
 - Inter-reliability of data across multiple studies is lacking, and those in the pain field have not agreed on the necessary components of any assessment, which may not be the same as the components currently collected on clinical records.
 - Pain researchers tend to focus on their areas of expertise; however, given the multi-factorial components underlying chronic pain, more collaboration across disciplines is needed.
- 5) Methodological and regulatory issues in clinical trial development and implementation
- The FDA's Patient-Focused Drug Development (PFDD) recognizes that patients and caregivers play a significant role in drug development, particularly on what measures are meaningful to them.
 - To match the right drug with the right patient, in the Phase II trial setting, responders to the treatment or placebo could be identified and included or excluded for the second stage.
 - EMA, which is collected in a real-world environment and focus on a subject's momentary state, can augment other standard measures. EMAs can be useful in illustrating individual variability.
- 6) Challenges in developing a complex composite measurement
- Factors affecting pain depend partially on the nature of the pain condition, but researchers also must think about commonalities across pain conditions and determine whether different biological or sociological factors should be considered.
 - Clinicians should be encouraged to screen every chronic pain patient for psychosocial distress
 - Patients with chronic pain repeatedly stress the importance of functioning in daily life and participating in social activities, which providers and researchers should recognize when considering how to study and treat pain.
 - There is a need for a data repository specific to pain researchers with standardized data and optimal sharing, suggesting that virtual pain centers could help integrate the community and develop the desired constructs for measurement.

- More data are needed to better understand how pain varies as a function of the social context.
- Providers and researchers must resist the tendency toward oversimplifying the complicated, multivariable chronic pain condition.