

POSITION PAPER 51

18 December 2015



Response to NHS Supply Chain Generic Specification Project

Environmental Setting

The population of the UK is increasing alongside life expectancy. This will lead to a proportionate rise in the number of wounds requiring treatment. In the growing area of type-2 diabetes (which is strongly correlated to age) and wounds requiring treatment, active cases are predicted to increase by more than 55% by 2025¹.

There is a significant variety of wounds, with every patient reacting to them in an individual way. Wound management is greatly variable, defined by patient need and can often be complex and challenging to treat successfully. In addition, the desired outcome can impact significantly on the in-patient population, ability to discharge and independent living. This is exacerbated by wounds often becoming more complex with an increasingly ageing and diverse population – along with an increasing frequency of comorbidities.

Summary

The SDMA welcomes any opportunity to continue contributing to the development of a cost effective wound care supply that enables the most modern, personalised and best treatment to be prescribed for patients.

This position paper highlights concerns regarding the project to establish generic specifications for wound dressings, as facilitated by the NHS Supply Chain.

In its current form, the SDMA believes that this project will:-

- ***Have a negative impact on patients and the development of clinical excellence***
- ***Result in a large increased cost to the NHS***
- ***Put frontline nursing services under greater pressure***
- ***Drastically reduce innovation***
- ***Have a negative impact on the UK economy***
- ***Be conducted with undue haste***
- ***Not be an open and transparent process***
- ***Be facilitated by a private company with vested interests***
- ***Be opposed by leading experts in wound care***

¹ Amos *et al.* (1997)

Would you want a surgeon or doctor to be just 'good enough' ? Would you want health care that is just 'good enough' ? Similarly do you want wound care that is just 'good enough' ?

The SDMA would welcome an open dialogue with all the agencies involved to discuss this project and alternative methods of achieving short and long term cost saving goals – whilst at the same time ensuring patient benefit and safety is improved.

Key Issues that the Generic Specification Project needs to consider are:

1. The changing patient demographics will mean that complex care needs of people with long term conditions will see a disproportionate incidence of 'hard to heal' wounds.
2. The increasing numbers of complex cases with underlying additional conditions means that patients' wounds will increasingly require the latest innovation and technology to ensure a timely recovery and discharge, along with quick and efficient management in the community.
3. The wound management needs of each patient varies greatly and can often be complex. A cost saving project that reduces the use of innovative and modern wound dressings is unlikely to be cost-effective or supportive of the best quality of life for patients.
4. The UK wound care market is world leading and a centre of clinical excellence, with patients directly benefiting from innovation and best outcomes. A reduced and poorly-invested market will erode any gains for the patient and services – as it will become commercially non-viable and clinically unattractive to deliver research.
5. It is currently unclear how any cost savings will be reused by the NHS, or whether any surplus generated will simply be absorbed by NHS Supply Chain. This is a critical point for any financial benefit to actually reach the NHS and be available for reallocation to improve patient's lives.
6. To date, there has been a lack of consultation with patient groups, specialists and industry. All stakeholders need to work together to ensure that the best solutions are found and hence deliver affordable clinically effective solutions.
7. Government investment to improve outcomes for patients through the Accelerated Access initiative and the November 2015 Comprehensive Spending Review directives prioritise partnerships between the NHS and industry to get the best outcomes for patients through innovation and best technology.
8. Many initiatives are already in place which, if properly implemented, could generate similar savings without destroying market competitiveness. These include the e-procurement and barcoding projects, the NHS Supply Chain 'Compare and Save' initiative, and the Accelerated Access Review. These would avoid the clinical and financial costs of a forced restructuring of the wound care industry. This will also align wound care with the latest iteration of the 'Five Year Forward View' and QIPP initiatives.

Detailed Comments

Wound Management in the UK

A vast number of wounds are treated every day by the NHS in both hospital and community settings, with at least 200,000 patients having a chronic wound². The cost to the NHS for managing these

² *The Burden of Chronic Wounds in the UK*, by J Posnett and P J Franks, Nursing Times (2008) vol 104(3) 44-5

wounds is estimated to be £5.3bn per year³. Of this amount, only £302m is spent on dressings in England, with just 43% being provided through NHS Supply Chain⁴. Wound dressings interact directly with the body. It is thus questionable whether any savings delivered by genericisation will be realised, as the costs of treating exacerbated complex cases is likely to significantly over-shadow these sums.

The purpose of this position paper is to demonstrate why the medium and long-term costs generated by this project are likely to greatly outweigh any short-term savings. It is important to view these costs in terms of the financial, clinical and patient experience. Most wound care is managed directly by nurses⁵, so any reduction in the efficiency of wound dressings is likely to have a significant impact on nurse resources. A disproportionate burden of the cost of dressings is accounted for by hard-to-heal wounds. Since around 85% of wound care costs are related to nursing costs and home visits, which cost up to £80 per time, any delay in healing will dramatically and disproportionately increase these costs, and have a significant impact on patient experience. This is magnified when co-morbidities interact against the underlying wound issue, often delaying healing. A recent wound care audit⁵ in five English NHS Trusts reported that up to 25% of all patients were found to have two or more contributing and underlying disease factors.

Industry has worked in partnership with the NHS to provide the innovative solutions and wound dressings now available. This includes substantial investments in product development and R&D. Since the 1970s, wound care has developed from standard gauze and cotton pads to advanced wound care – including moist wound dressings, antibacterial dressings, gel dressings, alginates, negative topical pressure, and many others. Currently, the UK market is seen as a world leader and centre of clinical excellence, with patients directly benefiting from innovation and best outcomes.

The impact of Modern Dressings on Patients and Quality of Life

Modern dressings have had a significant positive effect on patients' quality of life. The partnership between industry and the NHS has led to great improvements in pain reduction, odour control, exudate control, infection control and patient experience (comfort) – all allowing patients to more quickly regain a normal lifestyle. Modern dressings enable patients to engage socially, within a work setting and in leisure situations, all elements of a rewarding and meaningful life that enables contribution to society. They also are designed to facilitate the simplest self-care in a way that traditional dressings cannot.

Modern dressings can also help prevent further complications and ensure that wounds heal quickly and efficiently – thus improving both the benefit to patients, their families and dependents, and the cost to the NHS. This has particular relevance as the NHS models of care continue to evolve into primary care and less acute settings and people learn to live well with their long term conditions and inherent complications.

Training and Education

Training and education is vital to ensure that wound dressings are used correctly and provide patient benefit. It is a vital part of the service industry currently supplied to the NHS and is best provided in

³ *Health economic burden that wounds impose on the NHS*, by J F Guest et al., BMJ Open (2015), available at <http://bmjopen.bmj.com/content/5/12/e009283.full>

⁴ Rachel Repper, Trading Director, NHS Supply Chain (2015)

⁵ *Wound Care in five English NHS Trusts*, by Karen Ousey et al., Wounds UK (2013) vol 9(4) 20 *et seq.*

partnership. It will be increasingly needed as more complex demands are made in the future and resources for learning are stretched by service demands.

In addition, industry frequently supports in the provision of nursing capacity within the NHS. It is common practice for nurses with honorary contracts to supplement healthcare services and this is only commercially viable in a partnership driven environment that is mutually beneficial to all parties.

The National Formulary Project for Wound Care

Project Structure

The new Generic Specification project is aimed at immediately reducing market access, via NHS Supply Chain, to both acute and community NHS trusts and potentially, longer term, also to the Drug Tariff. The project is being sponsored by the Department of Health and the Clinical Review Board, and is being facilitated by NHS Supply Chain.

The main objective of the project is stated to ensure that the vast majority of wounds (80% by value) are treated by products that are simply 'good enough for purpose'. The intention is to make short-term cost saving on the purchase price of wound dressings – with a target of just £13.2m. It aims to achieve this by developing a limited National Formulary – the use of which will be mandated. The selection of wound dressings for this National Formulary will be based on their physical properties, with only a limited number of lower-price products listed.

Agnostic (unbranded) pricing may also be used, which would mean that all brands would disappear from the NHS Supply Chain catalogue and product from any supplier might be provided. Product from several suppliers would be interchangeable so that prescribers cannot choose the most effective treatment for each individual case.

Subject to a cap, the current two year extension of the NHS Supply Chain contract allows for 85% of their profits to be related to savings on product made during the period, regardless of the broader costs to the NHS. There is a risk that much of the savings generated by the National Formulary might simply be reallocated into the surplus reserves for the supplier (DHL International GmbH – who run NHS Supply Chain).

Areas of Concern

In its current form, the SDMA believes that this project will have a negative impact on patients and limit any development of clinical excellence – and that it is unlikely to deliver the savings expected. Some key areas of concern include:

- The process is not being carried out openly or transparently. There is a lack of consultation with patient groups, specialists and industry. This is evidenced by the fact that everyone involved with drawing up the generic specifications has signed a confidentiality agreement.
- Use of the 80:20 rule for wound care is too simplistic and any mandatory use of low performance products could lead to inappropriate wound care and an increased incidence of complications such as wound infections, pain and even amputation. This is a complex clinical area, with life-changing impacts when bad decisions are made and 80:20 will not enable prescribers to make best decisions for patient outcomes.
- Wound care products vary widely in their technical and physical capabilities. This leads to differences in performance, such as wear time and patient preference that are not being considered in this process and therefore genericisation (as already used in the pharmaceutical

industry) is not possible. Hence the project could lead to an obvious negative effect on both patient benefit and best use of human resources.

- A disproportionate burden of the cost of dressings is accounted for by hard-to-heal wounds, which can be defined as wounds that do not reduce by at least 40% in 4 weeks. Since around 85% of wound care costs are related to nursing costs and home visits, which cost up to £80 per time, any impact of delayed healing will dramatically increase these costs and reduce the patient's quality of life.
- Any reduced capability of wound dressings can often lead to poor recovery, pain and discomfort, poor clinical end-outcomes, delays in discharge from acute units and repeat admissions all with clear quality and cost implications.
- In particular, the use of lower performance products may well lead to an increase in the number of dressing changes needed – with the financial cost of the additional dressing changes and the clinical cost of repeated interventions far outweighing any savings on the dressing cost.
- There has been no direct consideration of any patient factors or feedback whilst developing the generic specifications for the National Formulary. This is despite the fact that wound dressings interact directly with patients and strongly influence pain, comfort and quality of life. For example, different products can have different absorbency or sensitisation profiles for different patients, which are very challenging to allow for in a generic specification.
- There is also an apparent lack of consideration of clinical evidence or clinical outcomes data, which again could lead to increased length of treatment related costs with negative impact on quality and safety.
- The use of generic specifications will make innovation in wound management less attractive for organisations wishing to invest – because there would be no value attached to developing against a generic specification. The current high level of rationalisation in the industry may be further stimulated, something which similar situations in the past have unfortunately triggered.
- Any reduction in innovation will have a significant impact on R&D and technical functions within the UK, with the danger of a loss of technical expertise in wound care products (in much the same way that expertise in the more traditional textile-based wound care products has already been lost).
- It may well lead to both reduced competition and the formation of dominant suppliers in the medium term – thus ensuring that any short term savings would be rapidly swallowed up. The volume of products involved will greatly increase the likelihood of manufacture outside the UK, with obvious consequences for manufacturing jobs and capacity in the UK.
- This process will greatly reduce future product innovation and development by impeding the Accelerated Access to new treatments. This critical NHS England initiative has been prioritised as a key strategy until 2020. It has received further investment in the 2015 Spending Review.
- This process will also greatly reduce future product innovation and development by smaller companies, as the market for them will be considerably smaller, less attractive and more difficult to access. Hence, a reduction of SME involvement in the market will be inevitable, despite Government statements of support for SMEs. They will be disadvantaged because they will find it difficult to plan in the feast-or-famine environment the project will create.
- Industry will be unable to offer existing levels of training, sponsorship and support to healthcare professionals. Less skilled nurses are now treating wounds, thus making training and education more important – a need that the NHS is currently struggling to resource.
- It will lead to a reduction in skill levels, with a consequent negative effect on patient safety and an increased risk of litigation.

- This project could lead to a two-tier NHS, with hospital patients having lower quality and less effective products being used to manage their wounds, leading to greater burdens on primary care sectors.

A number of critical clinical stakeholder groups are not represented in the current project. These include Burn Surgeons via BBA, Podiatry via FDUK and the Plastic surgery teams via BAPRAS. The NHS Supply Chain project group also needs to benefit from consultation with significant users of wound dressings to ensure that any resulting policy is appropriate, fit for purpose and adopted.

It might be speculated that one reason wound care has been chosen as an early part of the National Formulary project is the lack of a strong patient or clinical lobbying group.

In a broader international context there is simply nothing of the size or monopoly dominance of the NHS anywhere else in the world – so whereas in other markets suppliers may lose in one region and compensate in another, this is not the case in England. It will be literally ‘all or nothing’ – with all that that implies.

As a monopoly buyer, the NHS has a responsibility to the taxpayer to try and ensure that markets remain competitive and sustainable in the long term. This is completely at odds with the stated intention of this project to reduce market access – especially against a market which is already functioning well.

There is a view that profit margins in the wound care industry are disproportionately high. However, no evidence is given for this belief. In comparison to other medical device markets, the level of competition in the wound care sector is extremely high, which operates to constrain margins and maximise cost effectiveness. The very high number of individual products are testament to the competitive nature of the market.

The effective pre-qualification of suppliers would become vital, as poor pre-qualification procedures could risk product shortages, regulatory non-compliance and actual products supplied being less fit-for-purpose than original marketing samples.

Alternative Solutions

We acknowledge that the NHS needs to be as efficient as possible and to use its resources as well as it can.

However, this project has been launched despite the many initiatives already in place which, if properly implemented, could generate similar savings without destroying market competitiveness – to say nothing of achieving broader efficiency gains. Good examples are the e-procurement and barcoding project, the NHS Supply Chain ‘Compare and Save’ initiative, and the accelerated access review (which has just started to bring innovation into the NHS). In particular, and with an estimated saving of £2bn, the e-procurement and barcoding project can deliver the type of significant savings the NHS needs. Properly implemented, these other initiatives could deliver the savings required by government – but without the forced restructuring of the wound care industry.

Several large formulary schemes are already in place, where products have been selected due to clinical effectiveness, patient acceptability, performance, and clinical evidence – and are producing cost-effective outcomes. Interestingly, the generic specification project does not seek to emulate these successful schemes. Localised procurement and formulary schemes like these could be

allowed to flourish – especially as localised initiatives can progress more quickly and will be more tailored to local needs.

Several recent product and service innovations have led to significant savings and improved patient benefit. Good examples are multi-layer bandaging and topical negative pressure (both of which can greatly speed up healing times), and accelerating the transition from acute to care in the community. These have been delivered by collaborations between NHS and industry. Such initiatives should be encouraged – not discouraged.

The development of products that help in the prevention or diagnosis of wound problems would have an immediate impact on costs. A particularly good example is the cost of treatment of grade 4 pressure ulcers at around £16k each. Any techniques preventing the all-too-many leg ulcers progressing this far would save significant costs⁶.

The single most influential factor relating to cost is that the right wound care product is used by properly trained healthcare professionals. This reduces healing times (and hence costs) and improves patient benefits. The generic specifications project seeks to greatly restrict the number of wound care products available – thus reducing the likelihood of the right product being available.

The 2014 EU Public Procurement Directive has placed an increased focus on quality criteria – putting a clear focus on total economic value. The NHS has examples of this, e.g. the North West Procurement Development joint research project with the University of Liverpool describes value-based procurement and considers total acquisition costs over a contract period.

Moving Forward

The SDMA would welcome an open dialogue with all the agencies involved to discuss this project and alternative methods of achieving short and long term cost saving goals – whilst at the same time ensuring patient benefit and safety is improved. SDMA members are significant stakeholders in this area and are keen to partner with all to ensure maximum value for money is delivered whilst maintaining a safe experience for the patient.

No two wounds are the same. There is a huge variety of wounds, with every patient reacting to them in an individual way. The wound management needs of each patient is greatly variable and can often be complex. A cost saving initiative that limits innovative and modern wound dressings is unlikely to be cost-effective and will not support best quality of life for patients. Achievable savings are insignificant and are likely to be swamped by higher consequential costs (especially nursing costs), higher product usage and extended treatment times for hard-to-heal wounds.

Wound dressings are therapeutic and interact directly with the patient and their quality of life and should not be treated as simple commodities. Historically, projects of this type have been delivered in the pharmaceutical sector, and have often led to a lack of innovation and reduced access to clinically-advanced products. Furthermore, choosing products that are simply ‘good enough’ is contrary to the quality and clinical excellence initiatives within the NHS⁷.

There are many other cost savings initiatives in progress, some of which have only been running for a few months. These present the opportunity to generate similar savings, but in a way that does not

⁶ *Five Year Forward View*, NHS (2014) www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf

⁷ Wounds UK (2015)

greatly inhibit the benefits of competition. The NHS needs to look to itself to better share information and to act on such initiatives.

The SDMA fear that the Generic Specifications project is likely to fail in its long term objectives, with any short-lived headline savings leading to higher long-term costs and poorer patient outcomes. It is also likely to significantly damage the UK's position as one of the world's leading wound care centres of excellence.