Core Outcome Measures in Effectiveness Trials

What are outcome measures?

To decide which treatments are best for patients, it is important to look at the effect those treatments have on patients. Researchers do this by measuring an ‘outcome’. For example, in a study of how well a new asthma treatment works, ‘outcomes’ might include:

- A measure of how fast you can blow air out of your lungs
- Night time wheeze
- Asthma quality of life measure

Outcomes

What are the challenges in measuring outcomes?

At the moment, different studies looking at treatments for the same condition often measure different outcomes. For instance, imagine two studies of how to treat migraine.

- Study A - researchers measure days off sick as an outcome
- Study B – researchers measure symptoms of pain as an outcome

When the two studies are finished, we cannot compare or combine their results because they have used different outcomes. We would not be comparing like with like.

Another problem is when a study team set out to collect information on several outcomes but in the end decide to publish the results on only some of the outcomes. This sometimes happens when the findings for particular outcomes differ from those the team hoped for.

Why is this a problem?

Other researchers could struggle to work out exactly how effective a treatment is because:

- They don’t have full results from the study
- The information they do have might be biased

What is the solution?

If all studies in a particular health condition used the same outcomes, they could all be compared and combined. This would make the best use of all the research. When a set of main outcomes has been agreed for a health condition, it is called a ‘core outcome set’. If all studies in a particular condition, such as migraine, measured and reported all core outcomes, we could:

- bring together all of the studies to get a better understanding of which treatments are best and
- avoid the problem of some studies only reporting a selection of the outcomes that have been measured.

How are core outcomes agreed upon?

Deciding which outcomes should be core outcomes requires a great deal of discussion. Core outcomes have to be relevant to health professionals, but more importantly, they have to be relevant to patients and carers. Researchers also need to make sure that all these experts – patients, carers and professionals – agree on the core outcomes. To do this they use ‘consensus methods’.

What are consensus methods?

These are surveys, meetings and discussions where researchers draw together the opinions of experts. Patients and carers have not always been included, but now they are being included in recognition of their first-hand experience of living with a condition.

Why is it so important to involve patients in deciding on core outcome sets?

Core outcome sets need to include those outcomes that are most relevant to patients and carers, so it is vital that patients and carers are involved in their development. There are examples of where involving patients in the process identified an outcome that was important to them as a group but which might have been overlooked if the outcome set was developed by practitioners on their own.

How are core outcome sets used when they have been agreed?

When a core outcome set has been agreed for a particular condition, we hope researchers will use it in their studies, whilst adding in other outcomes if they wish. If every migraine study team used the same core outcome set, their findings could be compared and combined correctly.
long run, this will improve information about which treatments work and which don’t.

**What is COMET?**

COMET stands for the ‘Core Outcome Measures in Effectiveness Trials’ Initiative. It has been set up to help in two main ways:

- to support researchers in developing core outcome sets, and
- to provide the COMET database as a central point where researchers and patients can find out what core outcome sets have already been developed or are currently being developed.

COMET is funded by the UK Medical Research Council and the European Union and has links with researchers across the world.

COMET recognises the expertise and crucial contribution of patients and carers in developing relevant core outcome sets. We are developing resources to help researchers involve patients and carers in core outcome set development.

If you would like further information about COMET or are interested in getting involved please contact either Liz Gargon (COMET Project Co-ordinator, liz.gargon@liverpool.ac.uk) or Heather Bagley (COMET Patient and Public Involvement Co-ordinator, heather.bagley@liverpool.ac.uk). Further information on COMET can be found at www.comet-initiative.org.

**COMET would like to thank the many patients, parents and carers who gave their time to comment on the development of this summary.**

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The COMET team

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