

# A structured collaborative approach to appraise the clinical performance of a new product

## KEY WORDS

- ▶ Dressing performance
- ▶ Formulary additions
- ▶ In-practice appraisal

Effective wound management comprises the informed selection and application of products matched to the patient being treated, and to a clearly defined and achievable clinical objective shared by both the clinician and the patient. The authors detail an in-practice case series appraisal process used to examine the performance of ALLEVYN Life (Smith & Nephew Healthcare Ltd) in order to determine its suitability for a formulary listing.

In order to meet the costs of demographic and technological changes, healthcare providers will need to achieve unprecedented efficiency gains. The NHS has been set the goals of enhancing efficiency while improving care quality and outcomes (Department of Health, 2010). Consequently, the NHS is facing a future in which it will be striving not merely to maintain current outcomes using fewer resources, but to improve outcomes in the face of diminished resources. In the starkest of terms, the requirement is to deliver more with less. The challenge is how to achieve this goal.

The government acknowledges that in the absence of unlimited resources, the NHS will only be able to increase quality through implementing best practice and thereby increasing productivity (Department of Health, 2010).

In simple terms, effective wound management comprises the informed selection and application of products matched to the patient being treated, and to a clearly defined and achievable clinical objective shared by both the clinician and the patient. Thus the issue of efficiency in wound management should not be over-simplified into a solely product-based discussion. While products do impact upon overall treatment cost, their relative contribution is small compared to other costs such as clinician time and complications (such as admissions and surgical interventions).

What is vitally important is ensuring the process of selecting and using a dressing product is optimised. To achieve this, clinicians must have the necessary knowledge and skills to enable them to

identify a realistic and achievable clinical objective, agree this with the patient, select appropriate dressing products, review progression in line with treatment milestones and adjust the treatment plan as necessary. A key component of practice is, therefore, access to products that support clinicians in accomplishing wound management objectives as effectively and efficiently as possible.

This article details the appraisal process used to examine the in-practice performance of ALLEVYN Life (Smith & Nephew Healthcare Ltd) in order to determine its suitability for a formulary listing.

ALLEVYN Life has a number of unique features designed to improve the patient experience and in doing so increase the potential for enhanced practice efficiency. These features include a masking layer in conjunction with a specific indicator for dressing change, an ergonomic quadrilobe shape and high fluid handling.

The appraisal process was undertaken to determine the extent to which the features of ALLEVYN Life proved useful in clinical practice and if the anticipated intended clinician and patient benefits are actualised during in-practice use. The underpinning key objective was to ensure that the process of considering a product for listing was informed by robust in-practice clinical data, so that the potential value to be gained from adding a new product was clearly understood.

## METHOD

An in-practice case series appraisal was undertaken to determine usability, acceptability and clinical

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*“The four-week appraisal of the product involved community nursing staff across the Trust.”*

performance of ALLEVYN Life. Before using the product, all clinicians received education on the product from tissue viability staff, the local Smith & Nephew representative and clinical specialist so they could make an informed decision as to the appropriate use of ALLEVYN Life within the context of their clinical caseload.

The four-week appraisal of the product involved community nursing staff across the Trust who documented their experiences using the product. They used the dressing on wounds deemed suitable in their clinical opinion, in conjunction with local wound management guidelines and the product’s indications for use. The clinician discontinued use at any point if it was deemed clinically appropriate.

The appraisal took the form of a series of case reports in which the use of the product was carefully documented so it would be possible to place the clinicians’ opinions on the product within the context of their clinical practice. In order to ensure consistency of information gathering, a bespoke paper-based case report pro-forma was used. This ensured that specific information on the in-practice clinical performance of the dressing in relation to key criteria was gathered in each case.

The criteria upon which the clinicians were asked to document their experience of the product’s in-practice clinical performance were:

- ▶▶ Ease of dressing application
- ▶▶ Ability to conform to wound site
- ▶▶ Exudate management
- ▶▶ Patient comfort during wear
- ▶▶ Masking of exudate strikethrough
- ▶▶ Indicator for dressing change

- ▶▶ Ease of removal
- ▶▶ Overall dressing performance.

These parameters were carefully selected and acknowledge the importance of patient acceptability, dressing wear time and any pain at dressing change, as well as exudate management. Clinicians were also asked to indicate if they would recommend the product for use in their practice. No patient identifying information was collected. The anonymous data were entered into a database and analysed using Microsoft Excel.

**RESULTS**

A total of 109 case study pro-formas were completed by the community nursing staff and returned for analysis. These case reports documented the use and performance of ALLEVYN Life on 109 wounds.

**Wound characteristics**

Clinicians used ALLEVYN Life in a variety of clinical circumstances. The type of wound was recorded in 105 of the 109 case reports (*Figure 1*), the most common being pressure ulcers (27.6%, *n*=29) and traumatic wounds (which included skin tears), which comprised 22.9% (*n*=24).

Further data were collected on the location of the wounds treated (*n*=106). The analysis showed that ALLEVYN Life was used to treat wounds across 10 body locations (*Figure 2*). Most frequently it was used to treat wounds on the lower leg/shin (37.7%; *n*=40) followed by wounds on the buttock/sacrum/back (13.2%; *n*=14), arm/elbow/hand (9.4%; *n*=10), head/neck/shoulder (8.5%; *n*=9), and the abdomen, upper leg/knee and hip (all 6.6%; *n*=7).

**Product use**

Clinicians could access all the ALLEVYN Life dressing sizes available at the time (small 10.3 × 10.3cm; medium 12.9 × 12.9cm; large 15.4 × 15.4cm; and extra large 21 × 21cm) and were thus able to select whichever they deemed most clinically appropriate based on the specific needs of the individual patient and wound being treated. All sizes were used during the appraisal. Of these, the most frequently used was 12.9 × 12.9 cm (*Figure 3*).

**Dressing in-practice performance**

Clinicians were asked to document their experience

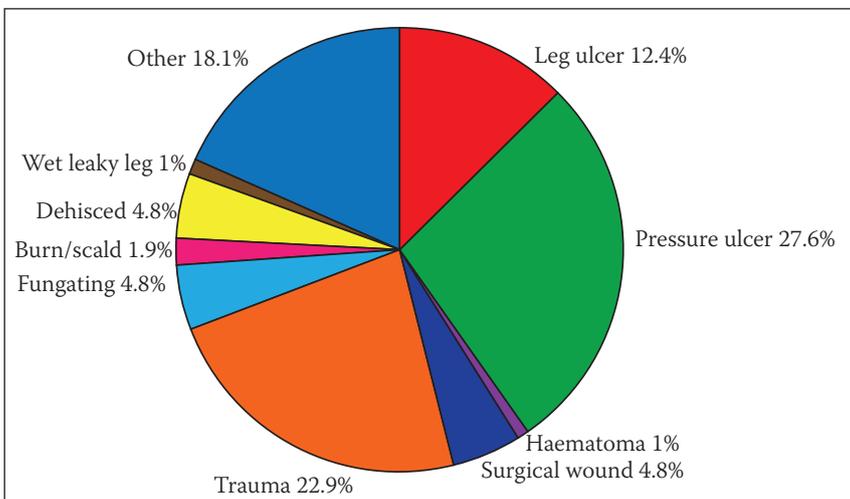


Figure 1. Types of wounds treated.

of the in-practice performance of ALLEVYN Life, rated against eight specified criteria as 'poor', 'fair', 'good', 'very good' or 'excellent'. The number of responses recorded was very consistent across all eight parameters, ranging from  $n=103$  to  $n=105$ . The rating for each of the criteria was summarised across all cases (Figure 4). For each of the performance parameters, the ratings of good to excellent predominated, constituting more than 90% of responses in each case.

Following their use of the appraisal product, the clinicians indicated whether in their clinical opinion there had been a change in three key wound characteristics — malodour ( $n=90$ ; 83% response rate), exudate level ( $n=99$ ; 91% response rate), and wound size ( $n=103$ ; 94% response rate). The majority of clinicians indicated that these decreased during the course of the appraisal period (Figure 5). Across all three characteristics there had been either a decrease or no change in over 90% of cases.

On discontinuing ALLEVYN Life, the clinicians were asked if they would recommend the dressing for use in their practice, with responses supplied in 103 cases (94.5% response rate). The majority responded 'yes' (98.1%;  $n=101$ ), with only two clinicians responding that they would not recommend the product (1.9%;  $n=2$ ).

**Dressing wear time**

During the appraisal period, the mean duration of ALLEVYN Life usage was 20.9 days ( $n=46$ ). As part of the appraisal, clinicians were asked to report on the wear time typically achieved during their use of ALLEVYN Life. They were also asked to specify what dressing they had been using previously and the typical wear time they had been achieving. In 80.7% of cases ( $n=88$ ), clinicians reported the type of dressing they had been using previously. In most cases, the dressing was foam (86.3%;  $n=76$ ), followed by hydrocolloids and superabsorbers (each comprising 4.6%;  $n=4$ ). The remaining dressings were non-woven (2.3%;  $n=2$ ), alginate (1.1%;  $n=1$ ) and other (1.1%;  $n=1$ ).

In 99.1% of cases ( $n=108$ ), the wear time typically being achieved prior to the application of ALLEVYN Life was detailed. On the basis of these responses, the calculated mean wear time achieved pre-ALLEVYN Life was 3.4 days ( $n=108$ ). With foam dressings, clinicians supplied a typical

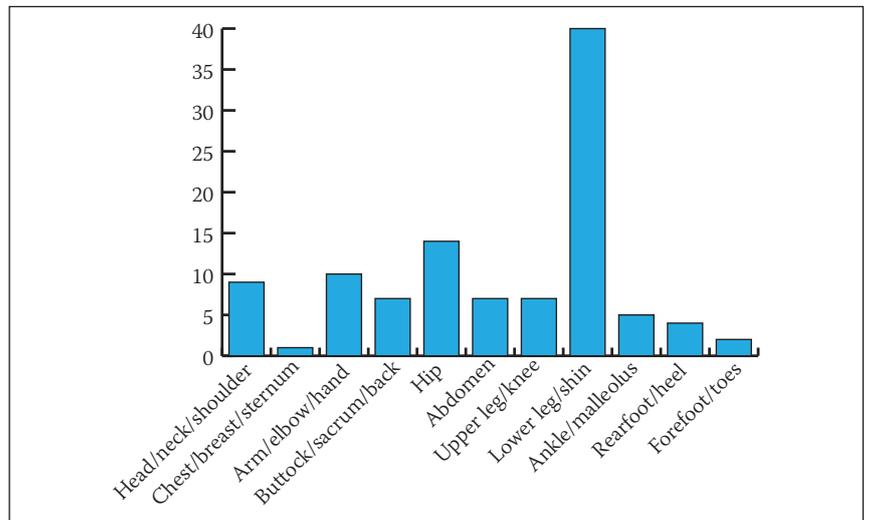


Figure 2. Location of wounds treated by ALLEVYN Life dressing.

wear time for all 76 cases, and the mean wear time calculated from this data was 3.4 days ( $n=76$ ). The wear time achieved typically during their use of ALLEVYN Life was supplied in 97 of the 109 cases (90% response rate). On the basis of these data, the mean wear time typically achieved during the appraisal of ALLEVYN Life was calculated at 5.2 days ( $n=97$ ).

In 97 cases, the wear time achieved with the use of ALLEVYN Life and that of the dressing previously employed was recorded and, therefore, the increase in wear time could be directly calculated (Figure 6). The mean increase in wear time achieved with the use of ALLEVYN Life compared with the dressing previously employed

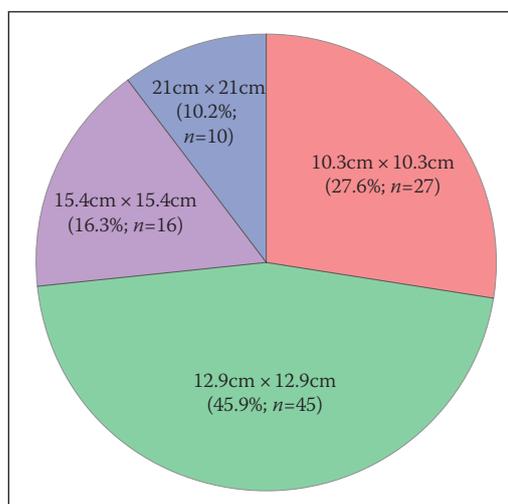


Figure 3. Range of dressing sizes used in the appraisal.

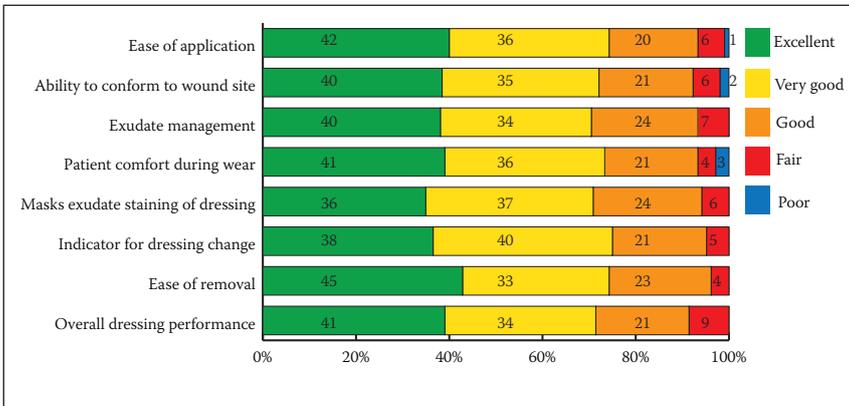


Figure 4. Dressing performance ratings.

was 1.7 days (from 3.5 to 5.2 days), a mean percentage increase of 48.7% over 97 cases. A further analysis was performed to examine the change in wear time when clinicians switched from a foam dressing to ALLEVYN Life. There were 70 cases where foams had previously been used, and both wear times had been recorded (Figure 6). The mean increase in wear time was 1.8 days (from 3.4 to 5.2 days). The mean percentage increase in wear time over these 70 cases was 52.9%.

**DISCUSSION**

With any new product it is important that frontline staff be involved and engaged in the appraisal process, since it will be these staff who will use the product on a day-to-day basis should it be listed on the formulary. It is also essential that the appraisal process includes the in-practice use of the products in a manner that accurately reflects the reality of how they will be employed within clinical practice.

As far as possible, the appraisal process was

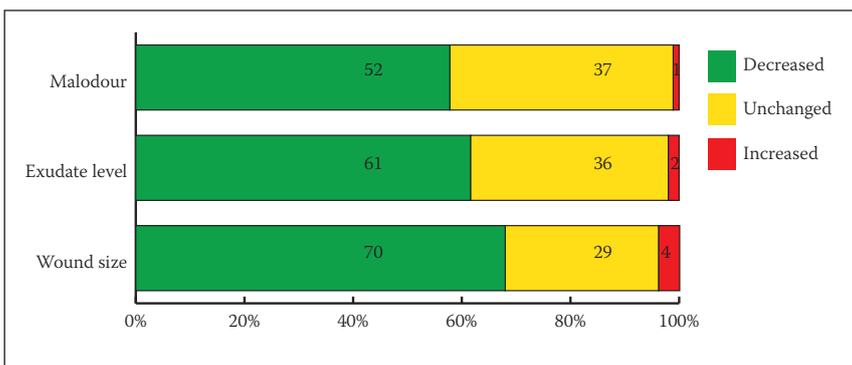


Figure 5. Changes in wound characteristics when dressed with ALLEVYN Life.

conducted with these aims firmly in mind. The objective was to generate credible data on which a decision about ongoing use of product could be made with complete confidence.

The results of the appraisal process suggest that ALLEVYN Life performed extremely well during in-practice use, proving highly acceptable to clinicians across the range of clinical performance criteria examined (Figures 4 and 5). Critically, for a new product with which the staff had limited familiarity, ALLEVYN Life was rated as good ( $n=20$ ) very good ( $n=36$ ) or excellent ( $n=42$ ) in terms of ease of application in 93.3% of cases. Similarly, the criteria appraising the performance of ALLEVYN Life once *in situ* generated extremely positive responses with ratings of excellent, very good or good being the predominant response ratings for ability to conform to wound site (92.3%,  $n=96$ ), exudate management (93.3%;  $n=98$ ) and patient comfort during wear (93.3%;  $n=98$ ).

A key feature of the ALLEVYN Life dressing is a masking layer designed to conceal the strikethrough of exudate and provide a clear visual indicator for dressing change. The appraisal results indicate that the masking layer and indicator functioned well in clinical practice. In 36 cases (35%), clinicians rated the ability of the dressing to mask staining of exudate as excellent, while 94.2% ( $n=97$ ) of clinicians rated the dressing as good or better. The ability of the dressing to provide an indicator for dressing change was also rated highly, with 36.5% ( $n=38$ ) of responses rating the performance of ALLEVYN Life as excellent for this criterion and 95.2% ( $n=99$ ) providing a rating of good or better.

The overall performance of ALLEVYN Life reflected the performance rating given to the individual performance criteria, with 91.4% of responses rating overall performance as good or better. Such positive performances prompted the vast majority of clinicians (98.1%) to indicate they would recommend ALLEVYN Life for use in their practice.

**Enhancing practice efficiency**

ALLEVYN Life has a number of unique features designed to enhance dressing wear time and aid clinicians in achieving the optimal frequency of dressing change. The development of a masking

layer in conjunction with a specific indicator for dressing change, an ergonomic quadrilobe shape and enhanced fluid handling capacity are all intended to facilitate optimisation of dressing change frequency. The appraisal data indicate that clinicians were able to achieve an extended wear time with ALLEVYN Life compared with that achieved previously (Figure 6).

Reducing dressing change frequency represents a key opportunity to enhance practice efficiency in wound management. If dressing change frequency can be reduced in a proportion of a wound management caseload, the opportunity exists to reduce clinician time associated with the management of those wounds. The clinician time released as a result could then be reallocated to other tasks including the enhanced management of other patients' wounds.

The most logical targets for any approach seeking to reduce the frequency of dressing changes are those wounds that are currently most resource intensive, i.e. wounds with a high frequency of dressing changes. A review of the appraisal case series data revealed that in 25.7% of cases ( $n=28$ ), the dressing used prior to ALLEVYN Life was being changed three or more times per week. In 71.4% ( $n=20$ ) of these cases, a foam dressing was used before ALLEVYN Life.

An analysis determined the change in wear time achieved when these frequently changed wounds were switched to ALLEVYN Life. In cases where the frequency of dressing change prior to ALLEVYN Life was three or more times per week across all dressing types ( $n=28$ ), the mean increase in dressing wear time achieved following a switch to ALLEVYN Life was 2.6 days (Figure 7). In cases where a foam dressing was used and was being changed three or more times per week, the mean increase in wear time with ALLEVYN Life was calculated to be 2.6 days (Figure 7).

A further analysis was performed using the wear time data to determine the case-by-case difference in dressing change frequency in the high change group (changed three or more times per week) after a switch to ALLEVYN Life. The mean difference in dressing change frequency with a switch to ALLEVYN Life was 2 days; from a mean of 4.7 changes per week initially to a mean of 2.7 changes per week with ALLEVYN Life ( $n=28$ ).

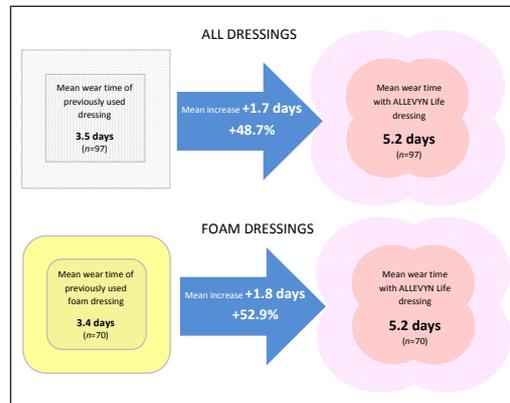


Figure 6. Change in dressing wear time following a switch to ALLEVYN Life.

This analysis suggests that across this category of high change frequency wounds it was possible, on average, to free up two visits per week following a switch to ALLEVYN Life.

### Releasing time to care

The primary care organisation in which this appraisal was undertaken covers a population of 161,100 people (NHS Knowsley Clinical Commissioning Group, 2013).

A large UK-based audit calculated the prevalence of wounds as 3.73 per 1,000 people, of which 74% are treated in the community (Drew et al, 2007). Extrapolated to the area covered by this provider this suggests that there are likely to be 601 patients with a wound at any point in time, of which 445 will be treated in the community. The appraisal data indicate that approximately a quarter of wounds were dressed three or more times per week, which would equate to 111 wounds. If a reduction in visit frequency of two visits per week (as was achieved in the appraisal) could be realised in 75% of this group (83 wounds) this would release 166 visits per week. Assuming the duration of each visit is 31 minutes including travel time (O’Keeffe, 2006), this would release over 85 hours of nursing time per week. Over the course of a year, this would free up approximately 8,632 visits (around 4,460 hours).

The financial value of this released time was calculated using published reference costs of nursing time of £70 per hour (Curtis, 2013). On this basis, in order to match the release of nursing resources associated with a reduction of

166 visits per week, an investment of £6,003 per week would be required. If the annual figure of 8,632 visits were to be matched, an investment of £312,190 would be necessary.

**A sizeable opportunity**

The huge potential for efficiency savings is apparent when this analysis is repeated for the UK population of 64.1 million (Office for National Statistics, 2013).

Applying the same estimates from the local analysis to the UK gives an estimate of approximately 235,363 wounds being managed by community providers. If, as in this appraisal, a quarter of wounds have a change frequency of three or more times per week, this would amount to 43,542 wounds. Making a conservative assumption that a reduction in visit frequency of two visits per week could be realised in half of this group (21,771), this would release 43,542 visits per week, equating to 22,497 hours of nursing time per week. Annually, this would release approximately 2,264,184 visits amounting to 1,169,828 hours of nursing time.

Using the reference cost for nursing time of £70 per hour, the investment that would be needed to buy-in nursing resource equivalent to that which could be released would amount to an investment of £1,574,769 per week — approximately £81.9 million per annum. Even with conservative

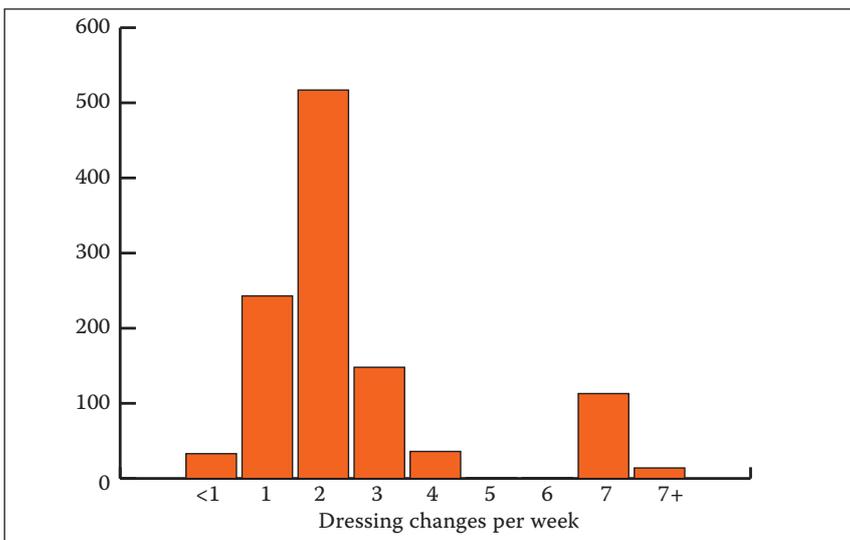


Figure 8. Community wound management practice survey – dressing change frequency data (n=1,106).

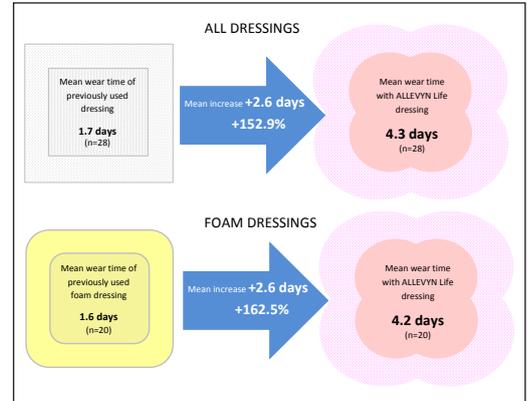


Figure 7. Change in dressing wear time after a switch to ALLEVYN Life in cases when the previous dressing was being changed three or more times per week.

assumptions, this analysis illustrates that there are significant efficiency gains to be made that could lead to considerable benefits to patient care.

**A realistic target**

A question that arises following this analysis is how representative the appraisal population is of the wider community wound management caseload. The analysis is based on the assumption that around a quarter of wounds are dressed three or more times per week and, therefore, there is a real opportunity to reduce change frequency among this sizeable group; but how does that compare with other providers?

As part of an ongoing approach to support practice development through appropriate use of wound management products, Smith & Nephew has engaged in a number of collaborative community wound management surveys across the UK. During 2013, eight surveys were completed in areas across the UK. Data from these were collated to generate a summary encompassing a total of 1,174 wounds. Dressing change frequency data were supplied in 1,106 cases (94.2%). The responses are illustrated in Figure 8 (Bielby, data on file). The results indicate that in 28.3% of cases (313/1,106) the dressing was changed three or more times per week, indicating that the issue of high change frequency is not unique to the appraisal population.

Further data from Ousey et al (2013) yield an even higher figure. In a survey of 4,182 wounds, with 29.8% were dressed three or more times per week. A repeat of the earlier resource-releasing

analysis using this figure of 29.8% would indicate that some 51,873 wounds are dressed three or more times per week across the UK. Making the same conservative assumption that a reduction in visit frequency of two visits per week could be realised in just half of this group (25,936 wounds), this would release 51,872 visits per week or 2,697,344 visits per annum. With a 31-minute visit duration, this would amount to 26,801 nursing hours saved per week and 1,393,628 hours per annum. Based on a cost of £70 per hour of nursing time, the value of the time released would be the equivalent to a weekly investment of £1,876,037, equating to an annual investment of approximately £97.5 million.

These data illustrate there is clearly a sizeable opportunity to enhance efficiency by reducing dressing change frequency.

The Smith & Nephew surveys also documented the reason for dressing change, with clinicians choosing a single response from 11 options. The reason for dressing change was supplied in 1,066 cases (90.84%) and responses are shown in Figure 9.

These responses show that in the vast majority of cases, dressing changes are routine. This further emphasises the opportunity that exists to enhance practice efficiency through training, education and the appropriate use of advanced products such as ALLEVYN Life, which include design features such as an exudate-masking layer and an indicator for dressing change, which are engineered to support both the patient and the clinician in extending dressing wear time and thereby optimising dressing change frequency.

**CONCLUSION**

In conducting a structured and thorough appraisal in which key aspects of product performance in-practice were explored, the process has clarified the possible clinical impacts that adoption of the appraisal product could have. In this case, the attributes of the product were well received by the clinicians using it who found it easy to use and rated the product's performance highly. In addition, ALLEVYN Life was seen to have a particularly positive in-practice impact on dressing wear time. This has the potential to yield considerable benefits in practice efficiency, freeing up the most important resource in wound management — clinician time.

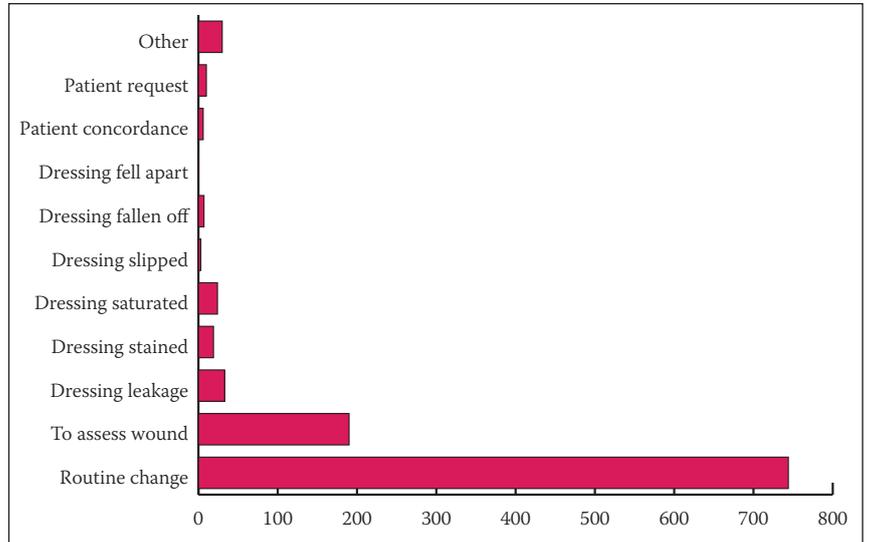


Figure 9. Community wound management practice survey — reason for dressing change data (n=1,066).

**Declaration of interest**

Alistair Bielby is a contractor for Smith & Nephew. This project was supported by an unrestricted grant from Smith & Nephew.

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