American Pain Society
RESEARCH
EDUCATION
TREATMENT
ADVOCACY
PUBLISHED BY ELSEVIER

The Journal of Pain, Vol 16, No 4 (April), 2015: pp 299-305
Available online at www.jpain.org and www.sciencedirect.com

Critical Reviews

Quality of Pain Intensity Assessment Reporting: ACTTION Systematic Review and Recommendations

Shannon M. Smith,[*] Matthew Hunsinger,[†] Andrew McKeown,[*] Melissa Parkhurst,[‡] Robert Allen,[§] Stephen Kopko,[¶] Yun Lu,[‖] Hilary D. Wilson,[**] Laurie B. Burke,[††] Paul Desjardins,[‡‡] Michael P. McDermott,[§§,¶¶,‖‖] Bob A. Rappaport,[***] Dennis C. Turk,[†††] and Robert H. Dworkin[*,¶¶,‖‖]

*Departments of *Anesthesiology, [‡]Psychiatry, [§§]Biostatistics and Computational Biology, [¶¶]Neurology, and [‖‖]Center for Human Experimental Therapeutics, University of Rochester School of Medicine and Dentistry, Rochester, New York.*
[†]School of Professional Psychology, Pacific University, Hillsboro, Oregon.
[§]Centrexion Corporation, Baltimore, Maryland.
[¶]Clinical Data Interchange Standards Consortium, Austin, Texas.
[‖]KAI Research, Inc, Rockville, Maryland.
[**]Evidera, Seattle, Washington.
[††]LORA Group, LLC, Royal Oak, Maryland.
[‡‡]Desjardins Associates, Maplewood, New Jersey.
[***]Center for Drug Evaluation and Research, United States Food and Drug Administration, Silver Spring, Maryland.
[†††]Department of Anesthesiology and Pain Medicine, University of Washington, Seattle, Washington.

Abstract: **Pain intensity assessments are used widely in human pain research, and their transparent reporting is crucial to interpreting study results. In this systematic review, we examined reporting of human pain intensity assessments and related elements (eg, administration frequency, time period assessed, type of pain) in all empirical pain studies with adult participants in 3 major pain journals (ie, *European Journal of Pain*, *Journal of Pain*, and *Pain*) between January 2011 and July 2012. Of the 262 articles identified, close to one-quarter (24%) ambiguously reported the pain intensity assessment. Elements related to the pain intensity assessment were frequently not reported: 31% did not identify the time period participants were asked to rate, 43% failed to report the type of pain intensity rated, and 58% did not report the specific location or pain condition rated. No differences were observed between randomized clinical trials and experimental (eg, studies involving experimental manipulation without random group assignment and blinding) and observational studies in reporting quality. The ability to understand study results, and to compare results between studies, is compromised when pain intensity assessments are not fully reported. Recommendations are presented regarding key details for investigators to consider when conducting and reporting pain intensity assessments in human adults.**

***Perspective:** This systematic review demonstrates that publications of pain research often incompletely report pain intensity assessments and their details (eg, administration frequency, type of*

Supplementary data accompanying this article are available online at www.jpain.org and www.sciencedirect.com.
The views expressed in this article are those of the authors and no official endorsement by the Food and Drug Administration (FDA) or the pharmaceutical and device companies that provided unrestricted grants to support the activities of the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public-private partnership should be inferred. Financial support for this project was provided by the ACTTION public-private partnership, which has received research contracts, grants, or other revenue from the FDA, multiple pharmaceutical and device companies, and other sources.
Address reprint requests to Shannon M. Smith, PhD, Department of Anesthesiology, University of Rochester School of Medicine and Dentistry, 601 Elmwood Ave, Box 604, Rochester, NY 14642. E-mail: shannon1_smith@urmc.rochester.edu
1526-5900/$36.00

http://dx.doi.org/10.1016/j.jpain.2015.01.004

pain). Failure to fully report details of pain intensity assessments creates ambiguity in interpreting research results. Recommendations are proposed to increase transparent reporting.

Key words: *Pain intensity, pain measurement, pain research.*

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations for 6 core outcome domains for chronic pain clinical trials[19] and the measures to assess these domains[3] have facilitated the standardization of outcome assessment in pain research. Although the vast majority of analgesic clinical research in humans assesses pain intensity, the methods of assessment vary among studies, which can affect the interpretation and meaningfulness of study results. For example, although there is good evidence that both current and recalled pain intensity ratings are valid,[1,12,13] other research suggests that recalling pain over time involves cognitive processes that may affect the validity of such ratings.[5,9,14,17] There is also debate about whether a single pain intensity assessment can provide adequate assay sensitivity compared to the average of frequently reported pain intensity scores,[10,11,18] despite the greater reliability of averaged assessments.[13] The assay sensitivity of pain intensity assessments also may be affected by the way in which the assessments are implemented.[4]

Given that there is no universal approach to assessing pain intensity in human adults, the onus is on investigators to be fully transparent about all aspects of their assessment method so that others can understand what elements of pain intensity are being measured and under what circumstances. This issue has been previously addressed in research with both adults and children,[15,16] although it is unclear whether these efforts have led to improved reporting of pain intensity assessments since their publication almost a decade ago. When the method of assessment is not fully described, there is ambiguity regarding how key data in the research were collected, making it unclear to the reader what instructions were given to participants and what, if anything, participants were advised to consider when rating their pain intensity. Additionally, failing to identify the pain intensity assessment used and elements such as the endpoints and anchors used, the type of pain intensity assessed (ie, average, worst, least, current), the specific pain location or condition participants considered, the time period rated, and the frequency of pain intensity assessments could reflect a lack of standardization in the assessment method. In order to appropriately interpret study results, either positive or negative, the reader must understand the outcome variable(s) assessed.

In an effort to simplify harmonization of clinical trial data and facilitate regulatory review, fundamental data elements for pain intensity assessments in analgesic clinical trials (ie, type of pain, location, time period assessed, assessment frequency) have been identified.[2] The Standardized Analgesic Database for Research, Discovery, and Submissions (STANDARDS) working group from the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public-private partnership with the U.S. Food and Drug Administration (http://www.acttion.org) undertook this systematic review to evaluate the extent to which these standard data elements and other elements of human adult pain intensity assessments (ie, the specific assessment method used, whether endpoints and anchors were defined) were reported by authors of more recent research, including clinical trials and nontrial studies, published in 3 major English-language pain journals (ie, *European Journal of Pain*, *Journal of Pain*, and *Pain*). We also tested the hypothesis that more complete reporting of the fundamental elements of pain intensity assessments would occur in clinical trial articles than in articles describing nontrial research, given that many clinical trials are subject to review by regulatory authorities.

Method

Study Selection

We selected articles reporting empirical research (ie, clinical trials, observational studies, and experimental studies involving manipulation without random group assignment and blinding) in noncognitively impaired human adults where ≥1 patient-reported measure of pain intensity was used (ie, visual analog scale [VAS]; numeric rating scale [NRS]; verbal response scale [VRS]; verbal descriptor scale [VDS]; any or all of the Brief Pain Inventory [BPI] intensity questions assessing average, least, worst, or current pain; short-form McGill Pain Questionnaire [SF-MPQ] VAS; or the SF-MPQ Present Pain Inventory [PPI] VRS). The second author (M.H.) searched all issues of 3 major English-language pain journals (ie, *European Journal of Pain*, *Journal of Pain*, and *Pain*) published between January 2011 and July 2012 to identify articles. In order to ensure that all qualifying articles were identified, a second search was completed by a medical librarian using an electronic database (http://www.pubmed.gov; see Supplementary Appendix 1 for a description of the search strategy), and the second author (M.H.) carefully reviewed the results. Using these 2 methods, 262 articles that fulfilled the criteria were identified (see Supplementary Appendix 2).

Data Extraction

The first and last authors (S.M.S., R.H.D.) created an initial coding manual to evaluate descriptions of the type of pain intensity assessment, definitions for the anchors, frequency of assessment administration, time period to be rated, type of pain intensity rated (ie, average, least,