

The COMET Initiative's Guide to Selecting Outcomes in Clinical Trials

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Video Abstract

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Abstract

People can learn a lot from clinical trials – like whether a new treatment works, whether it has serious side effects, or whether it would be cost-effective. How much a trial tells us, though, depends on what the researchers looked for and how they measured those outcomes. Unfortunately, people doing trials often don't consult with patients – or even with other researchers – about what outcomes to focus on. With each researcher choosing their own outcomes to measure, comparisons between trials are difficult, and without input from patients, the most relevant ones are sometimes missed. It's increasingly clear that selecting relevant outcomes is an important part of trial design, and that standardization could get more out of each trial, reduce waste in research, and move science and health care forward faster. To help, the COMET Initiative has written a new handbook on how to choose the most important outcomes. COMET recommends following a four-step process to agree on a core outcome set, or C-O-S. This is a minimum set of outcomes; individual trialists can always add more outcomes as needed. The first step is to define the scope, including the specific health condition, target population, and whether the C-O-S will apply to certain interventions only. Second, check the COMET database to see if others have already done any of the work. If not, register plans to develop a C-O-S with COMET, so that others will know it's being worked on, preventing unnecessary future duplication. Step three is to prepare a protocol describing how the new C-O-S will be developed. This needs careful thinking about which groups of people – patients, caregivers, health professionals, and researchers, for example – should have a say in what is measured. The final step is the process for determining the outcomes. Systematic reviews can identify those used in past and ongoing studies, and gathering opinions from various stakeholders can identify which outcomes are most important. A good way of doing this is through an internet survey using the Delphi technique, which allows people to anonymously rate the importance of each suggested outcome and consider feedback in a way that helps groups reach consensus. A face-to-face meeting might also be helpful to bring thoughts together and finalize the C-O-S. Once the C-O-S is set, it's time to move on and decide how to measure the outcomes. Similar techniques can be used to reach agreement on this as well. If you'd like to know more about developing a C-O-S, check the handbook for more detailed guidance on any of the steps. It's free for everyone to read, and will show you how you can be part of this methodological revolution in clinical trial design.