

# Evidence in wound care: the recent NICE guidance on Debrisoft monofilament debridement pad for use in acute or chronic wounds

## CONTRIBUTORS

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It is highly likely that we have seen a significant change in the attitude to evidence when related to wound care products. In March, the National Institute for Health and Care Excellence (NICE) released medical technology guidance (MTG) on wound debridement (NICE, 2014). There are important issues associated with this, not least the level of clinical evidence that NICE acknowledged in making this recommendation.

There are two schools of thought when assessing clinical evidence: the Cochrane approach is to make a systematic review of those randomised, controlled clinical trials (RCTs) which meet specified criteria. Cochrane does not make recommendations on the basis of the evidence. The alternative is the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach which reviews all of the available evidence according to the hierarchy and makes recommendations on that basis. NICE uses the latter approach (NICE, 2012).

The relative merits of these two approaches has become subject of discussion (Harding, 2000; Cutting et al, 2007; Maylor,

2007; White 2008; White and Jeffery, 2010; Beeckman et al, 2012). A number of eminent physicians have counselled against taking a dogmatic approach to evidence, i.e. to be open-minded about any hierarchy (Black, 1998; Rawlins, 2008). Professor Sir Michael Rawlins (Chairman of NICE) has stated *'Hierarchies attempt to replace judgement with an over-simplistic, pseudo-quantitative, assessment of the quality of the available evidence. Decision makers have to incorporate judgements, as part of their appraisal of the evidence, in reaching their conclusions. Such judgements relate to the extent to which each of the components of the evidence base is fit for purpose. Is it reliable? Does it appear to be generalisable?'* That is, a hierarchy of evidence cannot replace clinical judgment as a means of seeking a more robust approach to the assessment of evidence. To identify the advantages of any therapeutic intervention is the scientific judgement derived from the sum of available evidence (Rawlins, 2008).

In the case of the NICE debridement report, it is openly acknowledged that the available evidence is limited, there being no RCTs. Significantly, NICE refer to previous guidelines to emphasise the value of debridement in pressure ulcers (NICE guideline 29) and in diabetic foot ulcers (NICE guideline 119), again without relying on RCTs for support. In considering the evidence, NICE recognised that *'the lack of good quality comparative evidence is common in wound care.'*

Perhaps the best point at which the case now rests has been articulated by Treadwell (2007) *'We must never lose sight of the fact that evidence-based practices are guidelines, nothing more. They should never replace clinical experience and judgement or replace care tailored to the individual patient.'*

*Richard White*

**Given this NICE report on debridement, what is your view on the likely future for RCT evidence in wound care?**

**PG:** Key issues arise from the NICE MGT17:

- ▶ NICE issued guidance supporting the use of Debrisoft and its advantages over other technologies, while acknowledging the evidence submitted is weak
- ▶ The Committee recognised a *common* lack of good quality comparative evidence in wound care
- ▶ The Committee encouraged us to collect *better quality comparative evidence.*

This guidance indicates that the evidence used in the NICE process for medical technologies is not confined to RCT evidence. This is helpful on the grounds that in wound care research involving medical technologies it is difficult to meet the criteria of the classic double-blind RCT design (e.g. homogeneity of the sample, blinding of the intervention). Publication of this guidance provides the discipline of wound care with the 'green light' to develop and test alternative rigorous research designs, and methods of clinical and patient recorded outcomes data, to the RCT (Medical Research Council, 2000). The guidance is not an excuse for those of us working in the discipline of wound care to accept:

- ▶ The ignominious recognition of the lack of good quality comparative evidence to support clinical decision-making and patient care
- ▶ Expert opinion as a substitute for research evidence.

**TY:** It is very refreshing to see NICE considering a variety of types of evidence. The NICE medical technology process involves reviewing the claimed advantages of technologies and the value of introducing the specific technology compared with cur-

rent management of the condition. This is achieved by reviewing the evidence submitted from the company that sells/markets the technology along with expert opinion from those individuals that have clinical experience of the technology. If NICE provide positive guidance the technology is deemed to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages (NICE, 2014).

However, RCTs should continue to be undertaken to help reduce uncertainty over what is effective. By blending the RCT with other evidence sources, e.g. registries and outcome data it should be possible to see which interventions work in the real world in which clinicians practice.

**OA:** The NICE guideline focussed on the positive outcomes of the available evidence, and lack of conflicting data, while highlighting the lack of an RCT. NICE stated that they believe there should be more RCTs in wound care. Unless there is a significant change in how wound management companies market and review their products, trials of this type will not be conducted. When one company starts producing evidence based on RCTs, there may be across the market, because it will change the expectation of the payers and bodies such as NICE. Furthermore, we must differentiate between 'medical devices' and 'prescription medicines with licensed indications'. There is both a gap between regulatory as well as payer expectations for evidence between these distinct groups of interventions, all be it some interventions may for a given situation may span either classification.

**Given the NICE position on debridement in guidelines 29 and 119, do you feel that there is a need for RCT evidence?**

**PG:** There is a need for good quality comparative and prospective evidence to support clinical decision making and individualised

patient care, which is not synonymous with RCT evidence. RCTs can provide unbiased answers to research questions, and evidence, in research projects that are feasible and ethical to conduct. Wound care that requires the involvement of healthcare professionals arguably meets the criteria of a complex intervention (comorbidities, more than one component to the intervention, population heterogeneity, patient and family impact and perspectives). The challenge is to match the research question and the study population to the most appropriate research design to provide unbiased answers. In my view, this indicates the need for research designs that can navigate complex clinical problems and interventions, and enable the accrual of unbiased, generalisable evidence that can be translated into individualised treatment and care. The classic RCT does not meet this brief.

**TY:** My comments regarding RCTs in the previous question still apply here.

In the NICE clinical guideline (CG) inpatient management of diabetic foot problems (CG119), the guideline development group acknowledged that their communal experience, knowledge and expertise helped in the process of achieving consensus on the debridement recommendations as the RCT evidence was not of the highest quality. CG29 has recently been updated by NICE CG179. The NICE MTG17, appears at odds with the recently published prevention and management of pressure ulcer guideline (CG179) which does not specifically refer to mechanical debridement. This could be due to the different levels of evidence reviewed by the clinical guideline development group compared to the innovative approach taken by the medical technology group within NICE. This must be confusing for clinicians and potentially divisive if used on cost grounds to block the implementation of innovative technologies. It is important to review guidance from the wider wound care community, such as the European Wound Management Association (EWMA) document on debridement (2013).

**OA:** CG29 has been replaced by CG179, which states that debridement should be considered for patients with pressure ulcers, and that autolytic debridement is preferable in most cases to sharp debridement. CG119 relates to diabetic foot ulcers, and does not clearly state a view on debridement, stating that the wounds should be reviewed by a multidisciplinary foot team, using debridement techniques and products that suit their expertise and experience. MTG17 is a review of an individual product, rather than an assessment of all products available for a condition, so should be considered in conjunction with these clinical guidelines.

It is clear that there is a need for more comparative evidence regarding different techniques and products available for debridement, which may or may not be answered by an RCT. However, when the subject of reimbursement meets with uncertainty, payers are now beginning to trade 'price' with 'uncertainty of efficacy'. So improved comparative efficacy will command potentially higher reimbursement or market share, so whether it is RCT or real world data or a combination of both, there will always be a driver to raise the bar and standard of care from what it is at the moment. Companies who want to charge higher prices will need to provide a value proposition for their claims.

**NICE took account of health economic calculations and expert advice in arriving at the judgement in MTG17; would you recommend this approach for other aspects of wound care?**

**PG:** Health economic calculations are important components of evidence, and should also take patient and clinical benefits into account. We rightly challenge the use of unit costs versus treatment and care costs in procurement decisions. The NICE process of running independent health economic calculations, as they did in their deliberations over Debrisoft, is a particular strength in terms of minimising bias.

With regard to expert advice, this may

have a place in terms of providing the clinical context in which the medical technologies are used. Experts should include patients and carers, their voices and experiences need to be heard by those who control access to medical technologies, purchasing and supply. Overall expert advice is supportive of, but not a substitute for, research or routine evidence.

**TY:** The NICE debridement recommendations are an important step in the evaluation of wound management interventions and more should be made of economic models and (traditionally) weaker clinical evidence. I am strongly in favour of the inclusion of expert opinion as evidence. In my clinical practice, if a new technology becomes available I will always ask which clinicians are currently using the technology and then make contact for their opinion on clinical and cost effectiveness. This is reinforced by the value of peer networks such as the Welsh Wound Network and the All Wales Tissue Viability Forum, which are excellent forums for sharing clinical experience.

**OA:** Yes. Absolutely. In the absence of more high-quality evidence, this is a valid way of assessing a product, and reviewing its place in treatment. The use of posters and small local trials can add value in the absence of large clinical trials. Given that wound care has held a relatively 'evidence-free zone' we still spend significant NHS funding on a whole range of products, often dictated more by specialist opinion and favoured brands over evidence base.

### Is there still a need for RCTs in wound care? If so, where?

**PG:** Implicit in the four questions posed in this debate is a polarised question, namely, are you for or against the RCT? I have indicated that wound care is complex requiring complex interventions, which in turn require research designs and methods of data capture that can navigate the complexity. Particularly in relation to medical technologies

we need to be able to answer questions such as: when, how, how effectively (patient experience, clinical outcomes, and treatment and care costs), and why not. RCTs are not designed to answer such questions or generate this richness of contextualised evidence.

Patient involvement in research, and the increasing focus on individualised treatment and care, questions the hegemony of the RCT, not just in wound care research. The challenge is to develop and validate research designs, and methods, that can match this complex territory. A good starting point is to reduce measurement bias and lift the quality of methods of measuring wound care outcomes. Some of the studies cited in support of Debrisoft appear to have used measures that do not meet the requirements of the theory of measurement in terms of validity and repeatability (skin condition improved; overall performance of Debrisoft pad was rated good, very good, poor; partially successful debridement). New technologies enable accurate, comparative wound measurement. These together with valid, repeatable clinical measures that reflect patients' and clinical goals, and measure patients' responses to treatment over episodes of care, provide rigorous methods of data capture to incorporate into research designs to answer complex wound care questions, and generate research, and routine evidence.

**TY:** I do not think we should abandon RCTs, they are challenging to design and implement, however, they provide a scientific answer to questions over the efficacy of wound interventions. It is essential that RCTs supporting wound care practice are of the highest standard, correctly powered and based on sound methodology. This will help to eliminate the constant criticism levelled at low quality, poorly designed and underpowered RCTs which are sadly often seen in wound management. The skill is to blend RCTs and other sources to provide a clinically realistic evidence base for wound care practice. The NICE medical technologies guidance helps clinicians by reviewing new interven-

tions albeit with limited evidence to ensure that beneficial interventions reach patients without the indeterminate wait for the RCT, which for an individual with a wound must be a welcome step forward.

**OA:** RCTs would be useful to appropriately evaluate new products coming to market, competing against established products. What RCTs are unlikely to deliver, if funded by commercial organisations is comparative data, which is really what the NHS and NICE need. If the NHS were to invest in an RCT, this type of data may be available, but this would require huge, perhaps prohibitively investment. The true solution may well lie in collaboration and co-creation of evidence. NICE has already started new initiatives such as Commissioning Through Evaluation, which allows the 'value' story to be generated through a partnership of commercial and NHS partnership in collecting data, i.e. Patient Reported Outcome Measures (PROMs). [WUK](#)

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