



# Need for a core outcome set on work participation

Jan Hoving<sup>1</sup>, Cecilia Prinsen<sup>2</sup>, Regina Kunz<sup>3</sup>, Jos Verbeek<sup>4</sup>

## Does this intervention work?

Both practitioners and patients need to know if an intervention is effective and safe. Following the evidence-based medicine (EBM) approach research questions about interventions should be structured according to PICO (Patient, Intervention, Comparator, Outcome). To determine the impact of an intervention on a specific outcome, decision makers would like to see a body of evidence formed by multiple studies. It is the purpose of systematic reviews to provide this body of evidence. However, reviewers are challenged by studies that use heterogeneous outcome measurement instruments to measure similar outcomes of interest. For example, to evaluate if training and exercise prevent back pain at the workplace, researchers may report sick leave resulting from back pain, reduced physical functioning at work or the occurrence of permanent work disability. For the field of insurance medicine and occupational health ‘work participation’ is an important outcome concept. Not only are there several outcomes related to this ‘work participation’ concept, but the instruments that measure these types of outcomes vary as well. Lack of standardisation in outcome measurement and reporting significantly hinders the synthesis of research and, consequently, hampers decision making at the expense of the best possible treatment and social care for patients. Despite the existence of a body of evidence these studies are not fully suited to answer the simple question: does this intervention work?

## Effectiveness as the main focus of Cochrane

Cochrane Work ([work.cochrane.org](http://work.cochrane.org)) and Cochrane Insurance Medicine ([insuremed.cochrane.org](http://insuremed.cochrane.org)) have a joint interest in studies that measure work participation and promote high quality systematic reviews about the effects of interventions that prevent or reduce occupational disability, injuries and diseases. The Cochrane Work Review Group produces reviews with a focus on interventions that promote return to work (RTW) or prevent job loss in individuals with medical conditions such as cancer or depression that could easily result in work disability. To make their reviews more informative, both groups aim to standardise their outcome set for disability prevention and RTW interventions. Cochrane Insurance Medicine complements these endeavours by promoting the use of evidence by those who perform sick leave certification, evaluate work disability, establish a prognosis of claim duration, prescribe treatment of disabling conditions, or suggest RTW interventions, ideally with evidence from systematic reviews. To this end, researchers of Cochrane Insurance Medicine would like to see more high-quality Cochrane systematic reviews relevant to their field.

## Core outcome sets

The Core Outcome Measures in Effectiveness Trials (COMET) initiative brings together people interested in the development and application of core outcome sets ([www.comet-initiative.org](http://www.comet-initiative.org)). A core outcome set is an agreed minimum set of outcomes that should be measured and reported in all trials in a specific health area.<sup>1,2</sup> COMET has established methodological guidance on core outcome set development, which involves the identification and selection of outcomes that are considered ‘core’ (i.e. what to measure), and, in cooperation with COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) ([www.cosmin.nl](http://www.cosmin.nl)), on the selection of outcome measurement instruments that can be used to measure the core outcomes (i.e. how to measure).

The Outcome Measures in Rheumatology (OMERACT) initiative has been the front runner in the field of core out-

<sup>1</sup> Amsterdam UMC, Academic Medical Center, University of Amsterdam, Coronel Institute for Occupational Health, Amsterdam Public Health research institute, Amsterdam, the Netherlands

<sup>2</sup> Amsterdam UMC, VU University Medical Centre, Department of Epidemiology and Biostatistics, Amsterdam Public Health Research Institute, Amsterdam, the Netherlands

<sup>3</sup> Academic Unit EbIM, Evidence-based Insurance Medicine, Department of Clinical Research, University of Basel, University Hospital of Basel, Switzerland

<sup>4</sup> Finnish Institute of Occupational Health, Coordinating editor Cochrane Work, Kuopio, Finland

Author for correspondence:  
[j.l.hoving@amc.uva.nl](mailto:j.l.hoving@amc.uva.nl)

come set development. OMERACT is continuously working on the development of core outcome sets for different rheumatic diseases ([www.omeract.org](http://www.omeract.org)). Furthermore, OMERACT has developed a methodological framework that consists of three core 'areas': Death, Life Impact and Pathophysiologic Manifestations; and one strongly recommended 'area': Resource Use.<sup>3</sup> Since then, many medical disciplines have started to produce core outcome sets that are gaining rapid interest. The COMET database includes more than a thousand references of planned, ongoing or completed work on core outcome set development ([www.comet-initiative.org/studies/search](http://www.comet-initiative.org/studies/search)).

### Work participation outcomes used in Cochrane Reviews

Despite the increasing number of core outcome sets in other medical disciplines, a core outcome set for work participation is still lacking. We therefore explored the need for a core outcome set for intervention studies in the field of occupational health and insurance medicine. We performed a pilot review to gain insight into reported outcomes and outcome measurement instruments, their terms and definitions, and the type of outcome measurement instruments in Cochrane systematic reviews. To this end, we selected seven Cochrane reviews on patients with chronic medical conditions (such as cancer, inflammatory arthritis or mental disorders) that used 'work participation' as an outcome to measure the effects of interventions that targeted workers that were on sick leave or at risk of not fully participating in work due to their medical condition.<sup>4-10</sup> The reviews reported on a total of 82 trials (randomised controlled trials, range 3-25 per review). As evident from this pilot review, outcome definitions and characteristics differed widely because the studies:

- used a variety of outcomes including RTW, sick leave, absenteeism, work status, functional status, productivity or work functioning;
- reported outcomes measured at different follow-up times, ranging from a few weeks to 4 years after baseline;
- used different definitions and cut points, such as partial versus full RTW, 100% RTW, workers with no RTW, RTW in steady employment, event data such as RTW rate or sick-leave rate versus time-to-event data (time to RTW), average length of sick leave, number of work absence days or mean monthly sick leave;
- used different time periods (at work) to qualify for RTW: such as at least 2 weeks, 4 weeks or 8 weeks back at work;
- used different definitions of work status at baseline: patients with paid employment or no employment, with or without an employment contract were selected;
- used different sources to measure work participation: self-report data, often retrospectively, such as number

of absenteeism days in past weeks, months or years; questionnaires (such as health and productivity questionnaires) or administrative databases from occupational health services or insurers.

This heterogeneity in outcome reporting has been acknowledged by the recommendations for research by the authors of these Cochrane reviews. The Cochrane reviews indicated the need for a uniform assessment of work participation outcomes and outcome measurement instruments, the use of explicit definitions and cut points, definition of minimal clinically important differences, or better validation of measurement instruments. Furthermore, they suggested that randomised controlled trials include information on the different social benefits systems to better understand its impact on RTW and work disability in different countries.

### Need for core outcome set on work participation (COS-WP) for researchers

Variation in outcomes and outcome measurement instruments is considerable. The call for the development of a core outcome set in the area of work participation is supported by others in the field of occupational health and rehabilitation who highlight the need for a set of consistent definitions on key constructs and outcomes. This should improve the understanding of the outcomes that matter to the stakeholders, address the complexity of RTW outcomes, and help to understand RTW as a dynamic process.<sup>11</sup> Others have also discussed challenges in measuring work participation and emphasise the need for international standardisation by developing a core outcome set.<sup>12-15</sup>

Starting mid-2018, the Coronel Institute of Occupational Health of the Academic Medical Center in Amsterdam will start an international collaborative project to develop a COS-WP. We call on the international community of practitioners, clients and researchers in occupational health and insurance medicine to help us join forces for the development of such a core outcome set. To date several partners support this initiative, including Amsterdam Public Health core outcome set (APH-COS) focus group, Cochrane Insurance Medicine and Cochrane Work. The project will result in a universally applicable and broadly agreed COS-WP that should be used when conducting randomised controlled trials and systematic reviews so that we can achieve the best possible treatment and social care for our clients and patients.

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