NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

MTG review decision document

Review of MTG43: PICO negative pressure wound dressings for closed surgical incisions

This guidance was issued in May 2019.

NICE proposes no change to the published guidance if there are no changes to the technology, clinical environment or evidence base which are likely to result in a change to the recommendations. NICE proposes an amendment if the recommendations need revision to correct any inaccuracies or to update to current formats. The decision to consult on an amendment of published guidance depends on the impact of the proposed amendments and on NICE's perception of their likely acceptance with stakeholders. NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

Recommendation

Do not change the guidance.

Please see Appendix 1 for a list of the options and their explanations for consideration.

1. Original objective of guidance

To assess the case for adoption of PICO negative wound pressure dressings for closed surgical incisions.

2. Current guidance

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 in people who are at high risk of developing surgical site infections. Risk factors for surgical site infections are described in section 4.2.

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.

3. Rationale

There is new clinical and economic evidence since the publication of the original guidance. The new clinical evidence has been included in an updated meta-analysis and the results still support the case for using PICO negative pressure wound dressings for closed surgical incisions in the NHS. They are associated with fewer surgical site infection compared with standard wound dressings. Although the cost of PICO has increased slightly, Section 1 of the original guidance is not specific about the cost savings so it is unlikely that an updated cost model would require a change to the recommendations.

4. New evidence

The search strategy from the original assessment report was re-run. References from August 2018 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

4.1 Technology availability and changes

No changes have been made to the technology's mode of action, indication or CE marking since the original assessment and it is still available to the NHS. [redacted]

4.2 Clinical practice

There have been no changes to NICE's guideline on the prevention and treatment of surgical site infections which impact the recommendations made

in MTG43 PICO for negative pressure wound dressings. The guidance states that surgical incisions should be covered with an appropriate interactive dressing at the end of the surgical procedure. Expert advice was sought from two clinical experts, who both confirmed that the clinical pathway has not changed since the original guidance was published. Both experts used PICO for selected patients however their opinions differed about its benefits. One expert used it selectively to manage complicated or infected wounds, but less often in closed incisions whereas the other expert used it routinely in patients with wounds which are at high risk of surgical site infections to prevent wound breakdown.

4.3 NICE facilitated research

None.

4.4 New studies

Results from the NICE literature search as well as information from the company and External Assessment Group were used to assess new evidence. A total of 28 papers published after the original guidance were identified. These included 12 RCTs, 1 uncontrolled randomised trial, 8 cohort studies, 3 before and after studies and 4 economic studies. The 24 clinical studies included a total of 7,790 patients with PICO used in 3,754 patients. The included studies were conducted across a range of surgical specialities, such as: orthopaedics, vascular, breast, obstetrics, cardiothoracic, colorectal, reconstructive and general surgery. Of the 22 studies reporting on SSI outcomes, 3 studies (2 RCTs and 1 prospective cohort study) found a significant difference between PICO and standard wound dressings.

The guidance includes meta-analysis of the surgical site infection outcome from 19 studies across 4,473 patients (including 8 RCTs and 11 observational studies) comparing PICO wound dressings with standard dressings. The updated meta-analysis identified a total of 41 studies across 10,259 patients as relevant to this guidance review. These included 21 RCTs and 20 observational studies. The original guidance was based on a meta-analysis of 8 RCTs which showed a significant reduction in surgical site infection rates in favour of PICO dressings (n=1,804, odds ratio [OR] 0.51, 95% confidence interval [CI] 0.3 to 0.82; p=0.006). The updated meta-analysis based on 20 RCTs found PICO was associated with a significant reduction in surgical site infection compared with standard care (n=7,050 OR 0.60, 95% CI 0.47, 0.77, p<0.00001). The meta-analysis of the observational studies alone and the meta-analysis of all the studies were also updated with the new evidence. Results still showed a significant reduction in surgical site infection rates in favour of PICO dressings. For further details please see the EAG's evidence review report and meta-analysis report.

The studies added to the updated meta-analysis are summarised below:

Randomised controlled trials

Adrianello et al. (2020) – Study of 100 patients at high risk of SSI after major pancreatic resections. The difference in terms of non-organ-space surgical site infection comparing PICO with standard dressing was not significant (10.9 vs 12.2%, P = 1.00). Hematomas (4.3 vs 2%, P = 0.609) and organ-space infections (46.7 vs 43.8%, P = 0.836) were similar. Negative pressure wound therapy prevented the development of seromas (0 vs 12.2%, P = 0.027). The aesthetic result assessed on postoperative day 7 was better in the negative PICO group but it was no more evident on postoperative day 30.

Bueno-Llédo et al. (2020) – Study to evaluate whether the prophylactic application of PICO dressing on closed surgical incisions after incisional hernia repair decreases the risk of surgical site occurrences and the length of stay. At 30 days postoperatively, there was significatively higher incidence of SSIs in the control group compared to the treatment group (29.8% vs 16.6%, P < 0.042). There was no SSI in the treatment group and 6 cases in the control group (0% vs 8%, P < 0.002). No significant differences regarding seroma, hematoma, wound dehiscence, and length of stay were observed between the groups.

Costa et al. (2020) – A randomized clinical trial conducted at 24 trauma hospitals representing the UK Major Trauma Network that included 1548 patients aged 16 years or older who underwent surgery for a lower limb fracture caused by major trauma from July 2016 to April 2018. At 30 days, deep surgical site infection occurred in 5.84% (45 of 770 patients) of the PICO group and in 6.68% (50 of 749 patients) of the standard wound dressing group (odds ratio, 0.87 [95% CI, 0.57 to 1.33]. There was no significant difference in the deep surgical site infection rate at 90 days (11.4% [72 of 629 patients] in the PICO group vs 13.2% [78 of 590 patients] in the standard wound dressing group.

Flynn et al. (2020) – 188 patients undergoing laparotomy and bowel resection were randomly assigned to PICO or conventional dressings. Twenty-seven (14%) patients developed a surgical site infection; 13 received a PICO dressing and 14 received standard dressing (p = 0.73), indicating no difference in surgical site infections between the two types of dressing (OR = 1.1). Thirty-one (16.5%) patients developed other surgical site complications. Eleven of these patients received a PICO dressing and 20 received the standard dressing (p=0.06, OR = 2.1)

Fogacci et al. (2020) – 100 patients undergoing breast surgery who were at high-risk of surgical site infection. There were 3 complications in the PICO group, none which emerged with a wound infection. There were 13 complications in the control group, 5 which led to a wound infection. A mean of 3.78 people who received PICO required hospital admission as outpatients, compared with a mean of 4.18 people who received standard dressing. Average time to healing was 25.66 days in the PICO group and 31.46 in the control group.

Gillespie et al. (2021) – 2035 women having caesarean procedure were randomised to either PICO (n = 1017) or standard dressing (n = 1018). SSI occurred in 75 (7.4%) women treated with PICO and in 99 (9.7%) women with

a standard dressing (OR 0.76, P=0.06). Blistering occurred in 40/996 (4.0%) women who received PICO and in 23/983 (2.3%) who received the standard dressing (OR 1.72, P=0.03).

Hasselmann et al. (2020) – 139 patients undergoing elective open vascular surgery with inguinal incisions. Patients with bilateral incisions randomly received a dressing on one incision and the opposite dressing on the other. The incidence of SSI was reduced in the PICO group compared with the control group, 11.9% vs 29.5% in the unilateral group (n = 120), 5.3% vs 26.3% in the bilateral group (n = 19), respectively. No differences regarding other surgical site complications were observed between the groups.

Masters et al. (2021) – 462 patients having surgical incisions were randomised to PICO (n = 230) and standard dressing (n = 232). In the standard dressing group, 14 of 218 patients (6.4%) developed deep SSI. In the PICO group, four of 214 patients (1.9%) developed deep SSI. This gives a total rate of SSI of 4.2% (95% confidence interval (CI) 2.7% to 6.5%).

O'Neill and Martin (2020) – 40 patients randomised to PICO or standard dressing follow pancreatectomy and hepatectomy procedures. There were three incisional wound infections: two with standard dressing, one with PICO. There were six organ space infections: four with standard dressing and two with PICO. There were no significant differences in SSI rates between groups.

Peterson et al. (2021) – Study in 212 patients with obesity undergoing caesarean delivery. SSI occurred in 29.1% in the standard surgical dressing compared with 20% in the PICO group. The study was stopped early because of a low enrolment rate and lower likelihood of seeing a clinically significant benefit.

Svensson-Bjork et al. (2022) – RCT of 337 patients having fascia closure after vascular surgery. SSI incidence at 90 days post-operatively in bilateral incisions was 1.8% (n = 3/168) in the PICO and 4.8% (n = 8/168) in the standard dressing group, and in unilateral incisions 13.3% (n = 2/15) and 11.5% (n = 3/26), respectively (combined p = 0.49). No additional SSIs were diagnosed between 90 days and 1 year follow-up.

Walker (2018) – 50 patients having a knee amputation were randomised for this study, 25 in the PICO group and 25 in the standard dressing group. The primary end point occurred in 3 patients in each group, 2 conversions of below knee amputation to above knee amputation in each group, one shortening of an amputation in the PICO group and one haematoma wash out in the standard dressing group. There was no difference in wound infections between the two groups (28% vs 16%, p = 0.306)

Observational studies

Abadia et al. (2021) – Prospective cohort study of 200 patients undergoing elective colorectal surgery. No differences between the PICO and control groups were found. The incidence of SSI in the control dressing group was 19% versus 9% in the PICO group, which was substantially different (OR =

0.30, p = 0.02). No differences were found in hospital length of stay (12.33 days in PICO group vs. 12.39 days in the control group, p = 0.82).

Canton et al. (2020) – Study of 65 patients at risk of wound complications who underwent internal fixation for ankle fractures. The rate of minor and major complications between the two groups was not significantly different, although a positive trend towards a lower minor complications rate was noted in the PICO group (12.6% vs 34.7%). No complications or complaints were reported for the PICO dressing.

Chan et al. (2020) – Retrospective study of 154 patients who underwent brachiobasilic transposition arteriovenous fistula creation. 47 (30.5%) had PICO and 107 (69.5%) had conventional wound therapy. In the unmatched cohort, SSI incidence was lower in the PICO group (n = 1/47 [2.1%] vs n = 14/107 [13.1%], P = 0.035). However, incidence of SSI was comparable between PICO and conventional wound therapy after matching (n = 1/39 [2.6%] vs n = 9/78 [11.5%], P = 0.102). There was no significant difference in 30-day re-admission and 30-day mortality.

Facchin et al. (2021) – 26 post-bariatric female patients who underwent a brachioplasty followed by either a PICO (n = 14) or a standard wound treatment (n = 12) were analysed. None of the patients prematurely stopped treatment with PICO due to intolerance. The PICO patient group showed a significantly lower healing time as well as a significant reduction in the number of post-operative dressing changes and hospital stay.

Helito et al. (2020) – Study of 296 patients undergoing total knee arthroplasty. Patients who used PICO had a lower rate of complications (28.5% vs. 45.7%, p = 0.001) and a lower rate of reintervention in the operating room (2% vs. 8.5%, p = 0.001). Patients in the PICO group also had a lower incidence of hyperaemia (14.7% vs. 40.2%, p = 0.01), skin necrosis (2.1% vs. 8.5%, p = 0.04) and wound dehiscence (3.1% vs 10.1%, p = 0.03). The use of PICO was a protective factor for the presence of complications, with an odds ratio of 0.36.

Myllykangas et al. (2022) – This study included 82 patients treated with pectoralis major muscle flap for deep sternal wound infection. In the PICO group, the complication rate declined from 50.0% to 33.30%, major complication rate from 29.2% to 12.5%, and need for an additional flap from 14.6.% to 4.2% when compared to conventional treatment. The length of hospital stay decreased as well. Preoperative negative pressure wound therapy alone was associated with moderate decline in the complication rates.

Ryu et al. (2021) – Retrospective cohort study including 60 patients who underwent pre-pectoral breast reconstruction. The overall incidence of complications, major seromas, and frequency of reoperations were lower in the PICO group compared to the non-PICO group (18.9% vs. 52.2%, p = 0.007; 16.2% vs. 43.5%, p = 0.020; 2.7% vs. 26.1%, p = 0.006, respectively).

Tabley et al. (2020) – Study of cardiac surgery infections in 233 patients at high-risk. PICO was shown to provide both clinical and economic benefits over standard care across a range of different cardiac surgical patients. The rates of complications, including deep surgical wound infections and mediastinitis, were reduced.

Tormey et al. (2021) – Study included 162 patients who had breast surgery, 69 received standard dressing and 93 patients received PICO. In the cohort that received standard dressings, 30.4% of patients experienced complications. Following the implementation of the PICO device, this halved to 15.1%, a significant reduction (P=0.01). Analysis of complications by type showed that, with the exception of organ space SSI, the incidence rates of patients experiencing each type of complication were reduced with the application of PICO versus standard care.

Wikkeling et al. (2021) – Study included 108 patients who were treated for femoral endartectomy. Data of patients treated by standard care (n = 64) showed 32 (50%) patients developed complications. This reduced significantly in patients treated with PICO (n = 44), of whom eight (18.2%) developed a postoperative complication (p=0.0011). Average postoperative costs per patient were €3119 for those in the standard care group and €2630 in the PICO group.

4.5 Cost update

The company confirmed updated pricing for PICO, which is equivalent to a [redacted]. The EAG identified 6 economic studies done from a UK NHS perspective, 4 of which showed PICO dressings to be cost saving compared with standard dressings.

The internal team decided there was not sufficient change in the cost parameters to update the cost model. It understood that the technology price has increased since the original guidance but considered the increase to be in line with other cost increases since 2019. The effectiveness of PICO from the meta-analysis results has also changed. However, the internal team concluded that it is unlikely that an updated cost model would change the recommendations in the original guidance, which are not specific about the cost savings compared with standard dressings.

5. Summary of new information and implications for review

The new clinical evidence is consistent with the recommendations in the original guidance.

A cost update was not commissioned for this guidance review. Section 1 of the guidance is not very specific about the cost savings so it is unlikely that an updated cost model would change the recommendations unless the technology is shown to be cost incurring.

After the updated meta-analysis, the External Assessment Group concluded that the recommendation in the guidance regarding the reduction in surgical site infection remain valid. The internal team agreed and considered that with the new evidence it is unlikely an updated cost model would change the recommendations. Therefore, the review decision is to not change the guidance.

6. Implementation

The company reported that PICO negative pressure wound therapy is being used in [redacted]. It is used in the following types of surgery: orthopaedic, obstetric, gynaecological, colorectal, breast and cardiovascular. PICO is also used following other procedures which do not involve an incision.

7. Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

No equality issues were raised in the original guidance and no new equality issues were identified during guidance review.

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	N/A
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	N/A
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	N/A
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	N/A

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Notify the guidance for 'no change'	The guidance remains valid and is designated as no change needed. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	Yes
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

Appendix 2 – supporting information

Relevant Institute work

Published

NICE guideline NG125 Surgical site infections: prevention and treatment (2019, updated 2020)

NICE guideline CG179 Pressure ulcers: prevention and management (2014)

NICE guideline PH36 Healthcare-associated infections: prevention and control (2011)

NICE interventional procedures guidance IP467 Negative pressure wound therapy for the open abdomen (2013)

Registered and unpublished trials

Trial name and registration number	Details
The Effect of Negative Pressure Wound Therapy on Wound Healing in Major Amputations of the Lower Limb NCT04618406	Open-label randomised trial of 160 participants having major amputations of the lower limb Status: Recruiting Estimated completion date: December 2023
Negative Pressure Wound Therapy-PICO: Cosmesis in Repeat C-Sections NCT05266053	Randomised trial of 100 participants having caesarean Status: Recruiting Estimated completion date: July 2023
Evaluation of the PICO Negative Pressure Dressing System on the Fibula Free Flap Donor Site's Skin Graft. (PICOFLAP) NCT04628416	Randomised blinded multi-centre trial of 112 participants having skin graft Status: Recruiting Estimated completion date: December 2025
PICO- Single-use Negative Pressure Wound Therapy System NCT05064696	Randomised trial of 150 partipants having anterior total ankle arthroplasty Status: Recruiting Estimated completion date: September 2025

Trial name and registration number	Details
NPWT in Patients Undergoing Surgical Procedures for Management of GI Malignancies NCT04955730	Randomised trial of prolonged use of PICO in 300 participants having surgery for the management of GI malignancies Status: Recruiting Estimated completion date: December 2023
PICO above incisions after vascular surgery NCT01913132	Randomised trial of 644 participants with groin incisions after vascular surgery Status: Recruiting Estimated completion date: December 2024
PICO Negative Pressure Wound Therapy in Obese Women Undergoing Elective Caesarean Delivery NCT03414762	Randomised trial of 153 obese women undergoing elective caesarean delivery Status: Completed Study completion date: September 2022
Efficacy of Negative Pressure Wound Therapy After Total Ankle Arthroplasty (PICO-PTC) NCT03886818	Randomised trial of 48 participants who had total ankle arthroplasty Status: Recruiting Estimated completion date: March 2022
PICO 7 vs PICO 14 in Revision Hip and Revision Knee Surgery NCT05389410	Randomised trial of 100 participants having hip and knee replacements Status: Not yet recruiting Estimated completion date: November 2023
EvaLuating negAtive pressUre Wound theRapy in brEast coNserving Surgery (LAUREN) NCT05509829	Non-randomised trial of 300 participants having breast conserving surgery Status: Not yet recruiting Estimated completion date: December 2023

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