

# Research for real questions

By Margaret McCartney

Published: July 13 2007 18:43 | Last updated: July 13 2007 18:43

A couple of weeks ago I attended an excellent meeting at the Royal Society of Medicine, hosted jointly by the James Lind Alliance and the medical journal *The Lancet*. The meeting was called “How can clinical trialists serve the needs of patients and clinicians more effectively?” How can we use research findings, which, after all, are usually based on large numbers of people, to direct or aid treatment choices for individuals? It was one of those rare meetings that was still making me think a long time after.

The issue isn't an academic sideline but highly relevant for day-to-day medicine. Professor Stephen Holgate, who works at the University of Southampton, outlined the problems that research findings present when we try to apply them to the real world. Because of the exclusion criteria that are often applied to would-be participants in trials, he said, children and elderly people, who may respond quite differently to drugs, are usually left out. This means that data about how to prescribe for these groups are extrapolated from younger adult patients.

Consequently, important information about the effects of treatment in these groups may be lacking. The stringent criteria used to recruit people for asthma studies, for instance, have meant that only small numbers of “real life” asthma patients are included. Smokers are usually excluded and it has only been recently found that certain classes of drugs, mainly inhaled steroids, are much less effective in smokers than first thought. Conversely, smokers may benefit more from other types of asthma drugs.

But there is another side to fine-tuning research. A different speaker talked about how identifying sub-groups can run the risk of being utterly misleading if you don't get it right. For example, a few years ago *The Lancet* ran a paper “showing” that if you were born Libra or Gemini, you may as well not bother with aspirin for your heart attack – a placebo was just as good. Nonsense, of course, but the paper memorably demonstrated one of the many pitfalls bad analysis can result in.

Whether bad research findings or good often end up in my office, I still have the problem of trying to assess the relevance of research for the patient in front of me. The easy solution is to wait for standardised guidelines. But if these aim at equality and standardisation of care, they also work against thoughtful decision-making. And, as Holgate points out, much of the trials used as the basis of guidelines are not focused enough to translate to a wide variety of “real life” patients.

How can I hope to give people good information about the likely effect of treatment choices? The obvious solution is to involve more “ordinary” people in the nitty-gritty of clinical trials. There are problems with the image of trials – guinea pigs and monster scientists and the like – but the real problem is when either the trials aren't done, because they are assumed to be unnecessary, or are so badly designed or unfair as to be useless.

This creates far more problems. It is often easier for doctors simply to sit back and continue to prescribe an ineffective or even harmful treatment. If they admit they don't know what is best, they may well be letting themselves in for a lot of hard work, form-filling and dealing with ethics committees – instead of being congratulated on acknowledging a problem and starting to solve it.

The James Lind Alliance is trying to make sense of this situation and bring together the questions that patients have about the effects of treatment with those of researchers. Patients and, I suspect, most of their doctors want to know answers to basic but practical questions.

People with arthritis, for example, were not being asked in drug trials about their most disconcerting symptom, fatigue.

More research won't help doctors make better treatment choices. Better research will, as it lets us ask questions that patients and doctors want the answers to. If there is a way that will help us towards making better decisions for individuals, this has to be it.

*[www.lindalliance.org](http://www.lindalliance.org)*

*Margaret McCartney is a GP in Glasgow*

*[margaret.mccartney@ft.com](mailto:margaret.mccartney@ft.com)*

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