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Evidence and practical wound care – An all-inclusive approach

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ABSTRACT

The quest for evidence-based medicine leads one in search of *best available evidence* but what exactly is this? Convention guides us towards the putative gold standard of the randomised controlled trial (RCT) but this approach provides limited access to the gathering of evidence that is relevant to a 'real world' environment. Taking several examples from wound care including moist wound healing, negative pressure wound therapy and dressing wounds with gauze we show that if one takes biology into consideration, the "truth" becomes more relevant to everyday life. We suggest that solely relying on the RCT in the quest for truth is misguided and that the research community should embrace a circular model of evidence rather than a hierarchical one.

1. Introduction

The privilege of working in healthcare bestows a responsibility upon the clinician to identify and select those therapeutic interventions that are relevant to the patient's clinical circumstances and are most likely to achieve optimal outcomes. Best practice application and the associated clinical outcomes are inextricably linked to the skills of the clinician, the availability of appropriate resources and the repository of available evidence. The three domains of skills, resources, and evidence lead us towards the practice of evidence management. Evidence based management has been defined as "*the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients*" [1]. This statement generates additional challenges, that is; what is reliable and relevant evidence and should evidence dictate or support clinical practice? In wound care, particularly the care of the complicated wound e.g. leg ulcers, pressure ulcers and diabetic foot ulcers, the debate on what constitutes evidence, has continued for some years. At the heart of this debate are two facts: first, that wound dressings and bandages etc. are classified as Medical Devices in most countries and as such, do not require the rigorous testing demanded of pharmaceuticals. Consequently there are few randomised, controlled trials of these products. Second, wounds present as part of such a complex presentation as to make generalisation difficult.

2. Evidence: a hierarchy?

It is broadly accepted that in order to evaluate interventional medicine the application of a hierarchy of evidence is required so that currency may be applied according to its perceived value. This approach has been widely adopted around the world with the systematic review of randomised controlled trials (RCT) assuming pole position at the top of this putative hierarchy. At the lower end of this hierarchy lies the single case study ($n = 1$) with a range of other 'levels' of evidence lying in between. Although this "hierarchy" was criticised as early as 1989 [2], three years before the term Evidence Based Medicine was first coined formally [3], the putative pyramidal hierarchy became the authoritative model.

2.1. An abuse or misuse of evidence?

This 'pecking order' of evidence is used by many government healthcare agencies, such as the UK National Health Service (NHS) and the National Institute for Health and Clinical Excellence (NICE) as well as many overseas governmental agencies and academic institutions to rank evidence according to its perceived value in clinical care. In the Netherlands, following the commissioning of a working group the assembly of health care insurers (College Voor Zorgverzekeringen, CVZ) issued a report where virtually all of the advanced wound dressing categories were labelled "lacking

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evidence to justify their clinical use" [4]. More recently the "Dutch drug bulletin", an impartial organisation that seeks to promote a more rational approach to pharmacotherapy issued a publication where this point was taken even further. All antiseptic wound-dressing types, based on honey, silver and iodine, were declared "proven ineffective" in all complicated wound types. A strong recommendation was made to save costs, as *"these unproven and expensive antiseptic dressings have no place in today's clinical practice"* [5]. Assertions like these can have grave consequences for the individual patient [6]. Although RCTs do have a clear role to play, especially in the evaluation of pharmaceutical interventions, their intrinsic limitation is that the findings lack external validity [7]. The results of a clinical randomised controlled trial are, by definition, relevant only within the confines of the study parameters. Thus the inclusion and exclusion criteria selected during the study design process dictate to whom the findings can be applied. This selection process avoids the incorporation of undesired variables into the research process that would complicate clear analysis of the data. This rigour supports the research process admirably but what needs to be asked is whether this facilitates application of the findings to the 'real life' events that lie beyond the limitations of the study. There is a risk that such findings cannot be extrapolated to those individuals that do not 'match' the inclusion and exclusion criteria. This over-reliance on the RCT has been identified as "*doing a disservice to patient care, clinical investigation and education of health care professionals*" [8]. It has been argued that if observational and experimental study designs would be brought into a consistent alignment, both study types would be of equal value and lead to comparable outcomes [9]. Frear underpinned the importance of using observational ("real world") data when deciding which drugs to include in a formulary because these data have the potential to add crucial information which cannot be provided by experimental research (e.g. patient adherence, appropriate medication use, and cost-effectiveness) [10]. A review of observational studies published between 1985 and 1998, comparing the findings with those from randomised controlled trials of 19 diverse medical treatment regimens (e.g. CABG vs PTCA in coronary disease, multimodal treatment for breast cancer, laser vs electrosurgical salpingostomy, endarterectomy under local vs general anaesthesia), found that 17 of 19 treatment analyses from the observational studies fell within the 95% confidence interval of the results from the RCTs [11]. Criticism is rightly levelled at the relevance of *in vitro* findings to the clinical setting as the data they generate is more akin to 'virtual reality' rather than reality itself. The inclusion and exclusion criteria that are selected and incorporated into an RCT also create a degree of artificiality themselves as they select out (refine) the study population and thus make extrapolation to a wider audience difficult or impossible. Rigour is most definitely required in studies that impact on patient care but reflection on applicability to the lived experience should also be a consideration. White [12] has stated that criticism of the RCT should not be viewed as a disparaging act but one where the true merits of a blind faith approach needs to be considered. Others have shared similar views as reflected in: "The randomized controlled trial: gold standard or merely standard?" [13]. Here the authors state that not only researchers "believe" that the RCT is the only way, but also funders and publishers. It is now argued that there should be room to consider other forms of evidence in healthcare [14–17]. The principle being that an evaluation of **all** of the available evidence be conducted as part of a thorough and representative exercise. The over-valuing of the meta-analysis of RCTs, that omit some of the most basic values in medicine, like biological plausibility, bears the risk of the EBM-movement being critiqued as being evidence-biased rather than evidence-based [18], even more so as the EBM-movement has not come forth with a justification of the advocated hierarchy [19].

2.2. The whole truth?

In a recent meta-analysis of wound care Cochrane systematic reviews, it was concluded that "*strong conclusions could be drawn regarding the effectiveness of therapeutic ultrasonography, mattresses, cleansing methods, closure of surgical wounds, honey, antibiotic prophylaxis, compression, lidocaine-prilocaine cream, skin grafting, antiseptics, pentoxifylline, debridement, hyperbaric oxygen therapy, granulocyte colony-stimulating factors, prostanoids and spinal cord stimulation*" [20]. However, whilst this is helpful to clinicians, it is not all that it appears to be, only 44 out of 149 reviews were considered; a clear case of not evaluating all of the available evidence.

The 'traditional' model of evidence is that of a hierarchical pyramid. However, it has been stated that "*a trustworthy hierarchy of medical evidence is an illusion*" [21]. The problem being that the ranking of evidence in line with the various hierarchies will lead to different types of "truth" [22]. Underdetermination of the elements in any study raises the risk that findings can be interpreted in such a way that the conclusions seem plausible [23]. This has been described as: "*playing with the definitions of 'evidence' in order to reach predefined conclusions*" [24].

3. An evidence paradigm

These notions have led us to propose a novel portrayal of medical evidence where the most suitable representation would appear to be a circular model (Fig. 1). Although a "Circle of Methods" has been proposed for evaluating the more complex medical interventions [25], it is possible that the authors, at the time, supported a hierarchy of the various forms of evidence. Our circular model proposal intends to highlight one or more categories of evidence, while at the same time avoiding over-shadowing, or obscuring other forms of evidence. It has been argued that all types of evidence, including *in vitro*, animal studies, pathology series reviews, clinical case series and several other types should be taken into consideration when making informed decisions in clinical practice [26]. The range of evidence types chosen in the introductory notions of Robson and Barbul [26] on behalf of the Wound Healing Society has led to the publication of nine sets of guidelines providing a wider inclusion of evidence when compared to the "exclusive evidence" of the "MARCT"-derived approach ("meta-analysis of randomised controlled trials"). Four guidelines were published in 2006 for the treatment of pressure ulcers [27], venous leg ulcers [28], arterial insufficiency ulcers [29], and diabetic foot ulcers [30] followed in 2008 by publication of the guidelines for prevention of these four wound types respectively [31–34]. The work of this group was completed with the publication of guidelines to aid the healing of acute wounds [35]. Given the already "broad spectrum base" for these guidelines, we propose to modify this spectrum on two counts. Firstly, we propose to expand this spectrum by including PROMs (Patient Reported Outcome Measures) and the COHORT observational study. Secondly, we propose to take out what has been referred to as "STAT" (meta-analysis and consensus statement by commissioned panel of experts) [26]. The meta-analysis of randomised controlled trials, as well as consensus statements or documents are forms of analyses, synthesised documents. Although valuable for informing practitioners, they are not (pre-) clinical types of research. These methods should, therefore, not be part of the circle (input) but rather follow (output) on what was found within the circle. By utilising a funnel and receptacle, our model (Fig. 1) illustrates how all available evidence must be accumulated in order to acquire the most informative evidence summary, interpreted by experts [36].