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EDITORIAL

Is The Cochrane Collaboration prepared for the era of patient-centred outcomes research?

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In 2013 The Cochrane Collaboration celebrates 20 years of outstanding work supporting decision makers by providing reviews synthesising the best available knowledge. With a strong focus on randomised controlled trials (RCTs), The Cochrane Collaboration has become the world's largest producer of systematic reviews of healthcare interventions. One of the ten key principles of the Collaboration is striving for relevance “by promoting the assessment of healthcare interventions using outcomes that matter to people making choices in health care”.[1] Unlike systematic reviews from many other institutions, Cochrane Reviews already strive to address the needs of consumers and patients. All Cochrane Intervention Reviews have plain language summaries, and members of the Cochrane Consumer Network (consumers.cochrane.org) provide valuable input as reviewers. Some Cochrane Review Groups actively involve the public in the preparation of Cochrane Reviews.[2][3]

Are these efforts optimal in maximising Cochrane Reviews for day-to-day healthcare decision making? There has been little research on the extent to which patients and clinicians use Cochrane Reviews.[4][5] Most likely, Cochrane Reviews suffer the same fate as other systematic reviews: the information remains unused because clinicians and patients do not perceive the reviews as relevant for day-to-day use.[6] Many factors can negatively influence perceived usefulness. One important factor is the lack of information on outcomes that patients, caregivers, and clinicians notice and care about when making treatment decisions. In his commentaries, the late Alessandro Liberati drew attention to the discrepancy between outcomes studied in research and those most relevant to patients.[7][8] To him and many others, research studies failed at providing critical information necessary to make informed healthcare decisions.[9][10]

In the United States, the recently founded Patient-Centered Outcomes Research Institute (PCORI; www.pcori.org) aims to address the long-lingering disconnect between patient needs, patient engagement, and research. Over the next decade, PCORI will allocate 3 billion US dollars to support research on patient-centered outcomes.[11] Given the substantial amount of funding through PCORI, the issue of patient-centered outcomes will most likely become a prominent topic in coming years, and the Collaboration should seize the opportunity to be a leading force in this area.

Given the experience with involvement of consumers and patients in Cochrane Reviews, the Collaboration is well equipped to advance the field of patient-centered outcomes research. It is the largest single producer of systematic reviews worldwide, it is a leader in the field of systematic review methods, and its backbone is individuals driven by the motivation to improve health care. In addition, the Collaboration has an active consumer group. Nevertheless, a bit more attention to the vantage points that patients face when making healthcare decisions and some thinking ‘outside the Cochrane box’ might be required to face these new challenges.

Specifically, the strong focus on RCTs and readily accessible endpoints restricts many Cochrane Reviews to outcomes that are important to trial designers and sponsors but not necessarily important to patients. For regulatory purposes clinical trials focus primarily on outcomes that are easy to assess, such as symptom scales. Impairment of health status, however, is often related to severity of symptoms as well as intended and unintended treatment effects. Reviewers need to place more focus on outcome measures that reflect the entire continuum of patients' needs, including the impact of symptoms. In addition, many of the outcomes that patients care about relate to harms, which may not always be reliably assessed with outcomes used in RCTs. A broader focus on non-randomised studies will be necessary to cover the scope of patient-centered outcomes; especially rare but important adverse events are often measured more reliably with observational studies.

Furthermore, patients and consumers need to be engaged early (at the title registration stage) to identify outcomes that matter most to them. This will come with many challenges, the strong involvement of the industry in patient advocacy groups being only one of them. Initiatives such as INVOLVE (www.invo.org.uk) in the United Kingdom or Project CONNECT in the United States (www2.shepscenter.unc.edu/connect) demonstrate that patient engagement in research is achievable and important. There is guidance on how to best engage patients at the outset of a systematic review to identify patient-centered outcomes, but patient involvement at the planning stages of Cochrane Reviews varies and largely depends on the engagement of the Cochrane Review Group.

Finally, The Cochrane Collaboration has to live up to its responsibility as the largest producer of systematic reviews to identify and systematically aggregate gaps in knowledge. Just as clinical trials should begin and end with systematic reviews,[12] systematic reviews should routinely assess gaps in knowledge with respect to patient-centered outcomes to inform clinical trials. This means documenting important outcomes that are unmeasured and establishing the relative importance of both measured and unmeasured outcomes. At the start of every new trial, investigators should review what is still not known. With several thousand systematic reviews published every year[13] and almost 5000 completed Cochrane Reviews, the totality of this research would be a powerful tool to systematically highlight gaps in outcomes that are important to patients. Just as guideline developers who use the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach rank the importance of outcomes for decision making, consumers could rate the relative importance of outcomes from their perspective at the outset of a Cochrane Review. Such information would provide important guidance for Cochrane reviewers when selecting primary outcomes.

Following the completion of reviews, the Collaboration could aggregate outcomes unmeasured and rated as important in a ‘Cochrane Repository of Unmeasured Patient-Centered Outcomes’, which could inform trials and help prioritise future research needs.

Over the past 20 years, systematic reviews and The Cochrane Collaboration have influenced the practice of medicine in an unprecedented way. It is the panoramic view of systematic reviews that can help patients and clinicians connect the dots and make informed decisions. As researchers we need help from patients, caregivers, clinicians, and other decision-makers to determine what the important dots are. If we neglect this input, the panoramic view can become distant and removed from reality. A grass-roots movement like The Cochrane Collaboration should provide an ideal environment to take the next step and foster the generation of methodologically sound reviews that also focus on patient needs.

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Declarations of interest

The authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available upon request) and declare (1) no receipt of payment or support in kind for any aspect of the article; (2) no financial relationships with any entities that have an interest related to the submitted work; (3) no other relationships or activities that could be perceived as having influenced, or giving the appearance of potentially influencing, what was written in the submitted work.

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