How unified is our approach to wound care?

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With our NHS under increasing pressure from the demands of care delivery and financial cuts, it is ever more important that we, who are involved in wound care/tissue viability, objectively assess the quality of the service provided.

To this end, it is vital that we are aware of what we do, at what cost, and with which outcomes. To date, this has not been subject to formal, independent measurement, rather to occasional publications of local outcomes, issues, and commentary on care.

The clinical value of the whole class of 'modern wound dressings' has, rightly, been called into question of late. This has resulted in an exercise to independently 'evaluate' products with a view to streamline availability and use. At present, the UK is subject to the Medical Device Directives and the forthcoming Medical Device Regulation (2017), which in respect to wound dressings, defines the quality, safety and performance criteria essential for CE marking. All such products in section IXa of the Drug Tariff meet those requirements, that is to say they conform to the 'essential requirements' in statutory law. The situation regarding published evidence is rather different. The range of evidence available is wide, tending more towards case studies and small trials. Large randomised controlled trials (RCTs) are far fewer. The merits and value of one form of evidence over another are not the subject of this debate, they have been clearly expressed elsewhere (Rawlins, 2010). However, Guest et al (2015), in a report on different compression bandage systems, have made this point:

"These differences may also highlight some of the practical problems associated with wound care in the community and the lack of skills required to both select and apply appropriate compression therapy. Patients in our data set rarely saw the same nurse at successive visits. Hence, a lack of continuity of care and the practical difficulties experienced by non-specialist nurses in the community in achieving the correct levels of compression, as well as the lack of specialist involvement, may contribute to the poorer outcomes seen in clinical practice rather than controlled trials."

The point, not highlighted enough, is that the problematic patients seen by primary care nurses are 'real world' patients where narrow inclusion and exclusion criteria do not apply, so perhaps we need to change the way we assess evidence (Kaplan et al, 2011).

The delivery of the whole spectrum of 'wound care' in the UK is achieved predominantly by nurses. Whilst their commitment remains unquestioned, it nevertheless behoves us to question the methods and outcomes. Perhaps the most telling evidence published to date is that of Guest et al (2016), who interrogated the THIN database for a variety of matters related to wound care. The outcomes reported are not edifying insofar as they portray a somewhat dismal picture. This revelation is not to be attributed to the performance of any healthcare practitioners, but rather to policymakers and those responsible for funding. Guest's report shows the clinical demands to be far higher than previously thought and whilst clinical outcomes are disappointing, the problem lies in the overall strategy for delivering 'High Quality Care for All' (Department of Health [DH], 2008). To this end, those responsible for delivering care to the patient will be well advised to make sure that they are following the appropriate guidelines, using evidence-based methodology, and carefully documenting outcomes. Only then can a cogent case for appropriate funding be demanded. There is a clear need to undertake this exercise.

If we, and by 'we' clinicians, academia, relevant charities, industry and NHS management are all implicated, are to achieve 'High Quality Care for All' then a spirit of cooperation, cohesion, and candour will be required.

The purpose of this debate is to air a few issues related to these ideals, just to allow some of those with a vested interest to express their opinions. Hopefully it will form the basis of an ongoing dialogue, debate and, ultimately, progress. *Richard White*

In view of the recent focus on modern wound dressings from the DH, how do you see the future of this sector of the market over the coming decade?

SH, CET: The work programme from the Clinical Evaluation Team (CET) aims to be the first time a national collation of clinical opinion on products within the programme have been assessed. The goal by engaging with these clinicians, is the identification and development of clinical requirements per product group. This national opinion can be used working with suppliers to create and develop products that meet the national clinical opinion/need, displaying the performance of products against a defined criteria, rather than directly comparing products against each other, thus making the performance and delivery of all products more transparent.

HS, TVS: Having attended the workshops and roadshows held by the CET we are reassured that the methodology being used to identify criteria required of dressing products is thorough, robust, clinician-led and fair. Commercial companies will be able to match their products against this criteria and clinicians will more readily be able to select products that meet their local population's needs. The future of the wound care market will remain strong because of continued need — those companies that work collaboratively with the NHS and understand its need for cost-effective care delivery will continue to thrive.

JSH, WCAUK: The DH Health will support the NHS to function as a national purchasing organisation with national benefits. There is also a need to influence the ever-growing British National Formulary and the range of products listed, with a cap on the number of products within a category. This may have the effect of limiting the creation of 'copy' products and encouraging innovation, as new categories would contain only a limited range of products. We need a greater focus on appropriate use of dressings and a greater expectation of the clinician to demonstrate the delivery of evidenced-based care and that the patient is on an appropriate care pathway.

RR, LLC: Naturally, our main concern is that dressings should continue to be designed, developed and adopted with patient benefit in all its forms as their top priority. While we work very closely with Trusts, specialist clinicians and sponsors from industry in the running of our network of Leg Clubs, our focus is on improving and maintaining a service to our members within a social model of care, and we have confidence that our stakeholders will work together to introduce and provide the right dressings for patients.

CH, SDMA: The focus appears to be on reducing the unit cost of products rather than the overall cost of treating wounds. The process will drastically reduce variety, remove evidence-based decisions, and drive out clinical choice. The inevitable consequence of following this path means that the future of the wound care sector is bleak — for example, it will have a negative impact on patients and the development of clinical excellence; result in a large cost increase to the NHS; put front-line nursing services under greater pressure, and drastically reduce innovation (Surgical Dressings Manufacturers Association [SDMA], 2015).

MC, PAC-BHTA: The increasing involvement of National Institute of Health and Care Excellence (NICE) reviews of wound dressings and devices should, in theory, rationalise the number and quality of dressings and devices on the market to the benefit of patients and the NHS. Unfortunately, with the well-documented and notorious history of slow adoption of new technology by the NHS, which is exacerbated by the 'silo' budget and decision-making structure of NHS England in particular, I foresee new technology being launched in other developed markets sooner and arriving in the UK much later, to the detriment of patients and increased costs to the NHS. I know of current examples of UK wound care innovations already adopted across Europe and North America which have yet to be adopted by the NHS.

AD, ABHI: In line with other clinical specialities, we foresee greater standardisation of clinical practice and products, with increasing control at a regional level. This is likely to have a significant impact on a dynamic advanced wound care sector. The aim of these interventions would be to eliminate variation and drive down costs, both personnel and product. Given that the vast majority of costs in delivering wound care is driven by workforce costs, we would anticipate that standard protocols and algorithms would be employed, alongside more advanced diagnostic tools to enable less specialised clinicians to undertake routine wound assessments and dressing changes.

RW, WUK: Outside of the many 'enlightened' clinicians, few accept the value of modern wound dressings. This is, to some extent, attributable to the fetish for RCT evidence held in some quarters. As and until the real value of modern dressings becomes widely acknowledged, I fear that there will always be a strong negativity in the minds of those with agendas separate from patient care.

JF, WUK: I believe the focus on wound dressings will actually be beneficial for the whole sector, despite the initial fears caused by rumour and misinformation, the activity from the CET in England has been designed to develop standards which will be beneficial to both, clinicians when looking to purchase dressings and the commercial sector when considering whether they should develop new products. I

believe it will also act as a safety net reducing the likelihood of 'cheaper' products flooding the market as they may not meet all of the required standards — and if they do, then they deserve their place on the market. I think we will see some consolidation in the market — but in reality that is needed, there are far too many 'me too' products, claiming to differentiate in ways that don't matter!

Can you envisage tissue viability as we know it in the UK being unified and speaking with one voice? And if yes, what would this entail if it were to become a reality?

SH, CET: Tissue viability is a specialist area with clinicians always seeking the best product(s) to meet their patients' need. Clinicians are united behind the drive to achieve high-quality patient outcomes. Clinicians currently spend a lot of their time looking for the optimal products to best manage their patients, and this work is duplicated across every NHS trust. By engaging clinicians using these products, and collating national opinion on clinical criteria for a dressing category, with defined clinical evaluation of products against these criteria, it is hoped that TVNs can be confident in the impartial informed guidance of product performance and application. This can be used to aid their clinical decision by recognising their own clinical requirements and the product(s) that will best meet these needs based on their clinical knowledge of their working environment and patient outcome aims. Whilst reducing extensive duplication and fragmentation of approach.

HS, TVS: Differences of opinion are healthy, and maverick opinions are important to introduce different ways of looking at things and challenge 'herd' thinking. Whilst we strive for consistency, there are exceptions to every rule, even in wound care, so patients and clinicians are always going to want a choice. A plurality of voices and opinions is vital to ensuring that people receive skin and wound care that meets their individual needs.

JSH, WCAUK: Speaking with one voice means representing a range of healthcare professionals as well as providing specialist and generalist care for a range of wound types. In some ways, tissue viability is unified and does speak with one voice as it promotes accountability, responsibility, quality, evidenced-based care and improved patient outcomes. Whether industry, charities or individuals represent tissue viability there are advantages of being unified but making this a reality requires national Governmental support. A national representative(s) for tissue viability with responsibility for coordinating tissue viability is how I envisage this could be achieved most effectively.

RR, LLC: I think that tissue viability organisations have started to engage more proactively with each other — and that is a good thing. However, there is always a danger that specialist clinicians don't engage sufficiently with important outside groups such as government, educational bodies, individual Trusts and commissioning groups. This is much harder to do and perhaps the different tissue viability interest groups in the UK should appoint common champions who can drive the wound management agenda up the national priority list. This is something that we try to do in our charity, but it should be a key strategy for tissue viability as a whole.

CH, SDMA: This really is a question for clinicians and not for industry, but we believe that most TVNs and opinion leaders are already united in the belief that choice, clinical judgment and innovation need to be protected. This was made very clear by responses to the SDMA survey that asked nurses and TVNs questions concerning the selection of wound dressings (Brassington et al, 2015). The survey also showed that most nurses and TVNs currently have a choice when deciding on the most appropriate dressings for patients. We strongly support tissue viability speaking with one voice to ensure they have access to the best products and services leading to optimum outcomes for their patients.

MC, PAC-BHTA: Not necessarily, and that might not be a problem. UK tissue viability has traditionally been an international leader in wound care and can be justifiably proud. It is no coincidence this occurred because of a group of people who were curious and driven to improve outcomes. Some of these people were innovators and risk takers and succeeded despite being criticised for trying 'unproven technology' and 'wasting money on expensive dressings and devices'. The challenge in the future is how to continue to improve in the face of more controls (NICE) and restricted 'silo' budgets? The risk of 'speaking with one voice' is that voice becomes dumbed down to the 'lowest cost traditional remedies'. Industry and the NHS need to fund research-based wound care innovation and not just talk about it.

AD, ABHI: To protect the tissue viability specialism, it will be a necessity that the community speaks as one voice to provide a strong input into commissioning policy. To have impact, a unified organisation would need to foster strong links not only within the wound care community but, importantly, with commissioners, medicines management and procurement groups. To create a strong voice and platform, the tissue viability groups should consider more robust links with the national organisations such as the Royal College of Nursing.

RW, WUK: I suspect not in the next 5 years, and I do feel that this is to the general detriment of the discipline — patients and practitioners alike. A unified front with the courage to speak on all

issues important to improving patient care would be of value. Alas, too few voices are heard. Ideally, a UK tissue viability organisation would be capable of close interaction with legislators, industry and payers alike. The matters of import include healing rates, fundamental care standards, negligence and malpractice, education, mental health and continuity of care.

JF, WUK: I would love to see tissue viability unified, however, it is not the easiest of tasks! There have been several attempts to bring just the TVNs together in one organisation, but for a variety of reasons this has always stalled; to unify the whole of tissue viability would indeed be a challenge. There are some great organisations such as TVS working to try to raise the profile politically – but, unfortunately, they have no 'mandate from the people' to do so and, therefore, there is often a pull from many other directions. Whilst TVS are great at sharing some of the work they do, many others are less so and there is still a lot of 'silo' working. It would be really helpful to have just one central portal for information for a start; whilst Wounds UK aims to share all the information we receive — we can only share what is sent to us. Regional groups, such as that in the East of England make use of existing portals to share and spread information — however, this is still a local activity.

Given that wound management in primary care is of questionable standards, what are you and your organisation doing to improve matters?

SH, CET: The CET, which funded by the DH, is independently evaluating a range of wound care products — focusing on clinical quality against criteria of products, as identified by national clinical engagement. Bringing together professionals from across the NHS, along with additional stakeholder organisations, the CET will publish comprehensive, independent reports on the clinical quality of a number of wound care products available to purchase via the national provider. Using this clinical evidence, those working in wound management can confidently select the right products to aid delivery of care and enhance patient outcome.

HS, TVS: The premise of this question implies a negative perspective of the quality of wound care in the community. This question seems to unfairly target our community nurses who, as Kings Fund have reported, are struggling to deliver the high quality care they desire to under difficult circumstances (Maybin et al, 2016). Do we know that wound care in the acute sector is of a consistent high standard? We do know there are people out there living with tissue viability issues particularly, we suspect, lower limb swelling and wounds, who are not given the agreed gold standard assessment and resultant treatment therapies. The reasons for this are multi factorial and are more to do with systemic organisational problems than wound care itself. TVS, in partnership with other key organisations, will be commencing a raising awareness campaign for lower limb care and have already initiated conversations with NHS Improvement staff.

JSH, WCAUK: Wound Care Alliance UK has the objective of providing education for the non-specialist in all aspects of tissue viability. We have an annual tissue viability conference and an annual skills conference. We hold conferences in England, Scotland and Wales with highly skilled and qualified tissue viability experts providing education and leading the skills events. We also produce videos, posters, educational booklets and a quarterly tissue viability journal, which are published in association with Mark Allen Healthcare. We are stakeholders in NICE and represent tissue viability via a number of publishers, including Wounds UK.

RR, LLC: Education on leg health to both clinicians and the general public is one of the core objects or our charity. We publish standards of practice for all our Leg Clubs, which are available on our web site and, equally importantly, are followed up with training. We have recently published a Compendium of Best Practice for Leg Club Service Delivery, with support from the DH, which describes Best Practice in six key areas including patient advocacy and infection control. NICE have also recently endorsed a document that we have published comparing our own Leg Ulcer management practices with its own guidelines. Both documents are readily available over our own web site. As with the last question, it is important that wound care organisations, such as our own, consistently work together to create materials that describe clear and consistent standards of care within our field.

CH, SDMA: We believe that clinicians are striving to provide the best patient care they can. Limited resources are creating challenges in wound care — and neither industry nor clinicians are responsible for the resources made available. In conjunction with clinicians, industry provides extensive evidence-based training in the use of wound care products — as part of the obligations placed on it by the medical device regulations. It also provides a commitment to an ethical approach to ensure the appropriate uses of products (see SDMA's Code of Practice [SDMA, 2014]). Industry supports the development of care pathways, which can deliver consistency of care provision, achievement of best practice and compliance with local formularies.

MC, PAC-BHTA: The industries I am involved in have traditionally focussed on primary care and have increasingly taken a 'front-line' approach by training primary care staff and carers. A responsibility of the

industry is to ensure that their staff are properly trained and accredited through a recognised body, i.e. the professional standards authority, and to make sure this training is maintained. The NHS procurement agencies, in particular their governing body, the NHS Business Services Authority, need to recognise the value and importance of good training by industry and reflect that in their tenders and contract awards. At present they do not and have not shown any inclination to do so post the expiration of the DHL/NHS Supply Chain contract in 2018. On the contrary, recent presentations indicate that they see much of wound care sector as ripe for commoditisation and cost savings and at present refuse to include training as a cost element of the supply chain. If the 'gatekeeper' keeps the gates closed, industry will go elsewhere. Sorry to be negative, I am not ordinarily so and I am involved in several successful UK innovations in wound care in Europe and North America. Unless the NHS removes its structural barriers (silos and unit price focussed rather than value and outcome focussed procurement) then there is in my opinion, less cause for optimism in for wound care in the NHS.

AD, ABHI: Working closely with TVNs, industry partners have consistently delivered evidence based education and training to support appropriate wound diagnosis and use of advanced woundcare dressings. We are committed to continuing this support. Clinical evaluations, audit tools and ongoing formulary management with on line ordering systems is also provided. These are delivered to support the local wound care strategy and deliver consistency. In the future, we see evidence and data playing a bigger role, and industry developing digital tools to deliver real-world data that help inform clinicians' use of appropriate advanced wound dressings to deliver optimal patient outcomes.

RW, WUK: I am an academic about to retire, I can reflect on what has taken place over the past thirty years. I have seen many excellent educational programmes established in British universities, as high as Masters degree level, which have had a powerful impact. I have also see industry provide valuable educational support to clinicians, again with good effect on care. However, continuing education post-registration is very poor. The education of medical students in matters of wound care is still inadequate. The impact of wounds on the costs to patients and to the healthcare system is still not recognised in Whitehall and elsewhere.

JF, WUK: I don't speak for any organisation but I think standards in wound care in general need to be raised; I would say it is unfair to single out community staff who, as highlighted in the recent Kings Fund report are on their knees. The recent audit work by Guest et al (2016) clearly identifies the lack of assessment, diagnosis and consistent care in community — I would imagine that should the exercise be repeated in acute care — it would actually be worse as nursing staff struggle to know their patients sufficiently due to high turnover of patients and the increasing administrative load they face. NHS England and NHS Improvement are both working on wound care-related projects developing CQUINs around wound assessment and leg ulcer care and reinvigorating the 'Stop the Pressure' programme, there may also be review of what is happening in pre-registration training. WUK

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