Introduction

OMERACT: State of the "ACT"

WHERE DID WE COME FROM?

The Outcome Measures in Rheumatoid Arthritis Clinical Trials (OMERACT) initiative has been on the move since its inception. It is an excellent example of serendipity, of good ideas that come to mind, not by chance, but because the mind is ready to receive them. After several attempts in the preceding decade, in the early 1990s, the time was ripe for rheumatologists to come to consensus over a core set of endpoints to be measures in rheumatoid arthritis (RA) clinical trials. Simultaneous independent initiatives in different parts of the world came together in Maastricht, 1992, the venue for the first OMERACT conference[1]. A large area of common ground was discovered, enabling the proposal of just such a core set. This core set was adopted as the World Health Organization/International League of Associations for Rheumatology (WHO/ILAR) core set in a special task force meeting in Geneva, 1993[2].

Two other topics were also discussed at the first OMERACT conference: improvement criteria and indices. Groundwork was laid here for further discussions. These discussions helped the American College of Rheumatology Committee on Measurement in Rheumatoid Arthritis Clinical Trials (chair: David Felson) formulate their "preliminary ACR criteria for improvement in RA"[3]. These criteria allow trial results to be expressed as the percentage of patients that experienced important improvement of their disease activity. Besides being intuitively more relevant to the clinician reader than average results, these criteria probably discriminate better between levels of efficacy, because they combine the results of several measures into one result, with concomitant increases in power.

Several other indices are being tested prospectively, both in trials and in cohort followup studies. The Disease Activity Score has been adapted to include a reduced 28-tender joint count instead of the full Ritchie count[4]. OMERACT related topics have featured prominently at international conferences, including the ILAR meeting in Barcelona, and the ACR meeting in San Antonio, 1993.

In a separate but related initiative, groups of researchers have organized to start structured review of trials in rheumatology through the Cochrane initiative. It is not difficult to see how OMERACT, focussed on measurement methodology, and Cochrane, focussed on results, are closely linked.

On a more modest level, several OMERACT newsletters have been distributed to over 300 interested subscribers, with the support of ILAR and ACR. This newsletter is to be incorporated in the ILAR newsletter to appear soon. Also, a discussion list on OMERACT topics was started on the Internet (see Addendum for details).

OMERACT II

The second OMERACT conference focussed on the balance between efficacy of treatment and its cost. The focus reflected our recognition that in the evaluation of treatment, we must also confront the "dark side of The Force." The focus was generic, including all musculoskeletal (MSK) diseases. The objectives were twofold: (1) to stimulate the establishment of a common knowledge base among clinicians, researchers, health policy makers, and representatives from the pharmaceutical and biologics industry; and (2) to suggest priorities for a research agenda in this field.

The conference was organized into 3 parts: toxicity, health status measurement, and economics. Each part represented target areas currently undergoing rapid development. New instruments are appearing frequently, and with them comes the need to evaluate their validity in different settings. Producers and consumers of information connected with such instruments need to interact to optimize instrument application and data interpretation.

Where toxicity and economics are obviously two aspects of cost, health status (or health related quality of life) measurement may at first seem less related to the efficacy/cost tradeoff. However, on closer inspection, it can be seen that instruments that try to get a global impression of health status, by themselves, measure the tradeoff: patients experiencing side effects will report their quality of life as lower than patients who do not have such effects. Economic effects are more difficult to judge than health related quality of life (although seeing one's hospital bill can certainly lead to physical discomfort!), so that other instruments are necessary.

The format of the conference resembled that of OMERACT I: participants were primed with key articles before the conference. At the conference, plenary sessions alternated with small group discussions, based on tasks prepared beforehand. No specific consensus building was planned. However, interactive voting techniques were used in the plenary sessions to help formulate the research priorities in this area.

OMERACT IN THE FUTURE

OMERACT can be defined as an informal gathering of

people interested in measurement issues in MSK disease. Based on the results of this conference, a research agenda will be formulated that participants and others will be stimulated to address. Other interests of OMERACT include the continuing validation and refinement of the RA core set and the design of core sets for other MSK diseases.

MAARTEN BOERS, MD, PhD, MSc,
Departments of Internal Medicine and Rheumatology,
University of Maastricht,
Maastricht, The Netherlands;
PETER M. BROOKS, MD, FRCPA,
Department of Internal Medicine,
University of New South Wales,
Darlinghurst, Australia;
PETER TUGWELL, MD, MSc, FRCPC,
Department of Medicine and Epidemiology
and Community Medicine,
University of Ottawa,
Ottawa, ON, Canada.

Address reprint requests to Dr. M. Boers, Department of Internal Medicine/Rheumatology, University Hospital, PO Box 5800, 6202 AZ Maastricht, The Netherlands.

ADDENDUM: How to join and use the OMERACT Internet distribution list. As you may know, the list works by "reflecting" all messages sent to it: a message you send to the list will be sent to all subscribers, who can react in turn. To subscribe: get an account on the Internet; send an E-mail message to listserve@nic.surfnet.nl with only this text in the body of the message: subscribe omeract firstname lastname. Put your first and last names in the specified places.

To unsubscribe, use the same procedure, but send this message: unsubscribe omeract. You need not enter your name here. You will get an acknowledgment of your (un)subscription.

When you receive a message through the list, you can reply using the regular "reply" command of your E-mail system. You have to send your messages to this address to reach the list: omeract@nic.surfnet.nl.

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