Evidence is needed to fill clinical research gaps

Despite the avalanche of publications available (over 2 million research articles published every year in over 20 000 biomedical journals) there are still large gaps in the evidence underpinning the management of relatively common health problems. Surveys of published research show a mismatch between researchers and clinicians and patients' interest in an area; both in selecting which conditions to study and what treatments to investigate. In neurology, for example, Creutzfeldt–Jakob disease had a 100-fold higher publication ratio (number of publications per person with the condition), than that of stoke and transient ischaemic attack[1]. A survey of research into osteoarthritis of the knee, meanwhile, found that the evidence base was dominated by studies of pharmaceutical (59%) and surgical (26%) interventions, whereas 36% of survey respondents ranked knee replacement as the highest priority for research and 21% chose education and advice as their first choice[2].

This mismatch between what researchers study and what clinicians and patients need information about is not unique to these fields – and I believe it can only serve to widen the gap between busy clinicians and researchers in the field, to the detriment of both. Including consumers in setting research priorities and on the grant awarding panels, as exemplified by the Quality Research in Dementia (QRD) programme of the Alzheimer's Society, is one way of aligning research to clinical and consumer need[3]. Clinicians can also alert research funders directly to gaps in knowledge (in the UK you can suggest topics for the Health Technology Assessment Programme at http://www.ncchta.org/CONSULT.HTM).

Relevant reliable research

Researchers also have a responsibility to undertake research that is relevant and reliable. Reliable research is believable because steps have been taken to minimise the impact of random error (often just called error) and non-random error (bias). The most common type of question asked by a clinician is about the effect of an intervention to prevent or treat a health problem. The most reliable (least likely to be biased) answer to which is obtained from a well designed, and conducted randomised controlled trial (RCT). It is 250 years since James Lind proved in a 'fair trial' that citrus fruit cured scurvy (while previous medics had said that fruit was effective, none had proved it)[4]. This year, 2003, it is 55 years since the publication of one of the first RCTs in modern medicine (the MRC streptomycin trial)[5], and yet in huge areas of health care we remain ignorant as to whether our interventions do more harm than good. Given the huge investment we all make in health care, we really should know if this is worthwhile.

Examples abound where treatments based on sound theory turn out to be harmful (Dr Spock's recommendation to place babies on their fronts is one often quoted example), and therefore we should continually strive for well designed, large RCTs that answer questions of relevance to us (not just a sponsor). Involving practising clinicians and patients in research is one strategy for increasing the relevance of research and stopping it from becoming an 'ivory tower' exercise. Initial fears that consumer involvement in research may disadvantage basic science appear to have been unfounded; e.g. the QRD funds three distinct streams, cause, cure, and care, ensuring that basic and applied research are catered for.

RCTs in drugs became essential after the thalidomide disaster of the 1950–60s (along with increased animal testing and post-marketing surveillance), but RCTs are rarely done for other important interventions, like surgical techniques, and are currently seldom done for medical devices (such as dressings, or support surfaces). In this issue, for example, Sims' review highlights the lack of evidence for support surfaces in paediatric care. This means that there may be lower levels of evidence for self-help measures such as rest or exercise, or for an operation than a drug, when the repercussions of choosing the wrong intervention may be equally important.

Researchers and clinicians in wound care can sometimes be resistant to grasping the nettle of undertaking trials, perhaps because of awareness of the difficulties involved, or lack of appreciation of their power. Despite RCTs having been done in a huge variety of populations and settings, it is still common to be told that trials are not possible in certain areas of wound care (for example, as too many patients would be needed or the clinical picture is too variable). Large trials are complex to organise and costly to do, but the cost of not doing them is that we are left at the vagaries of promotional literature, charismatic proponents of the newest technique, case reports and anecdote when trying to make decisions about the best strategy for patients. Come back James Lind, all is forgiven.

Every month it seems there are new initiatives that vie for our time and energy. At the *Journal of Tissue Viability* we strive to help you keep up to date in an efficient way by publishing original and review articles. This provides evidence that readers then apply to particular patients or populations (an evidence-led model). In this edition (p. 174), for the first time, we are also trying to introduce a problem-led theme by answering problems suggested by fellow editorial advisors or readers. We aim to have a problem-based discussion integrating the research evidence, patient and clinician preferences and resource issues surrounding a clinical problem in every issue so do send us your queries. Our first example is about treating a venous ulcer in a patient intolerant of compression, and the answer highlights the lack of research into the management of this particular population. Here's hoping that there is a researcher out there who will pick up the gauntlet and start a trial to investigate effective strategies for healing the wound in this often neglected (by researchers) population.

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1 Al-Shahi R, Will RG, Warlow CP. Amount of research interest in rare and common neurological conditions: bibliometric study. *British Medical Journal* 2001; **323:** 1461–1462.
2 Tallon D, Chard J, Dieppe P. Relation between agendas of the research community and the research consumer. *Lancet* 2000; **355:** 2037–2040.
3 http://www.qrd.alzheimers.org.uk/ accessed 28 August 2003
4 Lind J. A treatise of the scurvy. In three parts. Containing an inquiry into the nature, causes and cure, of that disease. Together with a critical and chronological view of what has been published on the subject. Edinburgh: Printed by Sands, Murray and Cochran for A Kincaid and A Donaldson, 1753. http://www.jameslindlibrary.org/trial_records/17th_18th_Century/lind/lind_kp.html (accessed28th August 2003).
5. Medical Research Council. Streptomycin treatment of pulmonary tuberculosis. *British Medical Journal* 1948; **ii:** 769–782.