

Minimal Clinically Important Difference Module: Introduction

Challenges exist in determining the clinical significance of any change or difference observed in an outcome measure. The following series of papers highlight the findings and discussions during the OMERACT 5 Minimal Clinically Important Difference Module. There were 3 objectives for this module: 1. to review the methodologies and analytic issues associated with the determination of minimally clinically important differences (MCID); 2. to review the current status of MCID as they relate to core outcome measures in osteoporosis (OP), rheumatoid arthritis (RA), osteoarthritis (OA), and low back pain (LBP); and 3. to develop a research agenda for deriving MCID to meet the needs in OP, RA, OA, and LBP.

The program began with a brief introduction of the goals of the workshop and the process and procedures to attain these goals. This was followed by short presentations on a framework for classifying changes and differences and an overview of the methodologies for determining MCID. Then in a series of presentations, the current status of MCID were reviewed as they relate to core outcome measures in OP, RA, OA, and LBP. Finally, various analytic issues associated with the determination of MCID were presented. These presentations are more fully presented in the following papers.

The first paper is entitled “Looking for Important Change/Differences in Studies of Responsiveness” by Dorcas Beaton, *et al.* The objective of this manuscript is to review the conceptual literature on responsiveness and describe the nature of change that is commonly used to study responsiveness. The resulting taxonomy of change within studies of responsiveness is fashioned into a “cube” with the axes of the cube corresponding to the key features defining attributes of change and each cell within the cube defined by its place among the 3 key features.

The second paper is entitled “Minimal Clinically Important Differences: Review of Methods” by George Wells, *et al.* The purpose of this paper is to consider and classify in the cube the different methods that have been used in detecting important changes or differences for the purpose of developing the MCID for an outcome measure. This paper reports the findings of an extensive systematic literature search of relevant articles related to MCID and describes the 9 procedures found and their placement in the classification system.

The purpose of the next 4 papers is to identify existing work related to discrimination, responsiveness, and MCID for key clinical measures in OP, RA, OA, and LBP. Each paper is based on the results of an extensive literature review and the findings are considered relative to the classi-

fication system of the cube. The first paper is entitled “Discrimination of Changes in Osteoporosis Outcomes” by Ann Cranney, *et al.* Four clinical outcomes in osteoporosis were considered in this review: bone density, fractures, quality of life, and function. The second paper, by David Felson, *et al.* is entitled “A Review on the Discriminant Validity of Outcome Measures in Rheumatoid Arthritis.” The goal of this review paper is to critically assess the current state of knowledge with respect to discriminant validity of outcome measures used in RA with a focus on functional status measures and measures that are members of the RA core set. The third paper, by Nicholas Bellamy, *et al.* is entitled “Towards a Definition of Difference in Osteoarthritis.” The results of a systematic literature review and the findings for core OA outcome measures are reported. The fourth paper, by Claire Bombardier, *et al.* is entitled “Minimally Clinical Important Difference. Low Back Pain: Outcome Measures.” The goal of this paper is to identify information on the responsiveness of measures for LBP in the category of disease-specific functional status. The results of this investigation are reported for the Roland Morris Disability Questionnaire and the Oswestry Disability Questionnaire.

The next 2 papers are concerned with methodological issues associated with MCID. The first is entitled “Minimum Clinically Important Difference: The Crock of Gold at the End of the Rainbow?” by John Kirwan. He reviews a number of empirical and theoretical reasons on the elusiveness of the definition of a MCID, and considers issues of absolute versus relative change, area under the curve, and judgment of change in response to therapy. The next paper is entitled “Individualized Functional Priority Approach to the Assessment of Health Related Quality of Life in Rheumatology” by Jennifer Clinch, *et al.* Given the importance of considering patient-specific assessment of change, this paper focuses on questionnaires assessing change that is both disease- and patient-specific, and evaluates the experience and performance of the McMaster Toronto Arthritis Patient Preference Disability Questionnaire and the Problem Elicitation Technique.

The major emphasis of the OMERACT 5 MCID Module was focused discussions during a breakout session facilitated by a group leader and *rapporteur*. After the brief presentations, OMERACT participants were divided into 8 smaller groups to discuss the MCID that are needed, their priority, and the methods and procedures for obtaining them. Three groups focused on RA, 3 on OA, and one group each considered OP and LBP. A questionnaire was developed for each group to help focus discussions. The questionnaires

were completed by the participants and handed in at the end of the breakout session. The results of the questionnaire were analyzed and the findings presented in plenary at the end of the conference. Participants voted on key issues that would help form the basis for a research agenda.

The following papers and report on discussions at OMERACT, entitled “OMERACT 5 — MCID Module: Summary, Recommendations and Research Agenda,” provide an extensive consideration of the classification and methods that can be considered for outcome change/difference and MCID and their application in the areas of OP, RA, OA, and LBP. These discussions clarified gaps in our

knowledge on change that is commonly used to study responsiveness, and provided guidance on the next important steps that need to be considered.

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