Developing a negative pressure wound therapy service

THE IMPORTANCE OF AUDIT

THE ROLE OF QUALITY IMPROVEMENT

HOW TO MAKE THE CASE FOR A MANAGED SERVICE

INTRODUCING A NPWT SERVICE IN DIFFERENT HEALTHCARE SYSTEMS
Developing a negative pressure wound therapy service

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The successful transition of innovative wound care products from concept to widespread clinical use is not only reliant upon their demonstrated clinical effectiveness proven by randomised clinical trials, but also on the product’s cost-effectiveness.

Although cost-effectiveness is often inferred from clinical trial results, this does not always equate to true service costs where products are used across the healthcare system. Without careful management, and outside of the constraints of a clinical trial, products may be used less effectively and equipment downtime may be greater than anticipated. Controlling these variables is the key to the successful introduction of new therapies to the wider healthcare community.

This series of articles looks at the development of a negative pressure wound therapy (NPWT) service, guiding both managers and practitioners through the process of establishing a business case and then introducing and managing a service across both community and hospital-based environments. The model described could apply equally well to the introduction of any advanced wound therapy.

A number of synonyms are used to describe NPWT including topical negative pressure and vacuum therapy; the majority of the published research is, however, on the V.A.C.® Therapy (KCI Inc.) system. It is not known if alternative systems deliver equivalent results in terms of clinical or cost-effectiveness and the adoption of each system will therefore require separate modelling and business case development.

Trueman, in the opening paper, outlines the economic data supporting the introduction of NPWT and shows how audit can be used to identify current practice, establish need, and evaluate effectiveness following introduction.

Vig, in the second paper, looks at drivers for change and in particular the quality agenda and patient demand for new technology and improved outcomes, suggesting the use of the SIMPLE concept and audit to justify usage.

Williams, in the third paper, outlines the strategic framework needed to develop a business case supporting the implementation of a managed service for NPWT, identifying stakeholders and the process of providing such a service. Long-term issues such as product maintenance, product evolution and redundancy and educational support need to be factored into such a programme and specific documentation, product ordering and tracking mechanisms established if such a service is to function across care divides. Certainly our experience establishing and monitoring such a service has allowed the controlled introduction of NPWT based on the V.A.C.® Therapy system across the local healthcare district with a planned discharge process and an established budgetary system straddling health providers.

The final two papers by Willy and Bassetto et al, and the brief accounts by Bruhin and McGinnis (pp13-14), look at how NPWT has been introduced in different national healthcare systems, providing valuable insight into the different challenges facing healthcare professionals in Europe. Appropriate use of resources is an important consideration in the current economic climate and decisions about availability will often be based on the published scientific evidence. However, where this is lacking, patients should not be prevented from receiving therapy where it is deemed the best available treatment based on experience and clinical knowledge. Evidence of its clinical efficacy and cost-effectiveness using a robust system of audit is obviously the best way forward. Service development should be supported by formal training to ensure all clinicians are practised in equipment use and NPWT is used responsibly and effectively to improve clinical outcomes. By using NPWT in a more discriminating manner, it will improve the way it is delivered across acute and community settings and allow it to become an essential part of an integrated clinical care pathway.

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The importance of audit in justifying the cost-effectiveness of NPWT

P Trueman

There is a growing body of evidence to support the clinical use of NPWT in the management of chronic wounds and some surgical wounds. The most robust studies are in chronic wounds, such as diabetic foot ulcers and venous leg ulcers. However, studies have also shown NPWT to be effective in managing more complex wounds, including non-healing surgical wounds and trauma wounds, although the quality of the evidence in these indications is often less robust due to the difficulties of adopting randomised controlled study designs in these wound types.

ECONOMIC EVALUATION OF NPWT

In addition to the data on clinical effectiveness, there is a growing body of evidence that supports the economic use of NPWT. Economic evaluations in the management of diabetic foot ulcers, surgical and traumatic wounds and burns have shown NPWT to be a cost-effective intervention when compared to standard practice. In some cases, the findings have suggested that NPWT may show superior clinical effectiveness and result in lower overall treatment costs, when the totality of treatment costs, including hospitalisations and complications such as amputations and infections, are taken into account. The quality of some of the economic evaluations published to date has been limited by the availability of high quality data on current treatment patterns and a lack of agreement on what constitutes current practice. In most cases, the authors of the studies have sought to acknowledge these limitations by reporting their findings in a transparent manner. Without a clear understanding of what constitutes current practice in a locality, the types of wounds treated and the outcomes of current practice, decision makers are unlikely to be able to determine whether NPWT can offer any incremental improvements in clinical and economic outcomes.

As the evidence on the clinical and cost-effectiveness of NPWT improves, inevitably there are increased demands from healthcare professionals and patients for access to this advanced wound care technology, together with an increasing consensus on its clinical positioning. For healthcare commissioners and planners this creates some challenges. The acquisition costs of NPWT devices appear to be relatively high compared to traditional wound management modalities. Furthermore, while the evidence from published studies appears to make a convincing case for NPWT in the management of chronic wounds, the relevance of this evidence to local services needs to be considered. The findings generated within randomised controlled trials are unlikely to be reproducible in clinical practice and the heterogeneity of patients with chronic wounds and approaches to service delivery mean that additional local evaluations may be necessary to support widespread adoption.

UNDERSTANDING CURRENT PRACTICE THROUGH CLINICAL AUDIT

One of the limitations of published economic evaluations of NPWT is the availability of evidence on current practice relating to the management of chronic wounds. While clinicians in individual centres may have a good understanding of the effectiveness of their practice, quantitative evidence on patient characteristics, treatment modalities and outcomes are frequently absent or poorly documented due to the difficulties involved in data capture and management in wound care. As a result, business cases are often developed on the basis of expert knowledge and/or opinion on many parameters, which will be central to determining whether new treatments are an effective use of...
types against which novel treatments can be compared. Management practices in the region and gave detailed information on particular wound infected wounds. Across all acute wound types (with the sole exception of primary closures) antimicrobial were swabbed 4.5% were found to be MRSA positive. Wounds were not swabbed and 97 non-infected wounds were swabbed. Where wounds over 5 years however 10 people had wounds over 25cm2 in area while 3 wounds had been present for longer duration, only 3 had undergone Doppler assessment and only 2 received compression bandaging. Typically these wounds were of recent origin and small in size; however, 10 people had wounds over 25cm2 in area while 3 wounds had been present for over 5 years. 101 (12.2%) of the wounds were considered to be infected; 37.6% of all infected acute wounds were not swabbed and 97 non-infected wounds were swabbed. Where wounds were swabbed 4.5% were found to be MRSA positive. Across all acute wound types (with the sole exception of primary closures) antimicrobial wound dressings were the most prevalent form of dressing and covered 56 (55.4%) of all infected wounds. The authors concluded that this work provided a better understanding of current wound management practices in the region and gave detailed information on particular wound types against which novel treatments can be compared.

**BOX 1** Audit used to better understand wound types and treatments in one health authority (Adapted from the abstract on acute wounds by Vowden and Vowden, 2009)

A survey was undertaken in 2007 across all care providers serving Bradford, UK, to provide robust evidence on the types of wounds currently being managed in the region, as well as evidence on how these were being managed and the outcomes of treatment. 1735 completed questionnaires were returned, each marking the most severe wound experienced by a patient, which were subsequently divided into chronic and acute wounds for analysis. A total of 826 acute wounds were identified, of which 303 were traumatic wounds and 237 primary closures with smaller numbers of other acute wound types. In a subgroup of 96 lower limb traumatic wounds, 25 patients had wounds of 6 weeks or longer duration, only 3 had undergone Doppler assessment and only 2 received compression bandaging. Typically these wounds were of recent origin and small in size; however, 10 people had wounds over 25cm2 in area while 3 wounds had been present for over 5 years. 101 (12.2%) of the wounds were considered to be infected; 37.6% of all infected acute wounds were not swabbed and 97 non-infected wounds were swabbed. Where wounds were swabbed 4.5% were found to be MRSA positive. Across all acute wound types (with the sole exception of primary closures) antimicrobial wound dressings were the most prevalent form of dressing and covered 56 (55.4%) of all infected wounds. The authors concluded that this work provided a better understanding of current wound management practices in the region and gave detailed information on particular wound types against which novel treatments can be compared.

**BOX 2** Designing an audit

- Select a topic, agree why it is worth doing and define aims and objectives, eg:
  - Improve wound healing rates
  - Reduce the prevalence of chronic wounds within the community
  - Reduce the cost of wound care dressings within the healthcare community

- Decide who to involve and when to conduct the audit

- Define criteria (ie the aspects of care that need to be measured) and set standards

- Assess local practice
  - Decide which patients and care setting should be included/excluded
  - Decide what types of wounds to include (chronic and/or acute)
  - Decide what data should be collected, how much and how this is collected

Local resources. For example, evidence may be missing on key parameters, including the number of chronic wounds treated in a region over a given period of time, admission rates to hospital, length of stay, specifics of the wound management treatments used, and most importantly, the outcomes associated with treatment. Establishing high-quality evidence on the effect of current practice on these parameters is vital if we are to determine whether novel wound management modalities, such as NPWT, can provide any incremental benefit over current treatment. Clinical audit is an essential tool in this process. Best practice guidelines for conducting clinical audits have been made available by numerous bodies with an interest in evidence-based medicine, including the National Institute for Health and Clinical Excellence in the UK. There is increasing recognition of the value of audit to better understand the nature of wound care and the need to collate information on health status in order to evaluate innovative wound management practice. The study by Vowden and Vowden (summarised in Box 1) provides a detailed picture of treatment in a locality and offers valuable insights into how patients with acute and chronic wounds are currently managed. This example highlights how to capture detailed information. The key reasons for undertaking this audit were as follows:

- To understand the current burden of wounds in a healthcare setting
- To understand what resources are being consumed in managing wounds
- To understand the types of wounds being treated
- To provide a baseline for quality improvement initiatives

Audits of this type may be conducted prospectively or retrospectively. Adopting a retrospective approach, however, demands detailed and accurate patient records and as such may be more applicable to insurance-based health systems, where detailed patient records are available. Issues for consideration when designing an audit include which patients and care settings should be included and the most appropriate time to conduct the audit (Box 2). Attempts should also be made to ensure that the audits are designed to be naturalistic, providing a fair reflection of current practice. This means avoiding weekends or holiday periods that may reflect atypical patterns. In addition, consideration should be given to how the audit is to be used, eg as a comparative audit between sites, to monitor change before and after the introduction of new treatment practices, or to examine improvement over time.

**DETERMINING THE EFFECTIVENESS OF NOVEL THERAPIES**

Establishing the nature of current treatment provides a baseline against which novel therapies can be compared to determine whether the benefits presented in a business case are realised in practice. By conducting audits prior to and subsequent to the implementation of a new therapy, individual centres can generate a crude ‘before-and-after’ evaluation. This type of study lends itself to interventions where randomised controlled trials may be difficult to conduct. This could be for any number of reasons, including difficulties in recruiting patients to a study, the ethics of randomisation or simply practical problems involved in conducting a trial, including the cost and time involved.

Observational studies, such as before and after analyses using audits, inevitably generate weaker evidence than randomised controlled trials. Such studies are unable to control for the
heterogeneity of patients and/or wound types as would be the case in a randomised controlled trial, although there may be scope for using statistical methods to account for this. However, these studies do provide a valuable insight into whether new technologies might lead to changes in treatment outcomes in local practice settings, rather than in controlled trial settings, which are often artificially designed to exclude patients with complex needs and may provide a higher level of monitoring than usual care.

Some caution needs to be taken when designing such studies. The timing of the study is important; undertaking an audit of the impact of a new technology or treatment soon after its introduction may result in an underestimation of its performance. This may be because it has yet to be fully accommodated into treatment pathways and its positioning may not be fully understood by healthcare professionals. This is particularly the case for ‘disruptive’ technologies (ie innovative approaches that break from traditional solutions) such as NPWT, which may demand changes in treatment practices or pathways and take time to embed into local practice. However, undertaking an evaluation after a significant period of use may result in difficulties in removing a treatment that is perceived to be established and effective.

Wound management practitioners are encouraged to adopt evaluative approaches to the uptake of new treatments to ensure that scarce healthcare resources are allocated to efficient treatments and that patients receive beneficial treatments.

A number of studies in the field of wound care have used audits to establish the effectiveness of interventions. The example in Box 3 summarises a retrospective audit based on patient notes to determine the prevalence of pressure ulcers and impact of NPWT on hospitalisations and emergency care needs. The availability of detailed patient records means that it was possible to undertake a comparative, retrospective audit of effectiveness. The authors acknowledge that the number of patients receiving NPWT is small and further research is necessary. However, this retrospective research does provide some degree of reassurance to local commissioners about the benefits of NPWT and can be generated with relatively few resources, when compared to the alternative, which might involve conducting further randomised controlled studies.

**BOX 3 Impact of NPWT on pressure ulcer care (Adapted from Schwien et al, 2005)**

A retrospective study was conducted in the US to determine the prevalence of Stage III and Stage IV pressure ulcers in the home health population and to quantify the impact of NPWT in reducing acute care hospitalisations and emergent care in general, and wound infection or deteriorating wound status in particular.

Data from 1.94 million wound care assessments in 2003 and 2004 were evaluated to estimate pressure ulcer prevalence and a retrospective matched group analysis compared patients using (n=60) and not using (n=2,288) NPWT.

In 2003, 6.9% and in 2004, 7% of patients had pressure ulcers at the start of care. Of these, 23% were Stage III or Stage IV and 31% were ‘not healing’.

In the matched analysis group, it was found that those receiving NPWT experienced lower rates of hospitalisation (35% versus 48%, p<0.05), hospitalisation due to wound problems (5% versus 14%, p<0.01), and emergent care for wound problems (0% versus 8%, p<0.01).

**IDENTIFYING THE ECONOMIC IMPACT OF NEW THERAPIES**

Audit can provide a foundation for assessing whether a new treatment offers clinical improvements over existing treatments. This evidence can also be used to determine the economic impact of new therapies, by applying unit costs to resources used in treatment to determine the relative costs of different treatment pathways.

The first stage in assessing the economic impact of treatment is to understand the resources consumed. Resources might typically include staff time involved in consultations, hospitalisations, procedures and supplies, including dressings. Once these have been established, unit costs can be applied to the resource use estimates. Common sources of unit costs include national payment schedules (eg the Payment by Results national tariff in the UK), insurance claims databases and previously published academic studies.

For the purposes of wound care, the financial impact of a new treatment might be positive if it can:

- increase the likelihood of a wound healing (and not requiring further treatment)
- improve the time to healing
- reduce complications that might be associated with wounds, such as infections and amputations
- simplify the treatment pathway, for example, by reducing the number of dressing changes or hospitalisations.

If a new treatment can be shown to improve outcomes and reduce overall treatment costs per patient, then there is a strong case for considering more widespread adoption. If a new treatment improves outcomes but marginally increases costs per patient, then this too may be justified, although more formal economic evaluation techniques, such as cost-effectiveness or cost utility analyses (Box 4) may need to be applied to ascertain whether the improvements in outcomes warrant the additional expenditure.

**AFFORDABILITY VERSUS COST-EFFECTIVENESS**

There may be some cases where a new treatment is both clinically and cost-effective but is unaffordable. Affordability is distinct from cost-effectiveness. A new treatment may offer economic benefits over an existing treatment but
BOX 4 Two methods for assessing cost in relation to outcomes of treatment

Cost-effectiveness analysis – outcomes are measured in clinical terms, such as time to heal a wound.

Cost utility analysis – outcomes are measured by the value placed by patients on alternative health states, such as living with a chronic wound.

may be unaffordable within current budgets. Most often this arises due to difficulties in ‘moving’ money between budgets; for example, savings that result from reductions in hospitalisations or adverse events cannot be readily transferred to dressing budgets. In these cases, there may be a need to prioritise who can benefit the most from a treatment, acknowledging that it may be unaffordable to provide new treatments to all patients who could benefit.

In extrapolating audit data to explore the economic impact of new technologies, attention should be paid to identifying financial impacts that may lead to realisable cash savings (eg reductions in co-medications or hospitalisations) as well as those that may lead to opportunity cost savings but no cash savings (eg marginal reductions in nurse visits). While opportunity cost savings may lead to improvements in efficiency they should not be presented as cash savings that can be offset against the acquisition cost of a new technology.

There is an increasing demand for business cases to support the adoption of new wound care technologies\(^5\). Box 5 provides an example of the use of audit to support the implementation of NPWT in a UK hospital.

CONCLUSION

Demands for improved evidence on the clinical and cost-effectiveness of new technologies are to be welcomed, as ultimately this should lead to more efficient use of scarce healthcare resources allocated to wound care. However, very often business cases are built on assumptions and hypotheses that remain untested. Audit of current practice and the impact of new technologies is an effective means of testing the value proposition presented in a business case and should be more widely adopted among wound care specialists.

Audit and evaluation activities should be seen as integral to the business case for adoption of a novel technology. Without them there is a danger that the business case is accepted without any form of validation to determine whether the benefits presented can actually be realised. Manufacturers of new technologies should be encouraged to be actively engaged in supporting audits by providing audit templates and supporting resources, including staff time where appropriate.

REFERENCES

Developing a business case for NPWT as a value-added service

S Vig

This paper draws on the introduction of quality improvement in the UK to demonstrate how this framework can be used to build a successful business case for negative pressure wound therapy (NPWT). Economic constraints on healthcare spending require clinicians to deliver high-quality services with more effective targeting of resources and better outcomes for patients.

Within the National Health Service (NHS) in the UK there is a drive towards Quality, Innovation and Productivity (QUIP) with the intention of delivering higher standards of service. The anticipated benefits will be dependent on the following:

- efficient use of resources
- effective partnerships
- best practice

The NHS has to respond to the six challenges faced by all modern healthcare systems: ever higher patient expectations; an ageing society; the dawn of the information age; the changing nature of disease; advances in treatments; and a changing workforce. Globally, clinicians have a vital role in driving clinically effective and efficient treatment that recognises the value of clear patient pathways and integrated care. The challenge in the current financial climate is to ensure that clinicians and managers develop robust business plans that encourage both innovation and appropriate early adoption of new technology.

EFFICIENT USE OF RESOURCES

Evidence suggests that faster healing rates in both chronic and acute wounds can be achieved using advanced wound care products. This may lead to a reduction in nursing time with less frequent dressing changes, shorter hospital stays and in fewer wounds failing to heal or developing wound-related complications.

The global market for advanced wound management was valued at US$3.6 billion in 2008 and is forecasted to reach US$5 billion by 2015. This market is dominated by the US (valued at more than US$1 billion in 2008), with a market share of 45%, which is expected to rise to 48% by 2015. Emerging markets include countries such as South Africa where the advanced wound care market was US$48 million in 2008 and is estimated to reach US$117.1 million in 2015.

The major drivers for the rise in healthcare spending will be an increase in the incidence of chronic wounds, including venous leg ulcers, diabetic foot ulcers and pressure ulcers, exacerbated by an ageing population. Raised awareness of new treatments such as NPWT will add to patient expectations and demand for services.

Increases in revenue or increased spend by the healthcare sector need to be set against the current challenging financial climate and, in particular, the reduction in the gross domestic product (GDP) in the UK. For the NHS, the Treasury has stated that 'each primary care trust will have a 5.5% increase in allocations, but that this will be the last year of growth'. However, standing still will not be an option. By 2013–14 approximately £15–20 billion will need to be generated from existing resources to keep pace with the demands of the system. In 2010–11, radical and innovative approaches will be needed to deliver the priorities set out in the operating framework for the NHS and these will need to be clinically driven.

It is therefore increasingly important that any business case is based on an audit of current practice and that this provides evidence for cost-effectiveness and efficiency. For wound care, the benefits may be delivered over a longer time period and only within a clinically driven patient care pathway. Against the backdrop of increasing economic demands and the drive to do more with the same level of expenditure, there are many opportunities for clinicians to take the initiative and prove when and how NPWT can provide cost-effective wound care.
Clinical responsibility
It is a clinical responsibility to ensure that NPWT is used responsibly and effectively to improve clinical outcomes. It should only be authorised for appropriate patients, rather than using it for all wounds irrespective of outcomes. This approach would not only bankrupt any healthcare system, but also would not benefit patients. Healthcare commissioners, who are responsible for funding healthcare provision in the UK, are now discussing payment for integrated care within a structured framework. High standards of governance are expected with clear pathways of clinical responsibility and treatment goals. This is fundamental in wound care as the clinical pathways are only effective when a multidisciplinary approach is adopted.

DEVELOPING AN EFFECTIVE PATHWAY FOR NPWT
Efforts have been made to provide robust international consensus guidelines to identify appropriate wound-specific criteria for NPWT. For example, the World Union of Wound Healing Societies’ consensus document provides guidance for clinicians wishing to develop integrated care pathways for NPWT. However, further work needs to specify the expected length of time of application and to describe how to develop treatment goals for individual patients.

Introducing the SIMPLE concept
When deciding whether to implement any advanced wound care technology, a SIMPLE concept can be used to ascertain its efficacy in individual patients. This is an acronym designed to facilitate sensible decision making and may involve asking a number of questions to assess whether the intervention is Safe and sensible, is Indicated, achieves a Measurable difference, offers a Patient advantage, as well as the Length of time to review required and the desired treatment Endpoint (Box 1, p8).

Effective partnerships
Any business case that seeks to implement a ‘high-cost’ advanced wound care technology needs to consider carefully the opportunities for the overall community; cost savings should be explored across all healthcare settings rather than simply presenting the budget for the setting in which the business case is to be submitted. As Table 1 shows, multiple studies
have demonstrated that up to one half of all acute wounds may be treated within the hospital setting. This point stresses the need to look at opportunity cost savings across all healthcare settings.

Within a business case, integrated care pathways for NPWT should be agreed by all stakeholders or decision makers so that the right treatment is made available for the right patient at the right time, regardless of where the patient is within the healthcare system\(^\text{13}\). The stakeholder group should be diverse, including both providers and commissioners as well as patient groups, who are ultimately the focus of care. Identification of the key stakeholders is an important step as this also identifies the clinical champions, who will lead the wound care workforce (see Williams K, pp11-14).

Providers will be based in both the acute and home care settings, but increasingly also the private and commercial sector. NPWT and consumables are often funded within pharmaceutical budgets, which are set by advisors who demand high levels of evidence. It is therefore important to engage with this group of individuals when making a business case.

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**BOX 1 Using the SIMPLE concept as an aid to decision-making**

**Patient history**

84-year-old war veteran lives independently at home and has an excellent quality of life. He developed a surgical site infection, resulting in a superficial dehiscence of the laparotomy wound, measuring 10x20cm and extending down to the fascia.

**Options**

1. Manage conservatively with a hydrocolloid dressing; superficial dressing changed every 24 hours
2. Manage using NPWT; interface dressing changed every 72 hours

**S** Is the intervention Safe and sensible?

Both options are safe and sensible

**I** Is it Indicated in this patient?

Both options are indicated

**M** Will it achieve a Measurable difference compared to traditional interventions?

Both options allow wound healing and there are no randomised controlled studies that allow an evidence-based approach. Option 2 allows a safe and early discharge of a large complex wound, which is not possible with Option 1

**P** Is there a Patient advantage?

Patient wishes to maintain his independence. Option 1 does not allow the patient to go home. In addition, he is unable to tolerate the odour from the wound and the feeling that he is not in control. As the patient is slightly overweight, when he stands up, and if the dressing is soaked with exudate (especially towards the end of the day), he feels as if the dressing will fall off and it needs to be changed. This also limits the patient’s mobility. The patient feels more comfortable being managed with Option 2 and describes it as if ‘he is wearing a corset’

**L** What is the Length of time to review the wound?

The use of Option 2 is agreed with review of the wound every 48-72 hours

**E** What is the treatment Endpoint?

The endpoint will be the safe transition to a simple wound care dressing such as a hydrocolloid. This will be indicated when the wound shows evidence of granulation tissue formation and becomes more superficial
Clinical care pathways are also necessary when adopting a whole systems approach (Box 2). This considers all the factors and elements involved in managing complex wounds, including how the multidisciplinary team relates to each other and work together as a whole. Issues such as accountability and shared resources also need to be considered.

Every clinician from any healthcare setting who signs up to the integrated care pathway for NPWT should be able to stop therapy once an appropriate treatment goal has been achieved. Clinicians providing care need educational support to ensure that the clinical guidelines and pathways are followed. Any business model should therefore also discuss education/training needs and clinical governance of clinicians. This will guarantee a systematic approach to maintaining and improving the quality of patient care. Manufacturers of NPWT devices need to demonstrate committed educational and clinical support. In addition, in-house rolling educational programmes should be in place to ensure safe and appropriate practice.

**IMPORTANCE OF AUDIT**

New adopters of NPWT should collect robust data on wound types, wound healing rates and overall outcomes to provide a comparison with previous wound care practice. This data can help providers articulate to commissioners the wider value of their activities. This is especially relevant in wound care where large numbers of patients develop complex wound-related problems that require high-cost hospital care and are potentially avoidable. A robust system of audit can therefore allow clinicians to collect data rapidly to add to a body of evidence (Box 3). This will ensure that this treatment is widely recommended if the data supports this indication.

**Telemedicine and audit**

A business case may also need to discuss telemedicine, which would allow a ‘specialist’ in wound care to assess and monitor wound outcomes remotely or give advice to ensure that a treatment outcome is achieved. This would also permit interrogation of a database to quantify types of wounds treated and wound healing rates (outcomes). A database attached to telemedicine would contribute to a national or international audit tool and does not have to be product or industry specific, but rather wound care specific. This would also provide a comparison of international data where reimbursements and indications for therapy remain so variable.

**NEW NHS QUALITY FRAMEWORKS**

In the UK the NHS has introduced new frameworks to strengthen the focus on quality. These both have implications for making a convincing business case for NPWT.

**High Quality Care for All**

The recent publication in the UK, *High Quality Care for All*, examined the delivery of high quality care by frontline staff. Quality of care is defined as clinically effective, personal and safe. This report has helped to unite clinicians and managers on the principle of quality and to focus efforts on using innovation to drive up both the quality of patient care and productivity of healthcare services. The use of NPWT meets these principles on a number of levels, allowing:

- Safe discharge of patients with complex wounds, who would otherwise occupy acute sector beds
- Increased efficiency of bed usage, which can lead to reduced bed stock and head count
- Reduction in the number of dressings per week with associated time efficiencies and increased independence of the patient
- Earlier discharge, which can cause less disruption to the patient and family/carers, protection from redundancy due to time off work and more rapid return to normal life.

**Transforming Community Services**

The *Transforming Community Services* agenda provides a framework for the development of new and innovative ways to deliver services. This reviews how providers can best meet the future needs of patients and local communities and how change can be managed when transforming these services for patients. The *Transforming Community Services* agenda has reportable indicators that allows providers to ‘measure what we value’. Of these, there are...
two quality targets that may be directly affected by the usage of NPWT:

- Effectiveness in reducing complications – reduced incidence of grade 2 or higher pressure ulcers in older people treated in a community setting
- Effectiveness in reducing healing times – increased percentage of wounds that heal in a specified time.

These targets can only be achieved using a whole systems approach (Box 2). For example, a reduction in pressure ulcer development can only be maintained through an education programme for carers, enhanced nutrition input, management of comorbidities and appropriate pressure-relieving mattresses as well as excellence in wound care using appropriate dressings.

One marker of effectiveness will be the percentage of wounds that heal within a specified time. Current users of NPWT need to collect data on all wounds to demonstrate compliance with this target. This will also add to a body of evidence to demonstrate the effectiveness of NPWT in reducing time to healing.

CONCLUSION

A business case that incorporates the clinical benefits and financial savings of NPWT will have an advantage where the costs are financed by a single payer across a whole system. An insurer-based system where home care is funded separately or not funded at all may not see this advantage. For hospitals the discharge of a patient to a home care setting may allow an increased revenue return through an efficient use of hospital beds and reduction or reallocation of numbers of patients treated.

The strengthening of focus on quality will help to change the way in which an integrated NPWT service is delivered across acute and community settings. This can be measured using performance measurement criteria with a greater emphasis on audit to show cost-efficiencies and allow improved access to higher quality care.

Those who use and provide current NPWT services are best placed to design services that work well for patients and staff and to know what needs to change. The business case also has to demonstrate clinical and corporate responsibility across the sector. This requires identification of clinical champions who will lead the teams to deliver on quality, patient outcomes and financial governance.

REFERENCES

Developing a strategic framework to implement a managed service for NPWT

K Williams

This paper describes how to develop a business case for the implementation of a negative pressure wound therapy (NPWT) service. Successful integration of an advanced therapy into day-to-day practice requires a strategically managed approach to service provision.

IDENTIFYING THE NEED FOR CHANGE

Developments in the scope and use of NPWT1-3 have led to high demand in many specialties and settings. It is becoming increasingly necessary therefore to make NPWT available when it is required and for it to remain in situ as patients move from one healthcare setting to another. However, the change in responsibility during a transition of care often causes interruptions in treatment and delays in hospital discharges, especially when discussions around funding or resource application are involved4. To ensure consistent, high-quality patient care there needs to be a robust system in place that is sufficiently flexible to meet the needs of individual patients and be effective in providing cost-effective treatment across different healthcare settings. For many hospitals this will involve adopting a strategic and formal framework for implementing NPWT. The reasons for adopting a managed approach to service delivery are outlined in Box 1.

ASSESSMENT OF CURRENT PRACTICE

A written proposal or business case is often essential to secure funding for a managed service. Box 2 outlines the key factors that need to be considered when preparing a business case.

To produce a business case that involves a change in practice, there first needs to be an assessment of current practice. This will involve gathering data on previous practices, usage and costs. It is important that the data collected is robust and reflects previous, current and future predicted usage. This can be extrapolated from rental records from the manufacturer, patient-specific records, or in some cases a retrospective audit trail from available documentation or a combination of several methods. Ideally data should be collated from the longest available time prior to implementation to facilitate a credible comparison and to help identify the benefits of using NPWT in practice. This will provide a solid foundation for establishing what is being achieved and what needs to be changed.

BOX 1 Making the case – the potential benefits of a managed service

- Uses a centralised system for rental, maintenance and purchasing - reduction in rental costs; single maintenance contract paid quarterly and known in advance; reduced waste with all consumables purchased from one supplier
- Produces accurate records, including numbers of patients treated, specialty, wound type, length of treatment and outcome
- Eliminates delay in treatment
- Makes transition from secondary to community care seamless, with more patients being treated at home
- Reduces inappropriate use by limiting authorisation to those who are experienced and knowledgeable in the use of NPWT
- Units are futureproof to enable technological advances in products to be implemented effectively (ie replacement of older units with newer models)
- Supports integration of all wound treatment options in addition to NPWT

BOX 2 A check list for planning a business case

- What is your vision for the new service and what needs to change?
- What are the aims of your proposal?
- Who are your champions?
- How would your proposal improve patient care?
- What criteria are to be measured? Set standards and define how the service will be monitored to ensure planned benefits are realised
- What evidence (local, national or international) supports this development?
- How will costs be funded?
- What risks are identified?
An assessment of current practice should include:
- Current and previous usage broken down into specialties, costs, wound types treated and length of stay
- How the NPWT is currently authorised, accessed and applied
- Current process of transition from hospital to home care (and vice versa)
- Where the consumables and any current units are stored and their value
- Evaluation of delays in discharges due to problems transferring patients to a home care setting with NPWT.

By formulating accurate data around current usage and costs, wound types treated etc, it is possible to document supporting evidence for the implementation of a structured service and to show the consequences of doing nothing.

A strong business case will demonstrate improvements in quality of care for patients and staff, combined with better use of time, cost efficiencies and potential financial savings.

Once current practice has been assessed and formally documented, the next step is to look at what is required to resolve any current problems within the existing system.

**THE PLANNING TEAM**

In the planning stages, it is important that key organisational stakeholders (Box 3) are consulted to help shape what is needed and identify appropriate people for the planning team, who can assist in making the required changes to the service. Success will be dependent on engaging a limited number of people who have the required enthusiasm and drive, and who will act as ‘champions’.

This will ensure that the service is developed and successfully implemented in a timely and effective manner. Ideally, the individuals involved will be from procurement and medical electronics, and involve wound care specialists and a representative from the community.

It is important to work within a planned and manageable timeframe; this will depend on many factors including the commitment and enthusiasm of those involved.

**Identifying a leader with the required experience and skills in change and project management will ensure a structured and considered approach. The advantage of good leadership during this phase will help to inspire others, while subsequent good management will ensure ongoing sustainability.**

**DEFINING THE DESIRED SERVICE**

By consulting with other stakeholders, the planning team can start to work with those who will be required to carry out various aspects of the new service, which may help to resolve any anticipated issues prior to implementation.

Although healthcare settings share many similar structures and demands, each will have its own specific requirements. Therefore, before embarking upon setting up a managed service for NPWT, it is important to have a clear idea of what is needed and how it will be managed on a day-to-day basis (Box 4).

**Who will manage, monitor and review the implemented service?**

Responsibility for managing and overseeing the service on a day-to-day basis will often be decided by the structure within the organisation and how similar systems are currently managed. A shared responsibility between the tissue viability service and the medical equipment department can provide the optimum team for effective service delivery.

The more streamlined the structure of the service, the less waste will be generated in time, money and other resources. Ideally, NPWT units should be maintained and issued via the current equipment library within the hospital. This requires close cooperation with the manufacturers.

A central source will help to eliminate the **ad hoc** usage that may have previously existed, with all usage recorded in real time. This can prevent inappropriate use and facilitate more accurate record keeping, allowing the tissue viability team to monitor and review the usage of NPWT more easily. In addition, a retrospective audit can be used to identify efficacy and usage trends.

**Authorising treatment**

To ensure that NPWT is used appropriately and cost-effectively, it is important to identify the members of staff who are most qualified in its use and to limit the requests only to those who are sufficiently experienced and knowledgeable. The identity of the person who is responsible for authorising NPWT use should be known and issuing of the equipment withheld if its use is not authorised by a recognised professional. Staff
who may be considered suitable authorisers may include trauma and plastic surgeons, vascular surgeons, tissue viability nurses, orthopaedic surgeons, colorectal consultants and other specialist wound care professionals.

Some healthcare purchasing authorities in the UK; however; provide a list of wound types for which NPWT is indicated, thus limiting individual decision-making. This may prevent some patients from receiving NPWT, who may benefit from treatment.

In addition, it is important to assess the existing core competencies of staff and to meet their continuing education and training needs. This will ensure correct application by experienced and qualified practitioners and help to provide a consistent standard of service for patients.

Documentation to support the system

To support the single point of access, it is important to develop appropriate documentation at the outset. The use of an electronic database, stored on a shared network drive, combined with a paper ordering system can be an effective way of managing this, although the actual documentation system used will be dependent upon individual organisations and current methods.

An electronic database is useful to log unit loans and distribution of consumables. This can be bespoke or part of the existing medical device system. A paper trail for ward or unit use is needed to allow usage to be recorded within patient records and/or ward records. This will enable cross-charging and provides the means to pay for the managed service.

By highlighting the reduction in costs and the ability to access the service when it is needed, thereby reducing the time previously spent sourcing equipment, should provide a strong argument for the implementation of a managed service for NPWT.

FUNDING THE SERVICE

In making a business case, it is important to agree the required funding and predict future funding to protect the service. Identifying specific cost savings is often difficult despite the fact that increased efficiency will save costs. There may be initial capital costs and add-on costs in terms of needing additional staff to manage the system.

These costs may be offset by the projected savings in implementing a managed service as well as the more nebulous potential savings of reducing inappropriate NPWT use, eliminating delays in discharge, and simplifying access to NPWT and consumables.

One aspect of implementing a managed service is that it should address the possibility that equipment usage will increase once access is made easier and more efficient. It may be necessary in some instances to set up a negative budget line in anticipation of the predicted income and offsetting this over a 12-month period. Alternatively, initial investment could be used, which would then create an end-of-year surplus to offset this.

CONCLUSION

Regular evaluation of healthcare services is increasingly important as demand and expectations rise and more pressure is placed on available resources. A centralised managed service allows controls to be put in place that can lead to more appropriate and cost-effective use of NPWT and inform future improvements in service delivery. The ethos behind this is in keeping with the Productive Series initiative, while centralising the service management creates consistency and efficiencies in this element of service provision. This system can also be adapted for other areas of service provision as the systematic approach is based upon lean principles.
It is important in planning a business case to have a clear idea of what is required and to be able to implement this in a strategic and managed way. The success of all aspects of this service is highly dependent upon identifying the individual who has the necessary skills to lead this change, including credibility and a driving passion to make a positive difference for patients; ideally this individual will also have the skills and abilities to drive the process from the outset, and to improve the pathway of patient care.

REFERENCES

A GOOD PRACTICE EXAMPLE OF HOW TO IMPLEMENT NPWT IN THE UK

Elizabeth McGinnis, Tissue Viability Consultant, Leeds Teaching Hospitals NHS Trust, Leeds, UK

Leeds Teaching Hospitals NHS Trust is one of the largest trusts in the UK. Several years ago, following the appointment of a nurse consultant for tissue viability, a number of issues relating to the use of NPWT were identified. These included:

- Training, both at the implementation stage and as part of the ongoing support for staff, was inadequate. Clinical support was provided by a company representative, but a robust training process was lacking.
- There were no trust-approved procedural guidelines.
- There had been an almost exponential increase in the use of NPWT over the last few years within the trust.
- NPWT use had become an added cost pressure for the clinical management teams (CMTs).
- There had been no previous audit of practice.
- Cost-effectiveness of the rental process was dependent on the timely ordering and cancellation and transfer between wards of the equipment, which was not apparent.
- There was a question of potential conflict of interest, ethical practice and commercial advantage when clinical staff used a company representative to advise on patient selection and management.
- There was no clear process for the cleaning, decontamination, maintenance and repair of the therapy unit pumps etc.

Due to these concerns a working group was convened, which was led by the nurse consultant. Other members of the team included senior medical and nursing staff, business managers, supplies and health service managers and commissioner representatives.

The group were active in producing clinical guidelines on NPWT, which were approved by the trust. In addition, an audit of practice was carried out that identified current use of NPWT, associated costs and described patient outcomes. This was used to develop a business case for the trust to ensure cost-effective use of NPWT and clinically effective care for patients. The business case included details on the use of NPWT and the risks as stated above; the evidence base for NPWT; and the impact of this technique on the patient experience and the trust finances. The financial information included details of the previous year’s expenditure and proposed future spend. At this time an allocation of capital expenditure was used to purchase several new NPWT devices.

The business case also included an appraisal of the options to distribute NPWT devices to key clinical areas or to maintain these centrally and charge the wards a fee (30% less than the manufacturer’s rental price). The revenue from this would be used to fund a clinical nurse specialist (CNS) and the maintenance costs for the equipment. The CNS would be responsible for providing an equitable service for staff and patients through the training and support for nursing and medical staff in the trust. The business case was approved with the appointment of the CNS and all NPWT controlled centrally through the equipment library.

Through the inclusion in the working group of local management and commissioning staff and the close working relationship built up by tissue viability services between the trusts, an agreement was reached to ensure the seamless continuation of therapy in the community following discharge of patients from hospital on reaching appropriate evidence-based criteria.

Since the implementation of the business plan and appointment of the NPWT specialist nurse, an audit of patients in the local community trust has shown that 54 patients were discharged home with NPWT and continued therapy for an average of 23.5 days. It is estimated that there has been a saving on the number of inpatient days of at least two weeks for each patient. Over a year, this equates to 756 days. There have also been reports of increased patient satisfaction with early discharge and smooth transition of care following discharge from hospital.
Integrating NPWT into the German healthcare system

C Willy

In Germany, clinicians have the freedom to make treatment decisions for inpatients without restrictions. Payments are made on the basis of ‘diagnosis-related groups’ and clinicians can choose whether to prescribe expensive or low-cost therapies for patients. This has led to a high uptake in the use of NPWT in hospitals, with this treatment now considered an essential part of modern wound care in hospitals in Germany1-3.

In the outpatient sector, the range of services provided under the statutory health insurance (SHI) scheme (which covers more than 70 million people) is determined by The Federal Joint Committee (G-BA). This influential decision-making body provides a legal framework for the reimbursement of medical treatment costs. In addition, the G-BA decides on the quality assurance measures to apply to the outpatient and inpatient sectors of the public health service.

An important area of G-BA’s responsibility is the assessment of new methods of medical diagnosis and treatment. New treatments must receive a positive evaluation before they can be reimbursed by the SHI. A major obstacle to the inclusion of NPWT in the official catalogue of services for the health insurance scheme to date relates to a lack of documented evidence for the benefits of NPWT in the scientific literature4.

A decision about whether NPWT should be included was deferred with the result that this change in therapy was indicated, but that this change was only made after a delay, if at all5. For this reason, it is important to emphasise that a change in the wound management regimen should be considered if the aims of NPWT (promoting new granulation tissue formation, increasing perfusion, reducing oedema and removing exudate and infectious materials) are not achievable after two or three dressing changes. This will help to guide future use of NPWT.

REFERENCES
Introducing a NPWT service at Padova Hospital and surrounding area

F Bassetto1, L Lancerotto2, M Castoro3

The successful introduction of a new therapy in clinical practice depends on a number of factors: the solidity of the clinical and experimental scientific background supporting its efficacy; the social and healthcare characteristics of the area in which it is introduced; and the correct timing in relation to overall patient needs and knowledge development. If these points are not appropriately addressed, it can lead to the abandonment of the new therapy, with the loss of the potential opportunities the new approach may offer.

The introduction of NPWT at Padova Hospital first required approval by the Health Technologies Evaluation Unit, an independent unit within the hospital that evaluates the cost-effectiveness of each treatment with possible alternatives. Approval was preliminarily granted after a review of the published literature on NPWT demonstrated its efficacy both in the laboratory and in clinical practice. However, to obtain definitive approval for its widespread use, hospital staff had to carry out ‘trial cases’, which needed to support the theoretical cost-effectiveness of NPWT. The most significant of these involved a number of patients with sternal wound dehiscence. These wounds carry a high risk of infection and are slow to heal, requiring a prolonged hospital stay. The use of NPWT resulted in shorter healing times, with the ability to manage the patients in the outpatient clinic after a short hospitalisation. Following the success of these ‘trials’, a strategy was needed for the implementation of NPWT at the hospital.

DEVELOPING A STRATEGY FOR NPWT

In Italy, health care is primarily a public service that provides all the required services at no cost or with minor financial participation by the patient. It is organised on a regional basis, with the coexistence of a network of minor and major public hospitals and of an independently managed territorial service (‘socio-sanitary districts’). This raised a number of critical issues when introducing a new wound care technology that can be used for a wide range of clinical applications across multiple specialties. These included the need to have a uniform approach with sufficient numbers of trained staff in each unit and to guarantee a quick transition from hospital to home care, minimising the social and economic costs of hospitalisation and optimising the cost-effectiveness of the device.

Our strategy was to address these issues on multiple levels while maintaining an overall perspective of what needed to be achieved, centred around three key areas (Figure 1), as outlined below.

Centralised control

The plastic surgery clinic was identified as the centre of referral and all potential NPWT cases underwent evaluation by a plastic surgeon (on call 24 hours a day). For NPWT to be implemented it had to be considered as ‘the best possible option’. If the indication was confirmed, the device was applied by the requesting unit, after further approval of the Health Technologies Evaluation Unit. Periodical evaluation by the plastic surgery clinic was performed to decide when NPWT should be stopped and to plan the post-therapy strategy.

A uniform level of dedicated staff training

A selected number of people in each unit were given full responsibility for the care of all patients receiving NPWT. Specific workshops were set up for members of staff to receive intensive training in the practical application of NPWT.
Reduction in use of hospital beds
Patients undergoing NPWT were discharged to home care whenever possible. This required close collaboration with the territorial health case districts with training of selected staff using practical workshops. Patients were transferred to low daily cost units if they lived more than 60km from hospital or did not have adequate family support and could not be discharged.

MEASURING SUCCESS
The success of this strategy was evident through the following outcomes:

- **Quick uptake of NPWT by many specialties.** In the first 12 months, plastic surgeons were the primary route for referral with requests for its use in the following departments: orthopaedic, cardiac surgery, intensive care and chronic patient units. Reports of its efficacy created interest in other hospital departments, with requests for its use in metabolic disorders, spinal, hand surgery, neurology, infectious diseases units, medical and general surgery clinics and geriatrics departments.

- **Progressive reduction in inappropriate requests.** Evaluation by experienced plastic surgery specialists was effective in preventing inappropriate use of NPWT. This helped to justify the role of plastic surgery as the primary referral centre, where many patients were often followed up for definitive closure.

- **Good optimisation of costs with early discharge home.** More patients were able to be treated in the home care setting, with staff well trained in the use of NPWT. An essential aspect of the strategy was the 24-hour patient helpline for technical and medical enquiries. This meant that patients could be managed successfully in both the hospital and home care setting.

CONCLUSION
The introduction of a centralised system for NPWT at Padova Hospital has provided many benefits and the Health Technologies Evaluation Unit has been able to evaluate the number of patients treated, costs and patient outcomes. The positive results indicate an improved patient service. The data collected will lead to further research that has the potential to optimise the provision of NPWT with possible extension to a larger number of units and different specialties within the hospital.
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