Evidence in focus

# PICO◊ sNPWT clinical compendium

PICO◊
Single Use Negative Pressure
Wound Therapy System

September 2023

Smith+Nephew

## Key for icons


Closed incisions


Chronic/open/ non-healing wounds


Health economics


Link to full **Evidence in focus** summary


Link to open access reference


Link to published abstract

### Evidence pyramid

Level 1

Level 2

Level 3

Level 4

Level 5

## Abbreviations

| | |
|---|---|
| **ABPI** | Ankle-brachial pressure index |
| **ASA** | American Society of Anaesthesiologists |
| **ASEPSIS** | A quantitative scoring system used to identify and classify SSIs |
| **BIMA** | Bilateral internal mammary artery |
| **BHIS** | Brompton and Harefield Infection Score |
| **BMI** | Body mass index |
| **CABG** | Coronary artery bypass graft |
| **CDC** | Centers for Disease Control and Prevention |
| **DFU** | Diabetic foot ulcer |
| **DSWI** | Deep sternal wound infection |
| **FEA** | Finite element analysis |
| **ITT** | Intention-to-treat |
| **LoS** | Length of stay |
| **LS** | Least squares |
| **MTG** | Medical technologies guidance |
| **NICE** | National Institute for Health and Care Excellence |
| **NNT** | Number needed to treat |
| **NPWT** | Negative pressure wound therapy |
| **OR** | Odds ratio |
| **POSAS** | Patient Observer Scar Assessment Scale |
| **PP** | Per-protocol |
| **PU** | Pressure ulcer |
| **QALY** | Quality adjusted life years |
| **RCT** | Randomised controlled trial |
| **RRR** | Relative risk reduction |
| **sNPWT** | Single use negative pressure wound therapy |
| **SSC** | Surgical site complication |
| **SSI** | Surgical site infection |
| **SWD** | Surgical wound dehiscence |
| **TAA** | Total ankle arthroplasty |
| **TEWL** | Transepidermal water loss |
| **TKA** | Total knee arthroplasty |
| **tNPWT** | Traditional negative pressure wound therapy |
| **VAS** | Visual analogue scale |
| **VLU** | Venous leg ulcer |
| **WUWHS** | World Union of Wound Healing Societies |

# Introduction

PICO◊ Single Use Negative Pressure Wound Therapy (sNPWT) has a strong evidence base.

To date, **316*** clinical publications (peer-reviewed manuscripts and conference abstracts) regarding PICO sNPWT have been identified (166 unique studies). This evidence compendium contains summaries of the most relevant publications; it does not include all the publications due to the volume of studies.

## Levels of evidence*


**60**

RCTs, meta-analyses, health economics evaluations of RCTs

(**+50** studies that note PICO sNPWT studies)


**19**

Prospective comparative observational studies


**35**

Retrospective comparative observational studies


**62**

Case series and case studies


**90**

Expert opinion, case studies or bench research

*Up to 18 May 2023. Evidence analysis report; EA/AWM/PICO/030/v3.

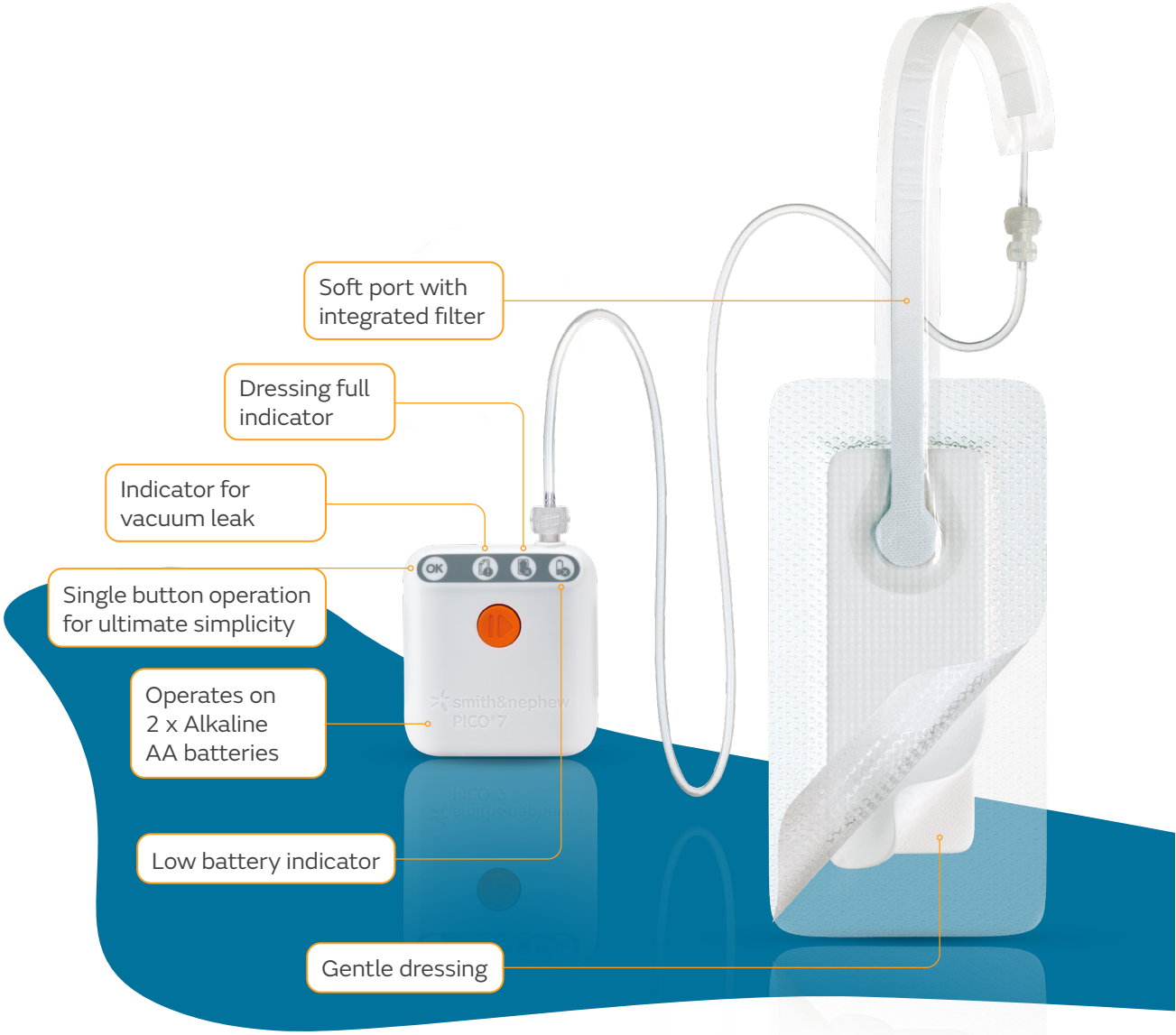
# PICO◊ sNPWT indication[1]

PICO sNPWT is indicated for patients who would benefit from a suction device (NPWT) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials.

Appropriate wound types include:

- Closed surgical incisions
- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts

PICO sNPWT systems are suitable for use both in a hospital and homecare setting.



# PICO◊ sNPWT multilayer dressing with AIRLOCK◊ Technology

Up to **80%** of the exudate is lost by evaporation[9]

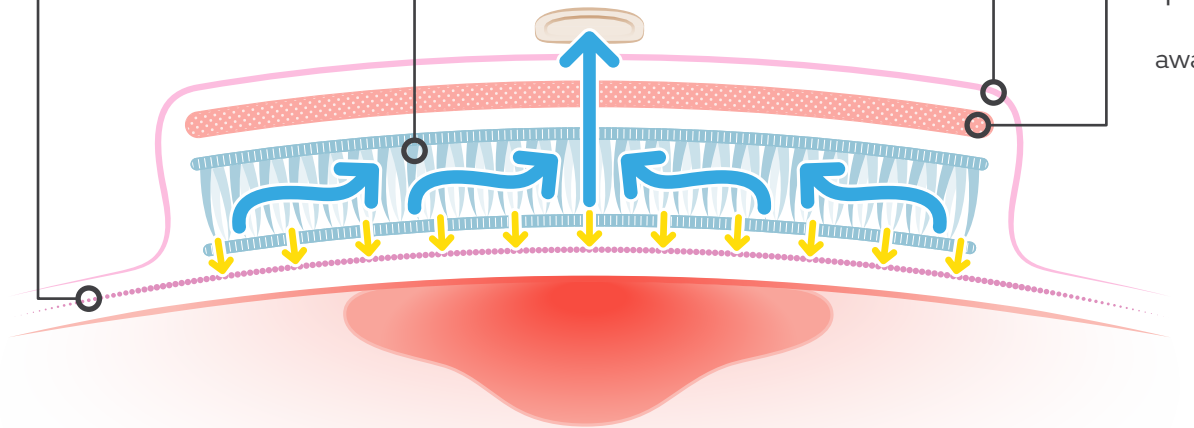
Up to **20%** of the exudate is absorbed by dressing[9]

**AIRLOCK layer**
Semi-rigid, honeycomb design maintains its form, even under pressure allowing air and fluid to flow* across the whole dressing area†[2–5]

**Top film layer**
has a high moisture vapour transmission rate and protects the wound from external contamination[6,7]

**Silicone adhesive layer**

**Super absorbent core**
locks exudate away from the wound[8]



*As demonstrated in benchtop testing. †As demonstrated in ex vivo studies.

# Consensus document/guidelines about prophylactic NPWT and PICO◊ sNPWT for closed surgical incisions

## World Health Organization

The World Health Organization recommends the use of prophylactic NPWT "in adult patients on primarily closed surgical incisions in high-risk wounds, for the purpose of the prevention of SSI, while taking resources into account."[10]

## World Union of Wound Healing Societies

WUWHS proposes NPWT is used in patients with closed surgical incisions who have intrinsic risk factors for SSCs or who have had a surgical procedure associated with higher incidence and/or higher consequence of SSCs.[11]

The 2019 *WUWHS Consensus Document on Wound Exudate: effective assessment and management*, recognises the benefits of sNPWT in the management of closed surgical incisions:[12]

- Provides a barrier to external contamination[11,12]
- Removes excess wound exudate[12]
- May aid healing by:[11,12]
  - Reducing lateral tension across the closed incision
  - Improving lymphatic drainage
  - Reducing the risk of wound infection and separation (dehiscence)

## National Institute for Health and Care Excellence (NICE)

NICE Medical technologies guidance: *PICO negative pressure wound dressings for closed surgical incisions* (MTG43).

NICE aims to improve health and social care in England through evidence-based guidance. NICE guidance helps people make efficient, cost-effective and consistent decisions about adopting new medical technologies. NICE guidance is internationally recognised.

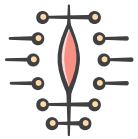
NICE recommends that PICO sNPWT should be considered as an option for closed surgical incisions in patients who are at high risk of SSIs.[13]

In a review of data from 31 clinical studies (15 randomised controlled trials and 16 non-randomised comparative observational studies), NICE concluded that PICO sNPWT is associated with fewer SSIs and seromas compared with standard wound dressings. Cost modelling suggests that compared with standard wound dressings, PICO sNPWT provides extra clinical benefits at a similar overall cost with standard wound dressings.[5]

## 510k clearance

PICO sNPWT is the first system indicated in the US to aid in reducing the incidence of both deep and superficial incisional SSIs as well as post-operative seroma and dehiscence for high risk patients in Class I and Class II wounds.[14]

# Introduction



**30%** of wounds persist for more than one year*[35]

1 year

Unhealed wounds cost on average **135%** more than wounds that have healed[36]

**PICO◊ sNPWT** has been shown to **significantly improve a variety of healing-related outcomes in a range of non-healing wounds indications**

| NON-HEALING WOUNDS | |
|---|---|
| VLU, DFU | Kirsner R, et al. (2019) |
| | Kirsner RS, et al. (2020) |
| | Patel A, et al. (2019) |
| DFU | Sharpe A, et al. (2018) |
| VLU, PU | Hampton J. (2015) |
| Dehisced surgical wounds | Hughes J, et al. (2020) |
| Hard-to-heal wounds of various aetiologies | Hampton J, et al. (2022) |
| | Hurd T, et al. (2020) |
| | McCluskey P, et al. (2020) |
| | Dowsett C, et al. (2017) |

Click on the author to navigate to study

When to use PICO sNPWT in non-healing wounds

*Data representing the National Health Service in the UK.

1. Kirsner R, et al.

# A prospective, randomised, controlled clinical trial on the efficacy of a single-use negative pressure wound therapy system, compared to traditional negative pressure wound therapy in the treatment of chronic ulcers of the lower extremities

Kirsner R, Dove C, Reyzelman A, Vayser D, Jaimes H. *Wound Repair Regen.* 2019;27(5):519–529.

## Overview

- A randomised, controlled, multicentre study conducted at 16 centres in the USA and two centres in Canada to evaluate efficacy and safety of PICO◊ sNPWT or tNPWT to manage lower extremity ulcers (>4 weeks in duration)
- In total, 161 patients were included in the ITT population (101 VLUs; 60 DFUs) and were randomised to receive either PICO sNPWT (n=80) or tNPWT (n=81)
  - The PP population (non-inferiority analysis) included 115 patients (PICO sNPWT, n=64; tNPWT, n=51)

## Results

- Reduction in wound area was significantly greater with PICO sNPWT than tNPWT in the PP population (88.7 vs 58.6% mean reduction; p=0.003) and the ITT population (p<0.001; Figure)
  - Significant LS mean reductions in wound area were also achieved with PICO sNPWT versus tNPWT in VLU (36.2%; p=0.007) and DFU (38.8%; p=0.031) subgroups
- Reductions in wound depth and volume in the PP and ITT populations (Figure) were also significantly greater with PICO sNPWT versus tNPWT (p<0.02, all comparisons)
- More patients had complete wound closure at 12 weeks with PICO sNPWT than with tNPWT (45 vs 22%; p=0.002; ITT population)
- Overall satisfaction with PICO sNPWT was significantly greater than with tNPWT

## Conclusions

In patients with VLUs and DFUs, PICO sNPWT significantly reduced wound area, depth and volume compared with tNPWT; complete closure of lower extremity ulcers at 12 weeks was more frequent with PICO sNPWT than with tNPWT.

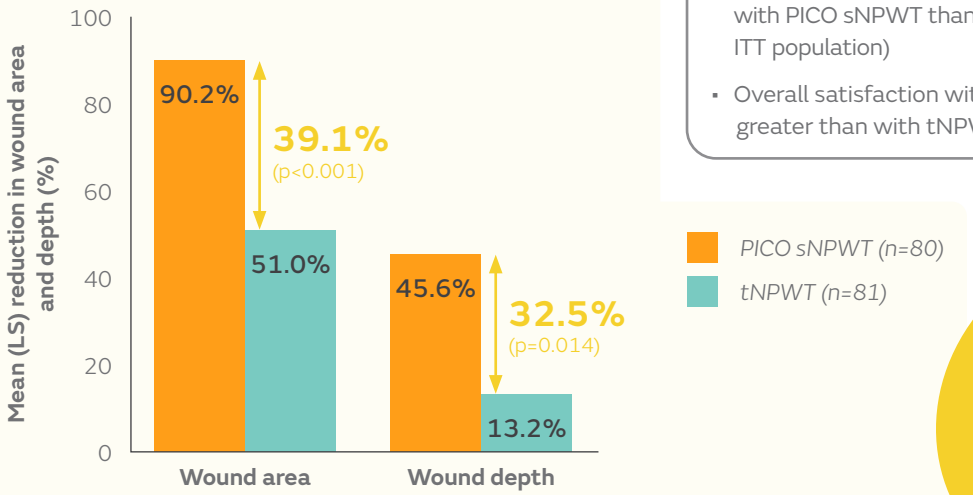



*Figure. Percentage reductions from baseline in wound area and depth with PICO sNPWT and tNPWT at 12 weeks* (ITT population; LS mean values)

**51%**
**relative increase in patients with complete wound closure**
at 12 weeks with PICO sNPWT versus tNPWT (p=0.002)

## 2. Kirsner RS, et al.

# A cost-effectiveness analysis comparing single-use and traditional negative pressure wound therapy to treat chronic venous and diabetic foot ulcers

Kirsner RS, Delhougne G, Searle RJ. *Wound Manag Prev*. 2020;66(3):30–38.

## Overview

- A cost-effectiveness evaluation of PICO◊ sNPWT and tNPWT in treating lower extremity ulcers (US payer perspective)
  - Time horizons of 12 and 26 weeks were used to show the effect on wound closure
- Analysis of data from Kirsner, et al., 2019 and US National 2016 Medicare claims

## Results

- For both ulcer types combined, switching from tNPWT to PICO sNPWT resulted in an estimated:
  - Expected cost saving per patient of $7,756 at week 12 and $15,749 at week 26
  - Decrease in total expected open ulcer weeks of 1.67 at week 12 and 5.31 at week 26
  - Increase in percentage of expected closed ulcers of 22.6% at week 12 and 31.0% at week 26
- Similar results were observed for VLUs and DFUs when analysed separately

## Conclusions

PICO sNPWT was estimated to be highly cost saving and reduced expected weeks to ulcer closure compared with tNPWT in patients with VLUs and DFUs, when analysed from a US payer perspective.

**$15,749** estimated cost saving per patient with PICO sNPWT versus tNPWT at week 26

## 3. Patel A, et al.

# Comparison of wound closure in chronic lower extremity ulcers between single use negative pressure wound therapy and traditional negative pressure wound therapy: a real-world analysis

Patel A, Delhougne G, Nherera L. Poster presented at: Wild on Wounds National Conference. September 11–14, 2019. Las Vegas, NV, USA.

### Overview

- Retrospective cohort study to assess wound closure rates with PICO◊ sNPWT and tNPWT in a real-world setting in patients with DFUs and VLUs
  - PICO sNPWT: DFUs (n=84); VLUs (n=62)
  - tNPWT: DFUs (n=86); VLUs (n=60)

### Results

- Compared with tNPWT, wound closure rates with PICO sNPWT were greater for all lower extremity ulcers (46.6 vs 34.9%; p=0.043)
  - Rates were also greater for DFUs and VLUs when analysed alone
- Compared with tNPWT, wounds treated with PICO sNPWT were 89% more likely to achieve closure (p=0.042)

### Conclusions

Lower extremity ulcers (DFUs and VLUs) of patients treated with PICO sNPWT were more likely to achieve wound closure than those treated with tNPWT in this retrospective analysis of real-world outpatient wound clinic data.

## 4. Sharpe A, et al.

# Using single use negative pressure wound therapy for patients with complicated diabetic foot ulcers: an economic perspective

Sharpe A, Myers D, Searle R. *Wounds UK*. 2018;14(4):89–93.

### Overview

- UK case series of four patients using PICO 7 sNPWT to help manage complicated DFUs
- Patients and carers self-assessed the dressing status using the dressing-full indicator
  - PICO 7 sNPWT (n=4)

### Results

- All four DFUs improved (mean ulcer area reduction, 49%), exudate levels were managed effectively and the frequency of dressing changes was reduced
- Total combined weekly clinician time saving using PICO 7 sNPWT was 279min (4hr 39min) for four patients
- Use of PICO sNPWT was estimated to release 13.5 clinician hours per patient on average over 12 weeks

### Conclusions

Frequency of clinician visits and dressing changes were reduced by using PICO 7 sNPWT to help manage DFUs, improving service delivery with potential efficiency savings compared with prior practice.

## 5. Hampton J, et al.

# Providing cost-effective treatment of hard-to-heal wounds in the community through use of NPWT

Hampton J. *Br J Community Nurs*. 2015;S14 (Suppl Community Wound Care): S16–S20.

## Overview

- Cohort case study involving patients with hard-to-heal VLUs and PUs treated in the community setting for >6 weeks
- Patients received PICO◊ sNPWT for 2 weeks followed by standard treatment appropriate for each wound
  - PICO sNPWT (n=9)

## Results

- Average weekly reduction in wound size was 21%
- With PICO sNPWT target wound size was achieved on average 10 weeks earlier than predicted with standard treatment
- In wounds that responded, wound size reduction was 6 times faster than predicted with standard treatment
- Mean savings of DKK 6,670 (€895)* per patient using PICO sNPWT compared with prior standard treatment

## Conclusions

Use of PICO sNPWT for 2 weeks helped to kick start the healing of chronic hard-to-heal wounds, which resulted in faster overall rates of healing and reduced costs compared with previous standard treatment.

*Exchange rate 1 EUR = 7.45550 DKK as of May 19, 2020.

6. Hughes J, et al.

# The burden of dehisced wounds in the community: using early results from a multi-centre service evaluation to propose a standard of care to improve patient outcomes and safeguard woundcare budgets

Hughes J, Costello M, Belshaw M, Horton H, Styche T. *Br J Health Care Manag.* 2020;27:16–25.

## Overview

- Analysis of a subset of 34 dehisced surgical wounds from a service evaluation of PICO◊ sNPWT
- The service evaluation adopted a previously published pathway for hard-to-heal wounds

*(Go to PICO sNPWT pathway)*

## Results

- After implementation of the PICO sNPWT pathway, 18 of 34 wounds (53%) healed within 12 weeks
  - Mean time to healing was 6.1 weeks
- Mean dressing change frequency reduced with use of PICO sNPWT from 4.7 to 3.2 times per week and remained at 3.3 times per week after returning to standard care
- Estimated savings of £16,577 for total wound care treatment over 12 weeks with PICO sNPWT versus standard care
  - Nursing time was reduced by 513 hours using PICO sNPWT compared with standard care

## Conclusions

Use of PICO sNPWT as part of a pathway for hard-to-heal wounds helped to support healing of dehisced surgical wounds, as well as reduce estimated total costs and release nursing time compared with prior standard care in this service evaluation.

**53%**
of dehisced wounds healed within 12 weeks

**513**
**nursing hours**
saved with PICO sNPWT versus standard care

**21.6%**
**estimated cost reduction**
with PICO sNPWT use versus standard care
(from £76,828 to 60,251)

7. Hampton J, et al.

# Multi-centre, international practice-based evidence using PICO◊ single-use negative pressure wound therapy: challenging current behaviours in wound care practice

Hampton J, Meagher H, Sharpe A, et al. *Wounds International*. 2022;13(2):46–53.

## Overview

- In service evaluation involving patients with non-healing wounds of various aetiologies:
  - Wounds were predominantly static or had minimal progression towards healing
  - Mean wound duration was 26.5 weeks
- 323 patients were treated with PICO sNPWT as part of a predetermined clinical pathway
- An economic model compared outcomes with the likely outcomes had PICO sNPWT not been employed

## Results

- Within 12 weeks of initiation of PICO sNPWT:
  - 52% of the wounds healed
  - Dressing change frequency reduced by a third (vs frequency before PICO sNPWT; 3.0 vs 4.7 times per week)
  - Costs were estimated to have reduced by 30% to £651 per patient

## Conclusions

With use of PICO sNPWT in a pathway for non-healing wounds, more than half of wounds had healed in 12 weeks and dressing change frequency was reduced compared with standard care. Overall wound care costs were estimated to reduce by around 30%.

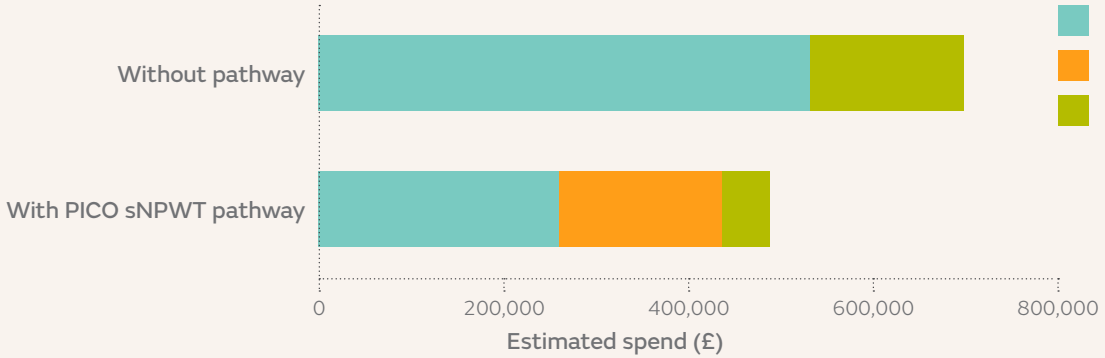



*Figure. Estimated total costs with and without use of the hard-to-heal pathway over 12 weeks (n=323)*

## 8. Hurd T, et al.

# Single use negative pressure wound therapy (sNPWT) in the community management of chronic open wounds deeper than 2cm

Hurd T, Gilchrist B. Poster presented at: Symposium on Advanced Wound Care/WHS Annual Meeting. July 24–26, 2020; virtual conference.

## Overview

- Retrospective two-year analysis of the healing of chronic open wounds >2cm deep (DFUs, VLUs, PUs and dehisced surgical wounds) in the home or community care setting following introduction of an integrated care bundle including PICO◊ sNPWT compared with standard care
  - PICO sNPWT (409 wounds; patients were significantly older with higher comorbidity score, both p<0.001)
  - Standard care (2,242 wounds)

## Results

- Use of PICO sNPWT to manage chronic open wounds >2cm compared with standard care resulted in:
  - Shorter mean healing times (46% relative reduction; 11.5 days)
  - Longer mean time between dressing changes (3.23 days)

## Conclusions

PICO sNPWT may help reduce healing times and frequency of dressing changes in chronic open wounds >2cm deep compared with standard care.

9. McCluskey P, et al.

# Impact of a single-use negative pressure wound therapy system on healing

McCluskey P, Brennan K, Mullan J, et al. *JCN*. 2020;34:36–43.

## Overview

- A service evaluation at seven centres in Northern Ireland and the Republic of Ireland
- Wound healing and health economic impact (in UK sterling and Euros) of using PICO◊ sNPWT versus standard care on hard-to-heal wounds over 12 weeks (or until healing) were assessed
- Median wound duration was 3–6 months; 36 wounds were included
- Eligible patients had:
  - Wounds >6 weeks in duration with no signs of clinical infection
  - <10% per week wound area reduction over 4 weeks
  - No NPWT in the last 6 weeks or contraindications for NPWT
  - ABPI >0.8 and <1.3 for VLUs

## Results

- Using PICO sNPWT, 20 of 36 wounds healed within 12 weeks (55.6%)
  - Mean healing time was 6.95 weeks
- Wound healing rate was greater for wounds with <3 months duration than those with ≥3 months duration (84.6 vs 71.4%; p=0.0125; Figure)
- Improvements in mean wound area per week with PICO sNPWT (-16.8%) continued after use (-18.9%)
- Dressing changes per week were less frequent with PICO sNPWT versus standard care (1.75 vs 3.56 changes; p<0.001)
  - They were also less frequent in the post PICO sNPWT phase (1.95 vs 3.56 changes per week; p<0.001)
- Use of PICO sNPWT was predicted to reduce costs versus standard care (Figure):
  - Total costs by 25% (£15,467) and 21% (€12,001)
  - Nursing resource costs by 59% (£31,494 and €27,517)

## Conclusions

In patients with hard-to-heal wounds, PICO sNPWT was most effective for wounds of <3 months in duration. It helped to reduce dressing change frequency and was predicted to reduce nursing resource costs compared with standard care.

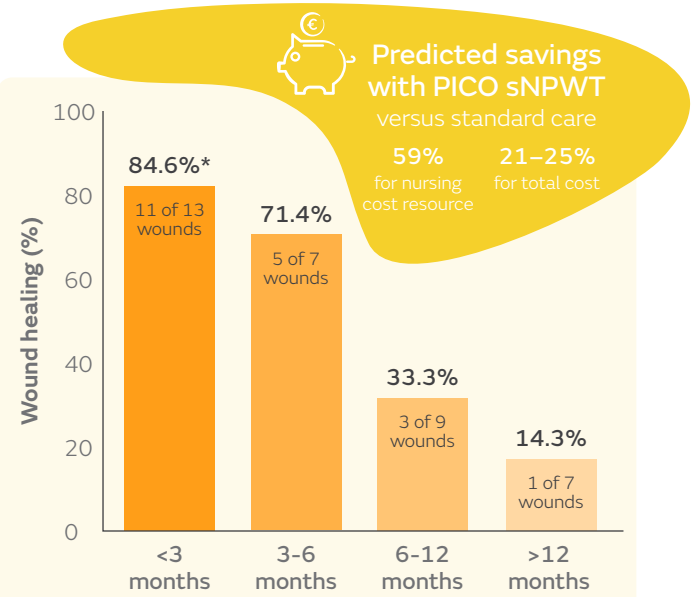



*Figure. Wound healing by duration of wound at baseline and predicted cost savings with use of PICO sNPWT (*p=0.0125)*

## 10. Dowsett C, et al.

# Use of PICO◊ to improve clinical and economic outcomes in hard-to-heal wounds

Dowsett C, Hampton J, Myers D, Styche T. *Wounds International.* 2017;8(2):52–58.

## Overview

- A prospective cohort study of 52 hard-to-heal wounds of varied aetiology and duration treated according to the PICO sNPWT pathway
  *(Go to PICO sNPWT pathway)*
  - Patients were switched from standard care to treatment with PICO sNPWT at week 0 for at least two weeks

## Results

- During PICO sNPWT treatment, wound area reduced by 13.4% more per week than pre-PICO sNPWT (p=0.006)
- After the PICO sNPWT phase, wound area reduced by 9.6% more per week than pre-PICO sNPWT (p=0.001)
- PICO improved the trajectory of wounds of over 1 year, and healing rates were almost three times greater in wounds of <3 months duration (94.1 vs 33.3%)
- Implementing the PICO sNPWT pathway was estimated to reduce total costs by 33.1% (£50,000) and release 119 nursing days over 26 weeks compared with predictions for standard care

## Conclusions

PICO sNPWT helped to significantly improve the healing trajectory of hard-to-heal wounds, resulting in reduced estimated costs and nursing time compared with previous standard care.

**119 days** Estimated released nursing days with PICO sNPWT compared with predictions for standard care

**33.1%** estimated cost reduction with PICO sNPWT compared with predictions for standard care

# Hard-to-heal pathway: when to use PICO◊ sNPWT

Figure adapted from **Dowsett C, et al. (2017)**

Back to Hughes J, et al.

Back to Dowsett C, et al.

## Entry criteria

- >6 weeks in duration
- <10% reduction in area per week over previous 4 weeks
- No NPWT in the last 6 weeks
- Not clinically infected*
- If VLU, ABPI confirmed as >0.8 and <1.3
- Not contraindications for negative pressure

Discontinue PICO sNPWT if contraindications are present

**Week 0 – Apply PICO sNPWT**

**Week 1 – Wound assessment and apply PICO sNPWT**

**Week 2, 3, 4 decision point**

### Weekly wound assessment

- Use simple length and width measures for areas and % healing calculation
- Change in exudate levels
- Change in granulation tissue (%)
- Change in pain levels

### Wound reduced in area by:

- <5% at week 2 (compared to week 0 area)
- <7.5% at week 3
- <10% at week 4

With no significant improvement in granulation tissue quality/quantity;† static (0%) or increased in size (deteriorated)

**Non-responder. Stop PICO sNPWT**

Wound requires further investigation or onward referal to a specialist service

**Wound reduced in area 10–40%**

**Use clinical and economic judgement to determine whether PICO sNPWT should be continued on a week-by-week basis**

Implement standard therapy when PICO sNPWT not in use

**Week 4–12 decision point -**
Continue weekly wound assessment

**Week 12 decision point -**
Final assessment and discontinuation from evaluation

**Wound reduced in area by >40%**

**Good responder. Stop PICO sNPWT**
(but can re-instate if wound healing rate stalls - at clinicians' judgement)

Implement standard therapy when PICO sNPWT not in use

*Wounds with overt signs of clinical infection (eg, increased pain, levels of exudate, cellulitis, etc) should be excluded from the evaluation. Colonised/critically colonised wounds are not excluded from the evaluation. Site standard protocol should be implemented to address bacterial burden.

†Wounds that have healed by <10% but have shown significant improvement in granulation tissue quality/quantity may be considered for further PICO sNPWT treatment based on clinician judgement.

# PICO◊ sNPWT provides NPWT at -80mmHg

Clinical guidelines and consensus groups recommend therapeutic negative pressure levels of **-50 to -150mmHg** for wound care[37,39]

**High or low** negative pressure levels are advised depending on exudate levels, wound type and pain experienced by patients[37,39,40]

PICO sNPWT consistently delivers negative pressure at **-80mmHg**, a level sufficient to manage most wounds with low to moderate exudate[40]

'There is seldom any reason to use a negative pressure greater than -80mmHg, but as the drainage of exudate may be improved at -125mmHg, this pressure level could be used during the initial treatment of highly exuding wounds.'[40]

PDF

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For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

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