Is the RCT *really* the gold standard of clinical evidence?

While the randomised controlled trial (RCT) is regarded by some as the 'gold standard' of clinical evidence, it is recognised that there are few such studies in the literature with little prospect of this situation changing.

The RCT is often regarded as occupying supremacy of place in the hierarchy of evidence, but others view this methodology as flawed. Some critics of the RCT consider it to be 'reductionist' as holism is excluded and the patient is reduced to a single dimension — of whether the intervention has had a statistical impact or not. At the 'lower' end of the hierarchy lies the case study or single case research. Here, there is allowance for holistic and real-life events to be recorded but critics state that there is little or no information provided on the cause of the problem/event. So where do the answers lie?

Is there a place for qualitative research where the aim is to obtain a complete and detailed description of the topic in hand, to assist our understanding of interventions, patients' beliefs and outcomes? Or should we aim to quantify by classifying elements and constructing statistical models in an attempt to explain what is observed?

If we are to be truly patient focussed should we therefore ignore the polarity of the argument and instead be ready to consider any form of investigation that is able to provide clinically relevant, valid and meaningful evidence as long as we remember to include the values of the individual patient in any evidence-based decision? KC

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What constitutes valid and reliable evidence for use in wound-care management decision making?

PB: Whenever a new wound management product is launched into the market the first question is always, 'Where is the clinical evidence for efficacy?'. I wonder how many healthcare professionals are disappointed in what the company has to offer? The situation within the wound care arena is that there are few RCTs carried out, and those that are don't necessarily prove that a product is fit for purpose on more than one aetiology.

There are many forms of evidence available; the single case report might highlight a successful, innovative use of a procedure, device or dressing, or may spark an idea for a research question which will then be used to explore a possibility.

What is disappointing is that so many studies are not published, especially if they are deemed by the researcher as failing to answer the research question. All work has value, even if it is only used to teach new researchers how not to do it!

PG: The UK Medical Research Council (MRC) developed a framework for the design of RCTs (MRC and Board, 2000). Woundcare Research for Appropriate Products (WRAP), has proposed that evaluation and evidence generation for wound care can be structured using an adaptation of the MRC Framework (*Figure 1*). The first two phases, theorising and modeling, guide the design of clinical interventions and the selection of measurement tools, before proceeding to the third phase, exploratory trials in real-life settings. When the data generated in such trials are deemed valid and reliable, using specified criteria, WRAP proposed that alternative forms of evaluation to the RCT — post-market surveillance studies in particular — can follow (Cowley and Grocott, 2007).

Essentially the Framework helps us to focus on identifying the underlying mechanisms of a clinical problem, for example, exudate. This includes demonstrating how the mechanisms relate and interact with interventions, such as the application of topical wound care products. In addition it requires correlation of the clinical outcomes with the original theoretical propositions and the modeling, including industrial and other laboratory based *in vitro* test methods (*Figure 1*).

While the RCT is regarded by some as the gold standard of clinical evidence, it is recognised that there are few such studies in the literature with little prospect of a major change. Should the wound healing community regard the RCT as the gold standard in wound care and accept that there will be fewer reported studies in years to come?

PB: While the RCT should still be considered as a remarkable level of evidence, it is also true that most RCT trials are open to some degree of criticism. It is extremely difficult to produce robust data which is incontrovertible. Perhaps within the wound healing community we should be asking ourselves why it is that healthcare professionals are not producing a variety of appropriate studies that are applicable to wound management. Wound healing is often an ambitious aim, perhaps the term wound management, within which several aims may be applicable, can highlight simple questions which may be answered by a variety of studies. If the

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question is 'Is dressing A, better at exudate management than dressing B?', then a variety of different wounds, both acute and chronic, could be included within a large cohort of patient evaluations. This would highlight the value, if any, of both dressings in the management of such wound types.

While the role of the observational study in evaluating a wound treatment might be contentious due to the possible multi-factorial problems of the subjects, it is still extremely useful and some would argue more so than the RCT. The chronic wound problems which pose a challenge to all those working in wound management may be included, and the effects of the treatment compared with other wounds of the same type and other types of chronic wounds, can be observed.

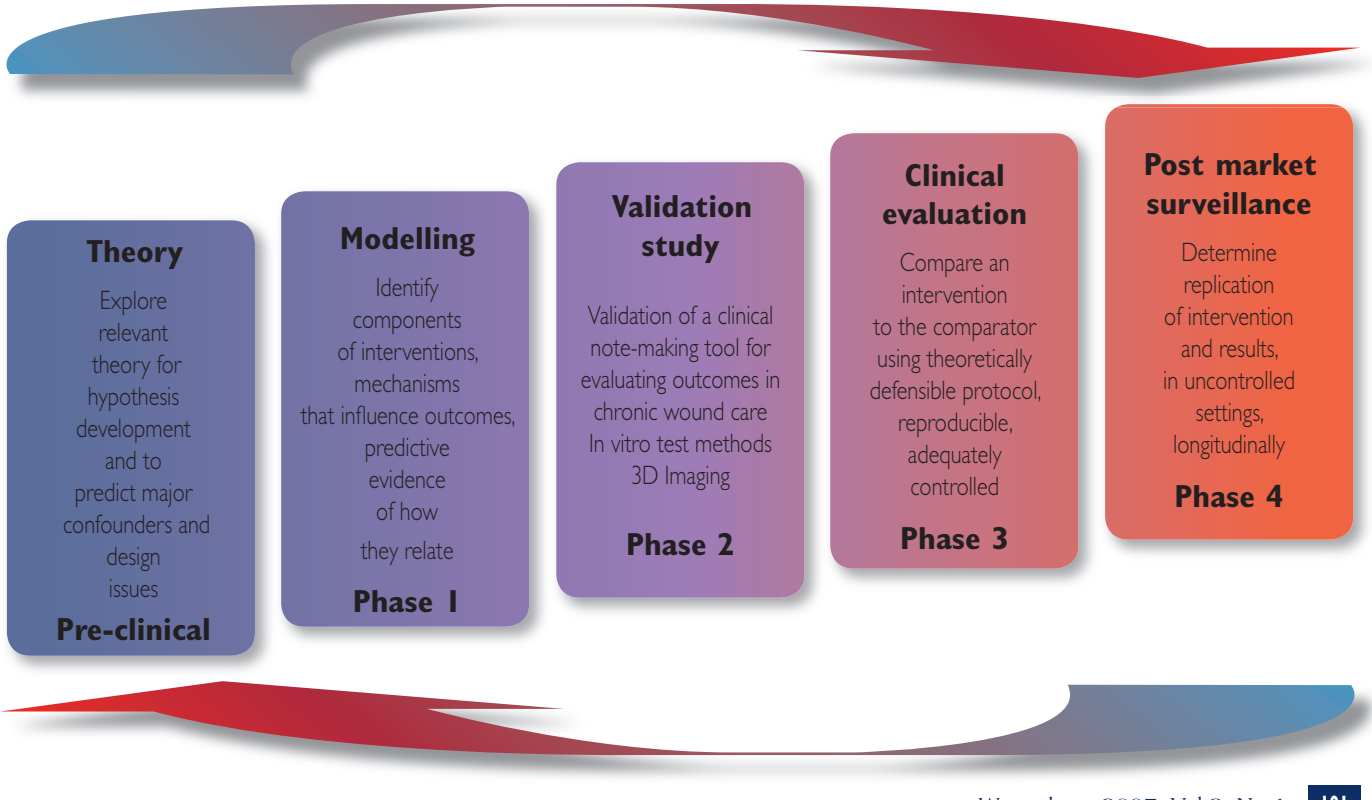
PG: Wound care is multifaceted and substantively context specific. The patient as the recipient of care is the focus. On the whole, philosophically and methodologically, the RCT is not suited to generate evidence to guide clinicians to answer the important 'how', 'when', and 'why' questions of clinical decision-making, at the individual and group level, for wound care. We would do better to collect routine prospective evaluation data using a robust clinical evaluation tool.

Are the findings and value of an RCT limited by the rigidity of the set inclusion and exclusion criteria?

PB: Yes and no, and necessarily so, since many subjects will be excluded due to co-morbidities, e.g. diabetes. Ironically, it is often these subjects whose wound healing difficulties pose the greatest problems in management. But if the study has deliberately included only those with a particular difficult chronic wound relating to a specific morbidity, it might provide conclusive answers.

Within the RCT it is easier to attribute the observed effect to the treatments being compared.

The findings of an RCT may pose further research questions, which may be explored using a different research method. So while the preliminary study findings may be initially disappointing, it is the responsibility of those working in the field to take up the challenge of further research.



PB: *Perhaps within the wound healing community we should be asking ourselves why it is that healthcare professionals are not producing a variety of appropriate studies that are applicable to wound management.*

PG: *The randomisation aspect of the RCT sits very uncomfortably with notions of personal choice: alternative routes to minimise bias can be followed without compromising patient goals or scientific rigor.*

PG: Strictly speaking the generalisability of such findings is limited to the study sample, with the proviso that statistically significant findings are generated to support or rebut the original hypothesis.

Can so-called lower levels of evidence (laboratory in vitro experiments, animal in vivo studies, clinical audit and properly conducted case studies and cohorts of cases) have a justified place in the evidence hierachy?

PB: Yes, because the evidence on which a clinician bases a management decision should not be arrived at on the basis of one type of study alone. While all types of research studies have their limitations and will invite criticism, when taken into consideration altogether they may form a robust raft of evidence.

Some clinicians have compared meta-analyses of RCTs and cohort case report studies and discovered no major differences (Benson and Hartz, 2000; Concato et al, 2000).

PG: Evidence generated from such studies can inform in a way that the RCT does not. The evidence hierarchy is inappropriate in my view. It is all about knowing when and why you need different forms of evidence.

In the search for truth in wound care are there situations when the RCT is totally inappropriate?

PB: No. While it could be argued that the RCT is self-limiting, it will never be inappropriate since it concentrates the focus of attention to a specific question.

PG: Yes, at a philosophical, methodological and practical level. I have argued the case for palliative wound care. People who fall into this group generally have more than one underlying medical condition, which may be unstable. As a consequence the wound is also generally unstable. Identifying wound care products that work in these circumstances is very problematic, let alone finding an alternative for randomisation purposes. All this renders the 'controlled experiment' aspect of an RCT unworkable. The individuals concerned may be approaching the end of life with personal priorities and goals for the time allowing.

The randomisation aspect of the RCT sits very uncomfortably with notions of personal choice: alternative routes to minimising bias can be followed without compromising patient goals or scientific rigor. In addition, sampling for statistical analysis purposes from this population presents an insurmountable problem for any trialist.

Depending on the response to Q4 when are alternative levels of evidence relevant and acceptable?

PB: I offer this up as a point of probable contention; perhaps as clinicians we should be less worried with the aetiology of the wound problem and more concerned about its effect upon the patient. The patient's priority may not be healing, it may be pain relief or reduction of exudate. Observational studies, including patients with a broad spectrum of wound aetiologies which can be evaluated together, may provide solutions within the broader context of wound management, rather than pursuing the search for what will 'heal' the wound. For some patients, healing is just not possible, whether due to co-morbidities, age, poor nutrition or terminal illness. Such patients seek help in the short term.

PG: I refer again to my response to question one, and, again, would substitute the term 'levels of evidence' with 'forms of evidence', with the proviso that any evidence that comes in to the public domain in support of particular treatments and care needs to be, transparently, of sound quality. The following quality criteria could be used to demonstrate such quality:

- Valid approach to collecting prospective observational data
- An analytic framework including an explicit chain of reasoning between general knowledge, individual data and the context from which it is derived
- Iterative theory building and validation
- All phases of the project, including evaluation techniques, meet the requirements of research governance. WUK

For more information on WRAP, please visit www.kcl.ac.uk/wrap

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