NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

MTG Review Decision

Review of MTG34: SecurAcath for securing percutaneous catheters

This guidance was issued in June 2017.

NICE proposes an amendment of 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. However, the recommendations may 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.

1. Recommendation

Amend the guidance to reflect the changes to the costs around using SecurAcath and its comparator. These factual changes proposed have no material effect on the recommendations.

Update the format of the recommendations and insert a section below section 1 titled 'Why the committee made these recommendations', in line with the current template wording and presentation.

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

2. Original objective of guidance

To assess the case for adoption of SecurAcath for securing percutaneous catheters.

3. Current guidance

1.1. The case for adopting SecurAcath for securing peripherally inserted central catheters (PICCs) is supported by the evidence. SecurAcath is easy to insert, well tolerated, associated with a low incidence of catheter-related complications and does not usually need removing while the catheter is in place.

1.2. SecurAcath should be considered for any PICC with an anticipated medium- to long-term dwell time (15 days or more).

1.3. Cost modelling shows that SecurAcath is cost saving compared with adhesive securement devices if the PICC remains in place for 15 days or longer. Estimated cost savings range from £9 to £95 per patient for dwell times of 25 days and 120 days, respectively. Cost savings result from shorter maintenance times and less need for device replacement with SecurAcath. Annual savings across the NHS in England from using SecurAcath are estimated to be a minimum of £4.2 million.

4. Rationale

The original guidance recommended the use of SecurAcath for securing percutaneous catheters (PICCs) with an anticipated medium- to long-term dwell time of 15 days or more. In total, 9 new full text papers and 2 abstracts were identified that are in line with the decision problem for MTG34. For the cost case, there has been a reduction in the cost of SecurAcath since the publication of MTG34. There has also been a decrease in the cost of the comparator technology (StatLock) and associated nursing time costs. The technology remains cost saving for a PICC with an anticipated medium- to long-term dwell time. However, the threshold analysis showed that SecurAcath was only cost saving if used for 21 days or more.

5. New evidence

The search strategy from the original assessment report was re-run. References from June 2017 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.

5.1 Technology availability and changes

The company confirmed that there are no changes to the technology, but stated that two new, larger sizes (10F and 12F) are now available. The technology is now available in eight sizes. The technology and comparator technology has reduced in price. The CE mark and indication remains unchanged.

5.2 Clinical practice

No new care pathways or significant changes to clinical guidelines relating to SecurAcath have been identified. The most relevant clinical guideline, Healthcare-associated infections: prevention and control in primary and community care (CG139, 2017), was updated in the same year as MTG34 was published. It makes no recommendations relating to catheter securement for the prevention of infection associated with vascular access devices.

Three experts were contacted and none of them identified any changes to clinical practice. All experts used SecurAcath for securing PICC lines. Two experts stated that this is the only subcutaneous anchoring device as other vascular access securement devices are adhesive based. All of the experts stated that special training is needed for the insertion and removal of SecurAcath, one expert mentioned that there are training videos for this. Pain can be experienced at the insertion site and there can be difficulties in removing the device. One expert stated that this pain is a result of poor insertion technique and that a lack of training could lead to more traumatic removal of the device. Two experts said that they are cautious of allergies, such as nickel, when considering using SecurAcath. Follow up correspondence with 2 experts found that medium-to-long term dwell time in practice is usually for a minimum of 3 months and up to 6 to 12 months. The experts said that in these instances it is usually known how long a PICC line will be in place for due to the treatment programme needed, such as chemotherapy, unless there are complications or the treatment plan is changed.

5.3 NICE facilitated research

None.

5.4 New studies

The updated literature searches identified 9 new full text papers and 2 abstracts which were considered relevant to the decision problem. These included:

- 2 prospective comparative studies with retrospective data used as a comparator (Culverwell et al. 2020 and Fitzsimons et al. 2020)
- 1 prospective comparative study (Dolcino et al. 2017)
- 1 retrospective comparative cohort study (Rowe et al. 2020)
- 2 prospective single arm cohort studies (D'Andrea et al. 2021 and Barone et al. 2020)

- 1 paper reporting on 3 different prospective single arm cohort studies (Pittiruti et al. 2019)

- 2 single arm retrospective cohort studies (Brescia et al. 2021 and Crocoli et al. 2021)

- 2 conference abstracts, one reporting a comparative service evaluation and one reporting a single arm observational study (Kay et al. 2020 and Pittiruti et al. 2016, retrospectively).

The studies reported used PICCs (n=5, including one abstract), central venous catheters (CVCs, n=3) and a mixture of both PICCs and CVCs (n=5, including one abstract). Four studies (D'Andrea et al. 2021, Crocoli et al. 2021 and Pittiruti et al. 2019 [studies B and C]) also reported on femorally inserted central catheters (FICCs), but results were aggregated with those for CVCs and PICCs. The EAC overall concluded that there is insufficient evidence to update the guidance. The full clinical evidence review report can be found in the EAC's review report.

NICE updated the literature search in February 2022 and found no additional studies to those reviewed by the EAC.

5.5 Cost update

There has been a reduction in the cost of the technology since the publication of MTG34, from £20 to £18, due to the inclusion of SecurAcath as part of the MedTech Funding Mandate. There has also been a decrease to the cost of the comparator technology (StatLock; from £3.47 to [redacted]) as well as associated nursing time costs (nurse time per minute decreased from £2.08 to £0.83 based on PSSRU Unit Costs of Health and Social Care 2019/20).

During the guidance review process, an error was identified in the original economic model. The economic model was corrected by KiTEC EAC during the review to account for the weekly replacement of StatLock devices. The correction did not impact on the overall conclusions of the original economic model.

The EAC updated the costs included in the corrected original model and found that SecurAcath was still cost saving for medium to long dwell times of PICC lines but that the extent of cost saving was reduced to a cost savings range from [redacted] to [redacted] per person for dwell times of 25 days and 120 days, respectively.

The full costing update can be found in the EAC's cost update report.

6. Summary of new information and implications for review

The new clinical evidence is unlikely to have a material effect on the recommendations in the published guidance as the new evidence is not high quality and reports results from mixed populations and uses. The new published evidence supports the committee's clinical conclusions from the original guidance. The evidence reports a low level of catheter related complications (including low levels of dislodgements, catheter migration and blood stream infections). None of the comparative studies found statistically significant differences in migration or dislodgement between arms. The EAC found that the new clinical evidence was not robust enough to prompt changes to the clinical parameters of the economic model. The EAC updated the costs in the model and found that the SecurAcath was still cost saving for PICCs with a medium to long term dwell time but to a lesser extent than in the original guidance. Given that 2 experts consider medium-to-long term dwell time in practice to be a minimum of 3 months and up to 6 to 12 months, the impact of this difference in cost is likely to be very small.

7. Implementation

The company's updated information states that around 142 NHS England hospitals use SecurAcath. SecurAcath was on the Innovation and Technology payment (ITP) programme and is now on the NHS MedTech funding mandate.

8. 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. 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.	No
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.	Yes
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

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'**
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. 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.	N/A
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	N/A
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	N/A

Appendix 2 – supporting information

Relevant Institute work

Published

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

Healthcare-associated infections: prevention and control in primary and community care (2012, updated 2017) NICE guideline CG139

The Sherlock 3CG Tip Confirmation System for placement of peripherally inserted central catheters (2015, updated 2019) NICE medical technologies guidance 24

The 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites (2015, updated 2019) NICE medical technologies guidance 25

Biopatch for venous or arterial catheter sites (2017) NICE medtech innovation briefing 117

SecurePort IV tissue adhesive for use with percutaneous catheters (2022) NICE medtech innovation briefing 288

In progress

None identified.

Registered and unpublished trials

Trial name and registration number	Details
Securing Central venous catheters to prevent catheter Dislodgment in children: the SECURED trial (ACTRN12620000783921)	RCT feasibility study (n=60, 30 in each arm). Intervention: SecurAcath Comparator: sutureless securement devices Children (neonate up to 18 years of age) requiring PICC insertion presenting with altered skin integrity and/or insertion of tunnelled non-cuffed CVC. Recruiting, date of last data collection not reported.

Trial name and registration number	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Appendix 3 – changes to guidance

Table 1: proposed amendments to original guidance

Section of MTG	Original MTG	Proposed amendment
1.1	The case for adopting SecurAcath for securing peripherally inserted central catheters (PICCs) is supported by the evidence. SecurAcath is easy to insert, well tolerated, associated with a low incidence of catheter-related complications and does not usually need removing while the catheter is in place.	SecurAcath is recommended as a cost-saving option for securing peripherally inserted central catheters (PICCs) with an anticipated medium- to long-term dwell time.
Why the committee made these recommendations		The evidence showed that SecurAcath is at least as good as other devices for securing peripherally inserted central catheters (PICC) with the benefit of not needing to be replaced at weekly dressing changes. It is also found to have a high rate of successful device placement and a low incidence of catheter-related complications. Cost modelling shows that SecurAcath is cost saving compared with adhesive securement devices if the PICC remains in place for 21 days or longer. Cost savings result from shorter maintenance times and less need for device replacement when using SecurAcath.
1.2	SecurAcath should be considered for any PICC with an anticipated medium- to long-term dwell time (15 days or more).	[section to be removed to be consistent with current template style and format]

1.3	Cost modelling shows that SecurAcath is cost saving compared with adhesive securement devices if the PICC remains in place for 15 days or longer. Estimated cost savings range from £9 to £95 per patient for dwell times of 25 days and 120 days, respectively. Cost savings result from shorter maintenance times and less need for device replacement with SecurAcath. Annual savings across the NHS in England from using SecurAcath are estimated to be a minimum of £4.2 million.	[Section to be removed to be consistent with current template style and format]
2.5	The list price of SecurAcath stated in the company's submission is £16.00 excluding VAT. During development of the guidance, the company updated the UK list price of SecurAcath to £20.00.	The list price of SecurAcath stated in the company's submission is £16.00 excluding VAT. During development of the guidance, the company updated the UK list price of SecurAcath to £20.00. The cost of SecurAcath has been updated in the revised cost model to £18 excluding VAT [2022].

5.9	NICE has published a resource impact report on SecurAcath. The estimated annual cost saving across the NHS in England is a minimum of £4.2 million, based on hospital episode statistics for the number of PICCs inserted.	NICE has published a resource impact template on SecurAcath which can be used to calculate the local resource impact of implementing the guidance.
5.25		For the guidance review, the EAC revised the model to reflect 2021 costs. Further details of the revised model are in the cost update in the review decision.
5.26		During the review, the original economic model was corrected so that the model accounted for the weekly replacement of StatLock devices. This meant that in the original guidance SecurAcath should have been cost saving by £12.60 to £148.54 for PICCs with medium to long term dwell times, respectively.
5.27		Based on the 2022 guidance review updated cost model, the EAC updated the costs included in the original model. It found that SecurAcath was still cost saving for medium and long dwell times of PICC lines but that the extent of cost saving was reduced compared to the original guidance. Cost savings result from shorter maintenance times and less need for device replacement with SecurAcath.