The ongoing evidence debate: time to decide

Patricia Grocott

Systematic reviews of evidence from clinical trials demonstrate a lack of good quality evidence to inform the choice of medical devices for clinical wound care. Evidence is also lacking in terms of patient outcomes and cost-effectiveness data to inform clinical guidelines, formularies, purchasing and procurement.

Not surprisingly, there is an ongoing debate as to why this situation remains. The debate revolves around the 'gold standard' methodology for determining the outcomes of clinical interventions, the randomised control trial (RCT), and its suitability for the evaluation of interventions in wound care. Unfortunately, instead of a measured debate on the subject, a polarised argument appears to be raging within the wound care clinical and academic communities. The argument is familiar, namely, that the RCT may be suited to researching interventions involving pharmaceuticals, but that wound care, the performance of medical devices in particular, requires different methodologies (Gottrup, 2008; Gottrup et al, 2010; Grocott and Campling, 2009).

Clinicians, nurses in particular, are raising concerns that the evidence from RCTs in wound care, such as it is, does not translate easily to inform day-to-day clinical decisions at the individual patient level. This was evidenced during the course of the recent 'Prove It' conference (see http://www.tissueviability.org/latest-news/prove-it-conference-2/) and various *Wounds UK* publications over this year (White and Jeffery, 2010; White et al, 2010). RCTs generate statistical generalisations at the group level. Extrapolation of such findings to the individual patient requires the clinician to determine whether the particular evidence generated from the RCT in question, or from the systematic reviews of the evidence, can be applied to an individual patient's care. RCT evidence is one form of information that can be valuable in clinical decision-making. However, it is by no means the only form of information.

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At the 'Prove It' conference, for which Sylvie Hampton and Lorraine Grothier should be congratulated for inspiring and making happen, dedicated clinicians and clinical academics were 'asking permission' to open the debate about what constitutes valid and clinically relevant evidence to guide practice, without being ridiculed by those who view the evidence generated by RCTs to be 'the only evidence'. Some of the speakers helpfully reminded us of the original aims and objectives of the originators of the Evidence-Based Medicine group, which appear to have been distorted over the years (Sackett et al, 1996). In 1996 they wrote an editorial in the *British Medical Journal* stating very clearly the following:

> 'Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patient's predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient-centred clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens.
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> … Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannised

Patricia Grocott is Reader in Palliative Wound Care Technology Transfer, King's College, London

by evidence, for even excellent external evidence may be inapplicable to, or inappropriate for an individual patient. Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients' (Sackett et al, 1996: 71).

In my view, the penultimate sentence reflects the mood of the 'Prove It' conference. The delegates were indicating that they felt 'tyrannised' by the pressure to generate and utilise the evidence from RCTs above all other forms of evidence, when they find the evidence does not translate into individual patient care. In addition, the design of published clinical trials, the validity of trial endpoints and sampling strategies in particular, were challenged, together with the inherent bias in company sponsored research.

Where do we go from here? As Sackett et al (1996) and more recent authors state (Nelson, 2010), without best evidence, standards of patient care are not maintained. Here is a harsh conclusion; wound care suffers from opinion-based, *ad hoc* practices which can be attributed to weak evidence, particularly evidence that is not valued and respected by the clinicians who need to utilise it. Case reports appeared to be of most use to the clinicians at the 'Prove It' conference, because of the detail and clinical context they provide with which clinicians can identify. Yet, case report methodology is poorly rated by clinical trialists.

It is time to re-group and to test a portfolio of research methodologies, applicable to the complexity of wound care. Professor Gottrup and colleagues within the European Wound Management Association (EWMA) Patient Outcomes Group have done considerable work to broaden the portfolio of research methodologies for wound care research and evidence generation (Gottrup et al, 2010). A programme of clinical studies to test out the recommendations of the EWMA Patient Outcomes Group, with an independent review of the findings generated by the National Institute for Health and Clinical Excellence (NICE), the Medicines and Healthcare products Regulatory Agency (MHRA), clinicians and industry may be the way forward.

The Medical Research Council's (MRC's) Framework for the Design of Complex Interventions could be usefully adopted as a gold standard for designing high quality, unbiased, intervention studies for wound care, including case reports (MRC, 2008). We particularly need studies that generate evidence at the individual, as well as the group level, in a time and cost-efficient process to suit the heterogeneous and complex nature of wound care interventions, as well as the rapidly evolving environment of wound care devices.

If wound care companies funded the methodology validation studies, we will all gain methodological insights; and the companies will have their products evaluated by independent research teams.

This Framework will highlight the gaps in our knowledge of the fundamental science behind wound care interventions, and how they relate to clinical problems and patient care. Without a fundamental science base, it is not possible to design credible intervention studies. The science base for wound care needs substantive pre-competitive research, funded by research councils and the Department of Health (DH). The Knowledge Transfer Network (KTN) official advanced wound care group is leading an initiative to secure such funding (see https://ktn.innovateuk.org/web/guest).

If wound care companies funded the methodology validation studies, we will all gain methodological insights; and the companies will have their products evaluated by independent research teams. Overall, it is time to break this circular argument, engage in prospective methodological validation, and decide what constitutes gold standard evidence to inform the care of patients with wounds. WUK

References

Gottrup F, Apelqvist J, Price P (2010) Outcomes in controlled and comparative studies on non-healing wounds: recommendations to improve the quality of evidence in wound management. *J Wound Care* **19(6)**: 237–68

Gottrup F (2008) Evidence controversy in wound management. *BMJ Rapid Responses*. 3 March, 2008

Grocott P, Campling N (2009) A methodology for evaluating wound care technologies in the context of treatment and care. *Eur Wound Management Assoc J* **9**: 27–38

Medical Research Council (MRC) Developing and evaluating complex interventions: new guidance (2008). MRC, London. Available online at: www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004871

Nelson A (2008) Improving care: the power of the pen. *J Wound Care* **19(9)**: 368

Sackett DL, Rosenberg WMC, Muir Gray JA, Haynes BR, Richardson WS (1996) Evidence based medicine: what it is and what it isn't. *Br Med J* **312**: 71

White R, Jeffery S (2010) The evidence debate in wound care: is patient welfare an issue? *Wounds UK* **6(3)**: 10

White R, Maylor M, Iverson C (2010) Evidence is 'in', ignorance is 'out': a dilemma for wound care products. *Wounds UK* **6(3)**: 114–6