

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Medical technology consultation document

# The VAC Veraflo Therapy system for acute infected or chronic wounds that are failing to heal

The National Institute for Health and Care Excellence (NICE) is producing guidance on using VAC Veraflo Therapy system for acute infected or chronic wounds that are failing to heal in the NHS in England. The medical technologies advisory committee has considered the evidence submitted by the company and the views of expert advisers.

**This document has been prepared for public consultation.** It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the public. This document should be read along with the evidence (see the [committee papers](#)).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and resource savings reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?

**Note that this document is not NICE's final guidance on VAC Veraflo Therapy system for acute infected or chronic wounds that are failing to heal. The recommendations in section 1 may change after consultation.**

After consultation the committee will meet again to consider the evidence, this document and comments from the public consultation. After considering the comments, the committee will prepare its final recommendations which will be the basis for NICE's guidance on the use of the technology in the NHS in England. For further details, see the [medical technologies evaluation programme process and methods guides](#).

**The key dates for this guidance topic are:**

Closing date for comments: 23 October 2020

Second committee meeting: 13 November 2020

[Details of the advisory committee](#) are given in section 5.

NICE medical technologies guidance addresses specific technologies notified to NICE by companies. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice.

If the case for adopting the technology is supported, the specific recommendations are not intended to limit use of other relevant technologies that may offer similar advantages. If the technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology in the NHS but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.

## 1 Recommendations

- 1.1 The VAC Veraflo Therapy system shows promise for treating acute infected or chronic wounds that are not healing. However there is not enough good-quality evidence to support the case for routine adoption in the NHS.
- 1.2 Research in the form of a randomised controlled trial is recommended to address uncertainties about the clinical benefits of VAC Veraflo (wound instillation with negative pressure therapy) compared with negative pressure wound therapy alone in the NHS.

### Why the committee made these recommendations

Acute infected or chronic wounds are normally cleaned, dead or infected tissue removed, and dressed. Some wounds are treated with negative pressure therapy, which uses a pump to suck excess fluid from the wound. Chronic non-healing wounds usually need more advanced dressings.

Medical technologies consultation document – VAC Veraflo Therapy system for acute infected or chronic wounds that are failing to heal.

Issue date: September 2020

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2 of 19

The VAC Veraflo Therapy system uses a machine attached to a dressing that covers the wound. It uses negative pressure therapy, but also slowly introduces cleansing solution onto the wound bed (wound instillation therapy). The fluid stays for a time and then is slowly sucked away, along with wound and tissue fluid. This allows the wound to be repeatedly cleaned without needing to remove the dressing.

The clinical evidence for VAC Veraflo is mostly low quality. The best available evidence does not show any clinical benefit over standard negative pressure wound therapy. Also, that evidence is from the US, and does not reflect the way VAC Veraflo is used in the NHS.

Although there are potential benefits for patients and the NHS, more evidence is needed to be certain of VAC Veraflo's clinical and cost effectiveness compared with standard care in the NHS. Therefore NICE recommends further research.

## 2 The technology

### Technology

2.1 VAC Veraflo Therapy system (3M+KCI) uses negative pressure wound therapy and wound instillation with topical solutions to promote wound healing. Wound instillation is a controlled process in which topical solutions are slowly introduced to the wound bed where they remain for a defined period before being removed using negative pressure. Treatment is delivered in automated treatment cycles allowing wounds to be repeatedly cleansed without needing to remove the dressing.

VAC Veraflo has the following components:

- VAC Ulta therapy unit – delivers VAC Veraflo therapy.
- Exudate canister – single-patient use, disposable canister (500 or 1,000 ml) which collects fluid.
- VAC Veralink cassette – instillation cassette which connects the topical wound solution container and dressing tubing to the VAC Ulta unit.

- VAC Veraflo dressing kit of clinician's choice (VAC Veraflo dressing, VAC Veraflo Cleanse dressing or VAC Veraflo Cleanse Choice dressing). The VAC Veraflo dressing kits include the appropriate dressing as well as VAC VeraTRAC Pad with tubing, VAC Advanced Drape and 3M Cavilon No Sting Barrier Film.
- Topical wound solution of clinician's choice indicated for topical wound treatment and compatible with VAC Veraflo dressings and disposable components (examples include Dakin's solution, Prontosan, and normal saline).

VAC Veraflo received a CE mark in March 2017 as a class II medical device. Each component part of the system, including sterile foam dressing kits, tube sets, and electrically powered accessories, are also individually CE marked.

## **Innovative aspects**

2.2 VAC Veraflo differs from other negative pressure wound therapies because it is designed to apply and remove a cleansing solution, as well as giving automated cycles of negative pressure wound therapy. The technology allows for repeated cleansing without needing to remove the dressing.

## **Intended use**

2.3 VAC Veraflo is intended to be used to treat acute infected or chronic wounds that do not respond to standard care and need additional therapy to promote healing and wound closure. Clinical scenarios that result in acutely infected or chronic non-healing wounds include surgical site infections, diabetic foot ulcers and pressure ulcers, which NICE has published recommendations and advice for.

2.4 The technology is used by healthcare professionals, such as surgeons, podiatrists, and tissue viability nurses, in hospital. Healthcare staff using the technology will need training, which is provided by the company.

Medical technologies consultation document – VAC Veraflo Therapy system for acute infected or chronic wounds that are failing to heal.

Issue date: September 2020

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4 of 19

## Costs

2.5 The cost for VAC Veraflo includes the cost of the:

- VAC Veralink canister (£44.51; cost for 1,000 ml canister)
- VAC Veralink cassette (£19.37)
- VAC Veraflo dressings (average dressing cost £84.36)
- rental of the VAC Ultra therapy unit (£16 per day).

It is assumed that consumables are changed 3 times a week.

For more details, see the [website for VAC Veraflo](#).

## 3 Evidence

### Clinical evidence

#### The main clinical evidence comprises 19 studies

3.1 The evidence assessed by the external assessment centre (EAC) included 19 studies, all of which were full-text peer-reviewed publications. Of the included studies, 9 were comparative studies (3 randomised controlled trials and 6 observational studies) and 10 were single-arm observational studies. The comparative evidence included a total of 636 people, of whom 365 had VAC Veraflo, 222 had negative pressure wound therapy, and 49 had dressings. For full details of the clinical evidence, see section 3 of the assessment report.

#### There are not enough data to make a meaningful comparison with advanced wound care

3.2 Of the 19 included studies, only 2 compared VAC Veraflo with dressings (Chowdry and Wilhelmi 2019; and Deleyto et al. 2017). Both studies were retrospective, and the EAC said that their methodology and reporting were not high enough quality to be able to have confidence in the results. The EAC concluded that there was not enough evidence to be able to assess the clinical benefit of VAC Veraflo over advanced wound care dressings.

Medical technologies consultation document – VAC Veraflo Therapy system for acute infected or chronic wounds that are failing to heal.

Issue date: September 2020

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5 of 19

### **The randomised controlled trial by Kim et al. (2020) is the most robust evidence**

3.3 The EAC considered the randomised controlled trial by Kim et al. (2020) to be the most informative study. It was in scope, made a relevant comparison, had a relatively large sample size (n=183, randomised), and a relatively high methodological quality. The study included people with acute (28%) or chronic wounds (72%) of various types. These included diabetic ulcers (43%), pressure ulcers (17%) and surgical wounds (13% dehisced and 13% non-dehisced). The EAC considered the other randomised controlled trials by Yang et al. (2017) and Kim et al. (2015) to be of low methodological quality, with potential bias.

### **The observational comparative studies were generally retrospective and of limited methodological quality**

3.4 The EAC considered all the comparative observational studies to be of poor methodological quality. It concluded that it was not possible to confidently say that the intervention caused the reported outcomes. Common weaknesses included:

- poorly reported patient selection
- small sample sizes
- use of historical control groups without an adequate description of how these were selected
- lack of statistical matching
- lack of confidence in how endpoints were measured, recorded and reported.

The EAC did not consider that any of the single-armed studies provided data that could reliably inform treatment in the NHS.

## **Heterogeneity in the study populations and variation in care pathways make it difficult to generalise data to the NHS**

3.5 The comparative evidence covered a range of populations. Some studies included people with a specific wound type, while others involved a range. According to the EAC, the heterogeneous nature of the study populations, combined with the relatively small patient numbers for each wound type made interpretation of results in specific patient groups difficult. Also, none of the studies were in the NHS or reported on UK populations.

## **The available evidence suggests that VAC Veraflo reduces bacterial bioburden but the clinical significance of this is unclear**

3.6 One randomised controlled trial reported a statistically significant ( $p=0.02$ ) reduction in bacterial bioburden (the number of bacteria in the wound bed measured in colony forming units) compared with negative pressure wound therapy (Kim et al. 2020). This was measured from the time of initial surgical debridement and first dressing change with VAC Veraflo. This was supported by data from a smaller randomised controlled trial ( $n=20$ ; Yang et al. 2017) and the comparative observational study (Goss et al. 2012), which also reported a reduction in bioburden with VAC Veraflo after 7 days of therapy. The EAC highlighted that the clinical significance of this outcome is unclear and may not be directly linked to improved wound healing.

## **It is not certain if VAC Veraflo has better outcomes than negative pressure wound therapy**

3.7 One randomised controlled trial reported no significant difference in its primary endpoint, the number of follow-on surgical debridements for VAC Veraflo compared with negative pressure wound therapy (Kim et al. 2020). Apart from a reduction in bioburden, there was no significant difference between VAC Veraflo and negative pressure wound therapy for any other secondary outcomes. These included the number of inpatient operating room debridements, time until wound closure or coverage, the proportion of wounds closed and the number of wound complications. The EAC

Medical technologies consultation document – VAC Veraflo Therapy system for acute infected or chronic wounds that are failing to heal.

Issue date: September 2020

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7 of 19

concluded that there was no evidence to support the claims for VAC Veraflo of a reduced need for debridement or other follow-on treatments, and improvements in wound healing, compared with negative pressure wound therapy.

### **The evidence to support claims of a shorter hospital stay is weak**

3.8 There was weak evidence to suggest that VAC Veraflo is associated with a shorter hospital stay than negative pressure wound therapy in some populations. These included people with acute wounds of the lower limb (Omar et al. 2016), people with infected extremity and trunk wounds (Gabriel et al. 2014, Kim et al. 2014) and people with surgically dehisced wounds (Kim et al. 2020; subgroup analysis only).

### **There is no published evidence on health-related quality of life or patient-reported outcome measures**

3.9 There was no evidence on the following clinical management outcomes: number of dressing changes, number of amputations or skin grafts, staff time, and use of other consumables. There was no published evidence on health-related quality of life or patient-reported outcome measures.

## **Cost evidence**

### **The company's comparators are negative pressure wound therapy and advanced wound care in 4 clinical scenarios**

3.10 The company presented a cost calculator model that compared VAC Veraflo with negative pressure wound therapy or advanced wound care. The model evaluated 4 clinical scenarios (lower limb, mixed wounds, prosthetic implant and surgical site infections) and combined the data to estimate a total cost for the whole population (the base case). The model assumed that surgical debridement was needed after treatment and that operating room visits and operations were for debridement only. It also assumed that consumables needed changing 3 times per week. Nurse training time on VAC Veraflo was believed to be negligible and was not included. The main clinical parameters driving the model related to length

Medical technologies consultation document – VAC Veraflo Therapy system for acute infected or chronic wounds that are failing to heal.

Issue date: September 2020



of hospital stay, length of therapy and the number of surgical debridements needed. Parameters were derived from 7 comparative studies. When all 3 parameters could not be sourced from the same study, the company applied scaling factors using data from another study. The 3 sources of costs in the model were from the therapies themselves, surgical debridement and hospital stay.

### **The company's estimates show cost savings over the comparators**

3.11 The company's base case results estimated a cost saving using VAC Veraflo of £3,251 per patient compared with negative pressure wound therapy. It was £8,312 per patient compared with advanced wound care. The main driver for these cost savings was a shorter hospital stay in the VAC Veraflo arm. The company's sensitivity analyses reported that the technology was cost saving in all of the individual scenarios that were used to inform the base case (from £300 to over £13,000). Results from a one-way deterministic sensitivity analysis found that changing individual parameters did not affect the overall direction of cost savings, but that cost savings were most sensitive to parameter or cost changes in length of stay. For full details of the cost evidence, see section 4 of the assessment report.

### **The overall modelling approach used by the company is not appropriate**

3.12 The EAC said that combining results from different clinical scenarios is not a usual method of establishing a base case. It said that a more appropriate approach would be to use a broader population as the base case, followed by scenario analyses for different subgroups. The EAC did not believe the model population was well defined, noting that the different populations included were likely to overlap. The EAC also noted that the company had used simple averages to estimate parameters in the base case, and these had not been weighted by study sample size or by underlying prevalence. The EAC did not agree with the company's method of estimating missing clinical parameters using scaling factors based on data from different studies. The EAC believed that, because of

the amount of structural and parameter uncertainty, the results from the company's sensitivity analyses were uninformative.

### **There is a lack of confidence in the informing clinical data**

3.13 The EAC noted that most of the clinical parameters used in the company model were derived from retrospective studies with low methodological quality. Some of the studies used involved people who did not match the scenario described. Three of the studies used by the company were excluded by the EAC in the clinical evaluation because they used a previous version of the technology (VAC Instill).

### **The EAC's changes to the model result in VAC Veraflo costing more than negative pressure wound therapy**

3.14 The EAC revised the company's model to address some potential limitations by:

- Including 2 new scenarios using relevant data from the studies that had been omitted by the company (Kim et al. 2020 and Omar et al. 2016). The randomised controlled trial by Kim et al. (2020) was regarded by the EAC as the most robust evidence and was the closest to being considered a base case.
- Only using data reported from a single study. In the absence of data, length of stay was assumed to be the same as length of therapy. When a study did not report the number of surgeries or debridement in both arms, no debridement costs were incurred.
- Updating technology costs to reflect current prices and excluding additional procedural costs that the company had included for the 'prosthetic implant subgroup'.
- Modifying some inputs concerning resource use and rounding techniques.

The EAC's base case (which used data from Kim et al. 2020 only) found VAC Veraflo to be more costly than negative pressure wound

therapy for all cost domains (length of stay, therapy and debridement), with an overall cost difference of £480 per patient. The EAC did not report a base case for VAC Veraflo compared with advanced wound care because there were not enough data to inform this analysis.

### **It is not certain that VAC Veraflo is cost saving**

3.15 Although the EAC made changes to the company model that aimed to improve accuracy and consistency, its analyses had similar limitations to the company's because there was not enough clinical evidence. The EAC's scenario analyses showed that VAC Veraflo was cost saving in all scenarios except for the EAC base case and that cost savings were mainly from shorter hospital stay. Results from probabilistic sensitivity analyses on the base case scenario showed a point estimate cost difference of £471 (95% credible interval -£1,085 to £2,015). The EAC highlighted that, because the credible interval crossed zero, it is not possible to draw conclusions from this analysis. The EAC's probabilistic sensitivity analysis at a scenario level showed that cost savings with VAC Veraflo were highly likely in 3 out of 9 scenarios. But there was considerable uncertainty in the other 6 scenarios. Based on these results, the EAC concluded that the cost saving potential is highly uncertain.

## **4 Committee discussion**

### **Clinical-effectiveness overview**

#### **VAC Veraflo shows promise but there is not enough evidence of its clinical benefits**

4.1 The committee noted that the evidence was mainly from retrospective observational studies of low methodological quality. It also noted that the most robust evidence (the randomised controlled trial by Kim et al. 2020) showed no statistically significant clinical benefit for VAC Veraflo compared with negative pressure wound therapy. The clinical experts explained that, in their experience, VAC Veraflo has shown benefits over

standard negative pressure wound therapy for appropriately selected people with difficult to heal wounds. The clinical experts said they had seen a reduction in dressing changes, faster tissue granulation, shorter wound healing time, and a shorter time to surgery. The committee felt that the technology showed promise and plausibility based on clinical expert advice, but that this was not supported by the available evidence. The committee concluded that there was not enough good-quality evidence to make a definitive judgement about the benefits of this technology compared with negative pressure wound therapy or advanced wound care in the NHS.

### **The evidence is heterogenous in terms of patient population and reporting**

4.2 The committee noted that the patient populations in the evidence are heterogeneous, involving a mixture of people with different wound types and comorbidities. The clinical experts agreed that the patient population eligible for VAC Veraflo is complex and broad. They also highlighted that the clinical pathway for people with non-healing wounds is not clearly defined and that clinical practice varies. The clinical experts said that the decision to offer VAC Veraflo requires specialist knowledge and experience. They added that it is used slightly differently in each of their clinics because of the different types of wounds they treat and the different aims of therapy. One expert said that in their clinic VAC Veraflo is used after debridement, especially for people who have an infection to help with healing. They also said that VAC Veraflo is most commonly used in people with diabetic foot problems before limb salvage. The committee was aware that outcome reporting is particularly problematic in this field because of the heterogenous population and setting, as well as the use of non-standardised definitions and measurements. The committee concluded that the complexity of the population together with the heterogeneity of the available evidence makes generalisation of study results difficult.

## Relevance to the NHS

### The best available evidence does not reflect NHS practice

4.3 None of the available published studies were done in the UK. The most robust evidence for VAC Veraflo came from a multicentre randomised controlled trial done in the US (Kim et al. 2020). One of the clinical experts explained that wound management in the US is likely to be very different from the NHS. The trial (Kim et al. 2020) involved specialist tertiary centres where the aim of treatment is to surgically debride wounds to acute status. Microbiology is then reviewed every 48 hours until definitive or reconstructive surgery can be done to close the wound. In these centres debridement may be done several times until microbiology results are sterile. The clinical experts said that this does not happen in the NHS. They also noted that in most of the included studies, chronic wounds were debrided back to an acute wound status before VAC Veraflo treatment was applied. Because of this, they said, caution was needed when interpreting its clinical efficacy in chronic wounds based on these studies. The clinical experts also explained that in the NHS, many people with wounds eligible for treatment with VAC Veraflo are not treated by acute surgeons but by tissue viability nurses and vascular clinicians. Other clinical experts also agreed that the care pathway evaluated in Kim et al. (2020) did not fully reflect their experience of using VAC Veraflo in the NHS. The committee concluded that the evidence does not fully reflect NHS practice and that data from non-UK studies are likely to have limited generalisability to the NHS.

## Outcome measures

### Length of hospital stay is not an appropriate outcome

4.4 Length of hospital stay before discharge was the main clinical outcome driving the overall costs in the economic modelling. The clinical experts said that, given how the technology is used in the NHS, length of hospital stay is likely to be a poor choice of outcome and does not take into

Medical technologies consultation document – VAC Veraflo Therapy system for acute infected or chronic wounds that are failing to heal.

Issue date: September 2020

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13 of 19

account other important clinical outcomes including quicker time to surgery (plastic surgery), better overall wound healing and reduced negative pressure wound therapy time. One expert said that the technology could increase the patient's length of stay but reduce the overall impact on other services because of faster healing. It was also noted that length of hospital stay may be confounded by other factors such as hospital discharge procedures and the availability of community care. The clinical experts agreed that, to fully understand the clinical benefits of the technology in the NHS, the entire wound healing journey should be considered. They also agreed that wound healing is the most important outcome. The committee concluded that the outcome of length of hospital stay is not appropriate and does not help with decision making.

### **There is no evidence on important clinical outcomes**

4.5 Some important clinical outcomes from the scope had not been reported in the evidence. In particular, none of the published evidence reported health-related quality of life and patient-related outcome measures (such as pain). The committee agreed that this was a substantial omission, and that how VAC Veraflo affects patient experience is poorly understood. One clinical expert also explained that improving the quality of granulation tissue in the early healing stages was an important benefit of the technology which was not in the evidence. The committee concluded that further research is needed on the technology's effect on key outcomes.

### **Other patient benefits or issues**

#### **VAC Veraflo has plausible benefits for people over standard negative pressure wound therapy**

4.6 The clinical experts said that people who are offered treatment with VAC Veraflo have usually had a non-healing wound for months and that this is likely to have made their quality of life poorer. They explained that when people see the rapidly improved appearance of their wound, which can happen after treatment with VAC Veraflo, it can give them much-needed

hope. The experts said that in their experience people tend to accept and respond well to therapy. They said other potential benefits were fewer dressing changes, and less wound exudate, odour and spoiling of clothing and bed linen.

### **VAC Veraflo may benefit people with protected characteristics under the equality act**

4.7 The committee heard that people who are older or physically disabled are more likely to have chronic and complex wounds. People with certain family origins (South Asian, Chinese, black African and African-Caribbean family origins) are more prone to poor wound healing because of their increased risk of diabetes. Age, disability, and race are protected characteristics. The committee also heard, however, that people with serious mental health or cognitive impairment may have difficulty keeping the system in place. The committee concluded that people with disabilities, including those with serious mental health or cognitive impairment, would not be disadvantaged by the recommendations, providing that clinicians act in the interest of their patients, in line with their usual responsibilities.

### **NHS considerations overview**

#### **VAC Veraflo is intended to be used temporarily to promote wound healing**

4.8 The clinical experts explained that in the NHS VAC Veraflo is used as a temporary treatment at a specific point in wound healing to speed up wound healing. They explained that it's usually used for about 2 weeks and that when the wound bed improves, treatment is changed to standard negative pressure wound therapy or standard wound care with dressings. One expert explained that once a wound has a good level of granulation tissue it can be treated with conventional dressings. They said that people are routinely discharged with open wounds that are then managed in community care. The other experts noted that in their experience, VAC

Veraflo is used as a bridging therapy and helps reduce the time between surgical treatments by preparing the wound bed for reconstruction.

### **VAC Veraflo should be used in hospital by specialist healthcare professionals trained in using it**

4.9 The clinical experts said that, because of the complexity of the wounds, a multidisciplinary team, including a trust specialist trained in using VAC Veraflo, should decide when to offer treatment with VAC Veraflo and when to stop it. The clinical experts thought that this level of specialism was not widely available in community care. Also, using the system in community care is difficult because of the frequency of dressing and other consumable changes. The clinical experts said that it is only offered in secondary or tertiary care. One clinical expert added that offering VAC Veraflo in a community setting should not be ruled out, however, if appropriate support mechanisms are in place.

### **Saline solution is the preferred instillation fluid to use with the system**

4.10 Different instillation fluids can be used with the VAC Veraflo. The most commonly used ones from the evidence were normal saline, Dakin's solution (Century Pharmaceuticals) and Prontosan (B Braun). One of the randomised controlled trials reported no statistically significant difference in outcomes for normal saline compared with Prontosan (Kim et al. 2015). The clinical experts said this reflected their experience in clinical practice. All agreed that saline solution was their preferred instillation fluid when using the VAC Veraflo for most wound types. One clinical expert said that there may be some wound types, such as an infected implant, that may need antimicrobials. One added that normal saline is easier for staff to find than other solutions because it's so commonly used.

### **A standard dwell time of 10 minutes and cycle length of 3.5 hours should be considered for VAC Veraflo therapy**

4.11 There was no evidence on the best dwell time and cycle length for VAC Veraflo. The clinical experts explained that the instillation solution needs



enough dwell time to infiltrate the wound and for the exudate to mix with the solution for it to be effectively removed. They said that the VAC Ultra device comes with standard manufacturer recommended settings but that it also enables healthcare professionals to modify settings based on clinical judgement. The clinical experts noted that in their experience the standard setting of 10 minutes dwell time and a 3.5-hour cycle length recommended by the manufacturer is normally appropriate for most wounds. One said that in some situations they increase the cycle length to every 1 to 2 hours at the beginning of therapy to speed up wound healing. The committee concluded the standard settings recommended by the manufacturer were appropriate.

## **Cost modelling overview**

### **Any cost modelling using the available evidence is likely to be flawed**

4.12 The key clinical parameters that drive cost savings estimates, such as surgical debridement and length of stay, were very uncertain. This is because the evidence was mainly made up of retrospective observational studies from outside the UK. The committee noted that there were no well-designed studies in the NHS. It concluded that more research was needed to establish the clinical and cost benefits of the VAC Veraflo in the NHS and that in the meantime any cost modelling was likely to be flawed.

## **Further research**

### **Randomised controlled trials of VAC Veraflo in the NHS are needed**

4.13 The committee concluded that further research is needed to address uncertainties about the clinical effectiveness of VAC Veraflo compared with negative pressure wound therapy alone in the NHS. It advised that research should compare VAC Veraflo with negative pressure wound therapy in randomised controlled trials in NHS hospitals. The clinical experts said that there are difficulties with running high-quality trials in wound care. These include nursing time, funding, and difficulty recruiting enough patients because of a possible lack of equipoise (that is, clinicians

Medical technologies consultation document – VAC Veraflo Therapy system for acute infected or chronic wounds that are failing to heal.

Issue date: September 2020

and trial participants may be unwilling to risk being randomised to a treatment that they believe to be inferior). Despite the challenges, clinical experts said that high-quality randomised controlled trials were still possible and necessary. The committee agreed that the primary outcome should be time to complete wound healing because it is the most important outcome for patients and clinical experts. Secondary outcomes should include the rate of wound healing and changes in wound volume, and health-related quality of life and patient-related outcome measures such as pain.

### **Registry and real-world data collection are encouraged**

4.14 Clinical experts noted that real-world data from other sources such as audits and registries would also be useful. The committee encouraged data collection from registries.

## **5 Committee members and NICE project team**

### **Committee members**

This topic was considered by [NICE's medical technology advisory committee](#), which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The [minutes of the medical technology advisory committee](#), which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

### **NICE project team**

Each medical technologies guidance topic is assigned to a team consisting of 1 or more technical analysts (who act as technical leads for the topic), a technical adviser and a project manager.

Medical technologies consultation document – VAC Veraflo Therapy system for acute infected or chronic wounds that are failing to heal.

Issue date: September 2020

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18 of 19

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ISBN: [to be added at publication]