

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Medical technology consultation document

### PICO negative pressure wound dressings for closed surgical incisions

The National Institute for Health and Care Excellence (NICE) is producing guidance on using PICO 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 supporting 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 PICO. 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: 11 January 2019  
Second committee meeting: 22 February 2019

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

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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 Evidence supports the case for adopting PICO negative pressure wound dressings for closed surgical incisions in the NHS. They are associated with fewer surgical site infections and seromas compared with standard wound dressings.
- 1.2 PICO negative pressure wound dressings should be considered as an option for closed surgical incisions with low amounts of exudate in people who are at high risk of developing surgical site infections. Risk factors for surgical site infections are described in the NICE guideline on [preventing and treating surgical site infections](#).
- 1.3 Cost modelling suggests that PICO negative pressure wound dressings provide extra clinical benefits at a similar overall cost compared with standard wound dressings.

## Why the committee made these recommendations

PICO dressings are designed to allow an even distribution of negative pressure on the surface of a closed wound and to be portable. Clinical evidence shows that using PICO negative pressure wound dressings for closed surgical incisions can lead to fewer surgical site infections, even when the risk of complications is high. Evidence also shows that using PICO dressings reduces the rate of seromas compared with standard wound dressings. Cost analyses suggest that using PICO dressings will not add to the overall costs of surgical treatment.

## 2 The technology

<p><b>Technology</b></p>	<p>PICO is a canister-free, single-use, negative pressure wound therapy system consisting of a sterile pump and multi-layered adhesive dressings. Each dressing has 4 layers: a silicone adhesive wound contact layer, which is designed to minimise pain and damage during peel-back and to reduce lateral tension; an airlock layer for even distribution of pressure; an absorbent layer to remove exudate and bacteria from the wound; and a top film layer, which acts as a physical barrier and allows moisture to evaporate. The pump is operated by 2 AA batteries and delivers a continuous negative pressure of 80 mmHg to a sealed wound. Once activated, using a push button, the battery drives the pump for up to 7 days and LEDs provide alerts for low-battery status and pressure leaks.</p> <p>Standard PICO dressings come in 10 sizes (10 × 20 cm, 10 × 30 cm, 10 × 40 cm, 15 × 15 cm, 15 × 20 cm, 15 × 30 cm, 20 × 20 cm, 25 × 25 cm, small multisite [15 × 20 cm], large multisite [20 × 25 cm]).</p> <p>The latest version of the technology is PICO7, which differs from the PICO dressings notified to NICE in having an improved pump to minimise leakage, and an integrated belt clip to allow easy transport of PICO.</p>
<p><b>Innovative aspects</b></p>	<p>PICO differs from conventional negative pressure wound dressings in that it:</p> <ul style="list-style-type: none"> <li>• has no separate canister</li> <li>• is portable and disposable</li> <li>• has a proprietary dressing layer that is designed to allow even distribution of negative pressure across the incision and zone of injury.</li> </ul>
<p><b>Intended use</b></p>	<p>The focus of this evaluation is the use of PICO for closed surgical incisions to prevent surgical site complications. It can be used in hospitals, communities and homes. PICO dressings can be applied by healthcare professionals including surgeons and tissue viability nurses. Training is required to place the dressings correctly (<a href="#">see section 4.8</a>)</p>
<p><b>Costs</b></p>	<p>PICO is available in 7 bundles with different numbers and sizes of dressings per pack. The dressing comes in 10 sizes (up to 25 cm x 25 cm). The list prices for PICO standard and multisite dressings range from £127.06 to £145.68 (inc VAT). All costs include single-use pump and 2 dressings.</p>
<p>Note that For more details, see the <a href="#">company's website</a>.</p>	

## 3 Evidence

### *Clinical evidence*

**Relevant evidence comes from 31 studies, 15 of which are randomised controlled trials**

3.1 Thirty-one studies provided evidence that was relevant to the decision problem in the scope, including 15 randomised controlled trials and 16 non-randomised comparative observational studies. The 15 randomised controlled trials were based on preventing surgical site complications in people with closed surgical incisions who were at high risk of complications after surgery; 1 was done in the UK. For full details of the clinical evidence, see section 3 of the assessment report.

**Randomised controlled trial evidence shows fewer surgical site infections with PICO dressings compared with standard wound dressings**

3.2 Eight of the 15 randomised controlled trials (Chayboyer et al. 2014, Gillespie et al. 2015, Witt-Najchrazak et al. 2015, Karlakki et al. 2016, O’Leary et al. 2016, Uchino et al. 2016, Hyldig et al. 2018 and Galiano et al. 2018) compared PICO dressings with standard wound dressings in people with closed surgical incisions in Australia, Poland, the UK, Ireland, Japan, Denmark and the US respectively. The external assessment centre (EAC) considered these studies to have acceptable internal and external validity and to provide relevant evidence on the effectiveness of PICO dressings. EAC ran a random effects meta-analysis of the 8 studies, pooled effect estimates from which showed a significant reduction in surgical site infection rates in favour of PICO across all types of surgery (n=1,804, odds ratio [OR] 0.51, 95% confidence interval [CI] 0.3 to 0.82; p=0.006).

**Results from observational studies support the randomised controlled trial evidence**

3.3 Of the 16 non-randomised comparative observational studies, 10 (Adogwa et al. 2014, Matsumoto et al. 2014, Pellino et al. 2014, Pellino et

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al. 2014b, Selvaggi et al. 2014, Hickson et al. 2015, Fleming et al. 2017, Tan et al. 2017, van der Valk et al. 2017, Dingemans et al. 2018) compared the rates of surgical site infection using PICO dressings with standard wound dressings in people with closed surgical incisions. Pooled effect estimates from a random effects meta-analysis of the 10 studies showed a significant reduction in surgical site infection rates in favour of PICO when all types of surgery were considered (n=2,669, OR 0.27, 95% CI 0.14 to 0.53; p=0.001). The EAC considered the included observational studies to have acceptable levels of both internal and external validity, and concluded that the evidence was relevant to the decision problem. However, it noted that the observational studies may overestimate the clinical benefits of PICO dressings because of potential selection and publication bias.

### **Pooled analyses show a reduction in the rate of seromas with PICO dressings**

3.4 Two of the randomised controlled trials and 5 of the observational studies that compared PICO and standard wound dressings also reported rates of seromas in people with closed surgical incisions. Pooled effect estimates from a random effects meta-analysis of these 7 studies showed a significant reduction in the incidence of seromas in favour of PICO when all types of surgery were considered (n=771, OR 0.19, 95% CI 0.08 to 0.47; p=0.0003). The EAC noted that this reduction in seroma rates was mainly driven by the observational studies.

### **Reductions in surgical site infections with PICO dressings vary across different types of surgery**

3.5 The included studies considered the use of PICO dressings for 6 different types of surgery:

- orthopaedic surgery (2 randomised controlled trials and 3 observational studies, n=607)
- colorectal surgery (1 randomised controlled trial and 4 observational studies, n=209)

- obstetric surgery (2 randomised controlled trials and 1 observational study, n=2,911)
- plastic/breast surgery (1 randomised controlled trial and 1 observational study, n=420)
- vascular surgery (2 observational studies, n=193)
- cardiothoracic surgery (1 randomised controlled trial, n=80).

Analyses by surgery type showed that reductions in the rate of surgical site infection rates with PICO varied across different types of surgery: the reductions were only significant in obstetric surgery (OR 0.48, 95% CI 0.30 to 0.76; p=0.002) and orthopaedic surgery (OR 0.45, 95% CI 0.22 to 0.91; p=0.03).

### **There are limitations in the evidence but it is relevant to the decision problem**

3.6 The EAC noted the clinical and statistical heterogeneity of the studies that were included in the meta-analyses. There was wide variation in the risk characteristics of the populations, the definition of surgical site infections, how long the dressing was in place, and the length and frequency of follow-up. The analyses based on surgery type also included relatively few studies. Nonetheless, the random effects model included a relatively large number of study populations and the EAC concluded that the results were relevant to the decision problem.

### **PICO dressings may be linked to increased risk of skin blister and maceration in some people**

3.7 One randomised controlled trial (Karlakki et al. 2016) reported a higher overall rate of blisters in people who used PICO dressings compared with those using standard wound dressings (11% compared with 1%). The rate of blisters differed markedly between the 3 surgeons who took part in the study. For full details of the adverse events, see section 3.7 of the assessment report.

## **Cost evidence**

### **The company's cost model shows cost savings in people at high risk of surgical site infections with PICO dressings**

3.8 The company's cost model only included people at high risk of developing surgical site complications (infections and dehiscence). The results indicated that 90 days after surgery, PICO dressings are cost saving by around £101 per person.

### **The EAC's changes to the cost model more accurately reflect the costs and consequences to the NHS**

3.9 The EAC considered that the structure of the company's cost model was adequate for decision-making. However it identified some limitations in the model parameters and made changes to better reflect potential resource use in the NHS. Specifically, the EAC:

- applied baseline incidence rates and the cost of surgical site infections from a UK data source
- calculated the mean cost of surgical site infections by dividing the cost by the number of infections
- updated the number of PICO and comparator dressings used
- used clinical-effectiveness estimates based on the pooled treatment effect from the meta-analysis of the randomised controlled trials.

For full details of the changes and results, see section 4 of the assessment report.

### **The EAC's updated analysis shows that overall using PICO dressings is cost neutral but the cost consequences vary by type of surgery**

3.10 With the EAC's changes, the results of the cost model showed that 90 days after surgery, PICO dressings are cost saving by around £6 per person compared with standard wound dressings. The main drivers of these savings were the cost of PICO, the likelihood of a surgical site infection, the cost of a surgical site infection and the effectiveness of PICO



in reducing the incidence of surgical site infections. The analyses by surgery type showed that PICO was cost saving for colorectal, cardiothoracic and vascular surgery, but was not cost saving for orthopaedic, obstetric and plastic/breast surgery. For full details of the cost evidence, see section 4 of the assessment report.

## **4 Committee discussion**

### ***Clinical-effectiveness overview***

#### **PICO dressings are associated with lower rates of surgical site complications in people with closed surgical incisions compared with standard dressings**

4.1 The committee noted considerable evidence to demonstrate the effectiveness of PICO in reducing rates of surgical site infections (n=18 studies) and seromas (n=7 studies). The company conducted a number of fixed-effect model meta-analyses and the EAC ran additional meta-analyses using a random-effect model. The committee considered that the EAC's approach was more appropriate because of wide variation in the study populations, interventions and the definitions of surgical site infections. The committee concluded that there was convincing evidence that using PICO dressings reduces surgical site complications in people with closed surgical incisions. The committee considered that there was less certainty about how PICO dressings affect other surgical site complications, such as wound dehiscence, haematoma, delayed healing or excessive scarring due to a small number of studies included in the analyses

#### **Careful patient selection is important and should be informed by NICE guidance**

4.2 The experts advised that careful patient selection was important when using PICO dressings. The committee noted that the included studies only recruited people who were considered to be at high risk of developing surgical site complications, but that many of the studies did not explicitly state the definition of high risk. The experts advised that there were a

number of factors associated with an increased risk of surgical site complications, including age, obesity, cigarette smoking and diabetes. There are also several surgical situations that increase the risk, such as repeat operations and the need for emergency surgery. The NICE guideline on [preventing and treating surgical site infections](#), which is currently being updated, describes these risk factors in more detail, and the committee concluded that healthcare professionals should take into account the risk factors in the guideline when considering whether to use PICO dressings.

### **PICO dressings should only be used for closed surgical incisions with a low amount of exudate**

- 4.3 The clinical experts advised that PICO dressings should only be used for surgical incisions in which the amount of exudate was anticipated to be low. Large amounts of exudate may lead to the need for multiple dressing changes; this in turn may lead to an increased risk of suction loss and the need for additional dressings. The experts also explained that PICO dressings should only be used for closed surgical incisions, and not as a treatment for open surgical wounds.

### **Benefits of PICO dressings vary by type of surgery**

- 4.4 The committee noted that the published evidence included the use of PICO dressings in 6 different types of surgery, and that the meta-analysis identified a statistically significant reduction in the risk of surgical site infections when it was used in orthopaedic and obstetric surgery. The committee concluded that the type of surgery was an important factor in selecting people for PICO dressings, and that it should be considered in the overall risk assessment for post-operative complications. However, the committee considered that the evidence was too limited to make recommendations on the use of PICO dressing by individual surgery type.

## ***Side effects and adverse events***

### **Adverse events are uncommon but some people may develop skin blisters and maceration with PICO dressings**

4.5 The committee noted that adverse events were rare in the included studies but that skin blisters and maceration may occur when using PICO dressings. A clinical expert advised that skin blisters may develop because of skin tension, which is likely to be the result of the dressing being stretched over the wound. This was corroborated by the results of 1 study, in which the highest incidence of skin blisters was in people whose dressings were applied by trainee staff.

### **Pump failure may incur additional costs but this is rare**

4.6 The company stated that there had been around 147 cases of the PICO pump failing reported since its launch. The committee considered that pump failure would incur additional costs, including application of additional dressings and pump replacement, but it acknowledged that the reported rates of pump failure were very low.

## ***Relevance to the NHS***

### **The evidence for PICO dressings is broadly generalisable to the NHS**

4.7 The committee noted that only a small number of the studies included NHS settings; for example, only 1 of the randomised controlled trials was done in the UK. However, 9 of the studies included in the meta-analyses were done in European countries including Ireland, Italy, the Netherlands, Denmark and Poland. A clinical expert stated that PICO dressings were widely used across Europe and that both population demographics and the fundamentals of wound therapy were likely to be similar across Europe. The committee concluded that the evidence for PICO dressings was broadly generalisable to the NHS.

## ***NHS considerations***

### **Some training is needed in how to apply PICO dressings**

4.8 The clinical experts advised that training was an important consideration in the use of PICO dressings. Maintaining a seal is integral to the continued effectiveness of negative pressure but in creating the seal, it is important to ensure that the skin is not placed under excessive tension. The experts also described certain situations in which applying the dressing was awkward (such as on the lower abdomen after a Caesarean section or over bony protrusions, especially if there is excessive moisture). The experts also stated that training is important for healthcare staff who provide post-operative care both in hospital and in the community. They emphasised that a lack of knowledge may lead to dressings being removed too early, or to unnecessary dressing changes that are likely to negatively affect clinical outcomes and costs. The committee concluded that training was important in realising the benefits of PICO.

## ***Cost modelling overview***

### **The EAC's updated model is preferred to the company's base case for decision-making**

4.9 The committee noted the EAC's changes to the company's cost model (see [section 3.9](#)) and agreed that the updated model better reflected cost and resource use in the NHS. The committee considered the numbers of PICO dressings and standard dressings that were likely to be needed per person, and the importance of length of stay in hospital in determining cost calculations. It noted that the instructions for use suggest that 1 PICO kit (1 pump and 2 dressings) will last for up to 7 days after surgery. However, the clinical experts indicated that the number of dressings used and the length of stay vary widely depending on the type of surgery. The EAC explained that its calculations were based on the use of 1.09 PICO dressings per person with an average of 5.3 days stay in hospital. It also estimated the number of PICO dressings used by surgery type; for

example, it estimated 1.81 PICO dressings used for colorectal surgery and 1.58 used for vascular surgery. The committee concluded that although it agreed with the EAC's approach to cost modelling, there were uncertainties because of the heterogeneity of the populations considered.

### **Main cost drivers**

#### **It is likely that the additional cost of PICO dressings will be offset by a reduction in surgical site infections**

4.10 The committee noted how the rate and cost of surgical site infections affected the outcomes of the cost modelling. Having seen convincing evidence to support a reduction in the rate of surgical site infections with PICO dressings, the committee concluded it was plausible that the additional cost of PICO dressings compared with standard wound dressings would be offset by a reduction in the overall costs associated with treating surgical site infections.

#### **The model is most sensitive to the price and effectiveness of PICO dressings**

4.11 The EAC did sensitivity analyses, which showed that the cost model was most sensitive to the cost of PICO dressings and their effectiveness in reducing surgical site infections.

#### **The model does not include staff costs for applying dressings but these are negligible**

4.12 The committee noted that neither the company's original model nor the EAC's updated model included staff costs associated with applying PICO and standard wound dressings. Although applying a PICO dressing could take an additional 1 or 2 minutes compared with applying a standard wound dressing, a clinical expert noted that for appropriately trained staff any additional time was negligible.

## ***Cost savings***

### **PICO dressings provide extra benefits at no additional cost to the NHS**

4.13 The committee recalled the EAC's updated cost model, which suggested that PICO dressings were cost saving by around £6 per person (although the cost saving may vary by type of surgery). Overall, the committee concluded that PICO dressings are likely to provide extra clinical benefits at a similar cost to the NHS, compared with standard dressings.

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

### ***Committee members***

This topic was considered by the [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 each committee meeting, 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.

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