

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation document

SecurAcath for securing percutaneous catheters

The National Institute for Health and Care Excellence (NICE) is producing guidance on using SecurAcath for securing percutaneous catheters in the NHS in England. The Medical Technologies Advisory Committee has considered the evidence submitted 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 draft recommendations made by the committee. NICE invites comments from the public. This document should be read along with the evidence base (see sources of evidence considered by the committee).

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 effectiveness and resource savings reasonable interpretations of the evidence?
- Are the provisional 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 SecurAcath for securing percutaneous catheters. 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 public consultation. After considering these 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 guide](#) and [Medical Technologies Evaluation Programme methods guide](#).

Key dates:

- Closing time and date for comments: 09:00 20 February 2017
- Second Medical Technologies Advisory Committee meeting: 17 March 2017

NICE medical technologies guidance addresses specific technologies notified to NICE by sponsors. 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, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

1 Provisional recommendations

- 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 replacing while the catheter is in place.
- 1.2 SecurAcath should be considered for any PICC inserted for an anticipated medium to long-term dwell time (15 days or more).
- 1.3 Cost modelling shows that SecurAcath leads to cost savings if the PICC remains in place for 15 days or longer. Estimated cost savings range from £13 to £99 per patient for dwell times of 25 days and 120 days, respectively. Cost savings result from shorter maintenance times and a reduced need for device replacement with SecurAcath when compared with adhesive securement devices. Annual savings across the NHS from using SecurAcath are estimated to be around £2 million.

2 The technology

Description of the technology

- 2.1 SecurAcath (Interrad Medical) is a single-use device to secure percutaneous catheters in position on the skin. It is intended for use in adults and children who need a central venous catheter (CVC), a

long, thin, flexible tube that is inserted into a vein through the skin and positioned so that the distal tip lies in the superior vena cava.

2.2 CVCs are inserted using various access sites, including veins in the arm, chest, neck or groin; the choice in individual patients depends on a variety of factors such as anticipated duration of access needed (dwell time), reason for insertion and the quality and patency of venous sites available. There are 4 types of CVCs ([Dougherty et al. 2015](#)):

- Peripherally-inserted central catheters (PICCs): CVCs inserted into a peripheral vein in the arm, rather than in the neck or chest. PICCs may be used for short-term access (7 to 10 days), but are more typically used in people needing intravenous access for several weeks or months. They are used in inpatient and outpatient settings.
- Non-tunnelled CVCs: Short-term CVCs placed into a large vein near the neck, chest, or groin. Non-tunnelled CVCs are indicated for short-term access (usually 7 to 10 days) when peripheral access is impractical or in acute, urgent situations. Non-tunnelled CVCs need securing at the site of insertion.
- Tunnelled CVCs (also called Hickman lines): CVCs that are passed under the skin (tunnelled) from an insertion site near the neck or chest to a separate exit site, which helps to prevent infection and provides stability. Tunnelled CVCs are indicated for long-term access (more than 30 days) and do not need additional securing after the 'cuff' of the tunnel has healed.
- Implanted ports: CVCs placed entirely under the skin which are used for long-term therapies. Implanted ports have a lower incidence of complications compared with their length of use, have minimal risk of infection and do not need securing.

- 2.3 For the purposes of this guidance, CVCs referred to here are non-tunnelled CVCs that are usually inserted on a short-term basis and need securing to the skin to avoid displacement.
- 2.4 SecurAcath has 2 components, a base and cover. The base is made up of 2 foldable arms and 2 metal tips. The tips are inserted under the skin at the catheter insertion site, and are unfolded to form a subcutaneous anchor. The cover attaches to the catheter shaft and holds it in place when it is clipped onto the base. The device stays in place as long as the catheter is needed and can be lifted off the skin to allow full cleaning of the insertion site.
- 2.5 SecurAcath is a class IIB device first CE marked in 2012. It is available in 6 different sizes (3 F to 8 F). The smallest possible size should be used, depending on the size of catheter.
- 2.6 The list price of SecurAcath stated in the company's submission is £16.00.
- 2.7 The claimed benefits of SecurAcath in the case for adoption presented by the company are:
- no interruptions or delays in therapy because of improved catheter securement
 - fewer repeat procedures by improving vessel preservation and reducing reinsertions
 - fewer catheter complications (dislodgements, migration, thrombosis and infection)
 - a decrease in catheter replacement costs
 - a reduction in overall treatment costs because of fewer delays and complications.

Current management

- 2.8 Current options for catheter securement include adhesive devices (such as StatLock and Grip-Lok), steri-strips, tape and sutures (stitches).
- 2.9 NICE has not produced guidance on securing catheters for central venous access. The NICE guideline on [infection control](#) recommends that the skin at and around the catheter insertion site is cleaned with chlorhexidine gluconate in 70% alcohol and allowed to air dry during dressing changes. The insertion site should be covered by a sterile transparent semipermeable membrane dressing which should be changed every 7 days or sooner if the dressing is no longer intact or moisture collects under it.
- 2.10 Guidelines produced by the British Committee for Standards in Haematology on the [insertion and management of central venous access devices in adults](#) (Bishop et al. 2007) recommend using securing devices such as StatLock in preference to sutures, and discourage the suturing of catheters to the skin. A number of NHS trusts have produced local guidance on using catheter securement devices including SecurAcath.
- 2.11 The US Infusion Nursing Society's [Infusion Standards of Practice \(2016\)](#) refers to engineered stabilisation devices such as SecurAcath and StatLock. While it makes no formal recommendations on their use, it states that engineered stabilisation devices should be considered for vascular access devices because of the harmful consequences of inadequate stabilisation and securement. It also says that engineered stabilisation devices promote consistent practice among clinicians, reduce vascular access device motion that can lead to complications, reduce the number of interruptions needed for infusion therapy, and may lower costs of care. The document recommends that tape or sutures should be avoided because they

are not as effective as engineered stabilisation devices, based on good quality evidence from randomised controlled trials.

3 Clinical evidence

Summary of clinical evidence

3.1 The key clinical outcomes for SecurAcath presented in the decision problem were:

- rates of catheter migration and dislodgement
- rates of catheter-related infection, including catheter-related bloodstream infection, local infection or inflammation and thrombophlebitis
- number of unplanned catheter removals and reinsertions
- time taken to secure the catheter
- patient and clinician satisfaction scores
- pain while in situ and on insertion and removal
- quality-of-life measures
- device-related adverse events for example catheter malfunction, thrombosis and vessel erosion.

3.2 The external assessment centre assessed 11 studies on SecurAcath, 9 submitted by the company and 2 identified independently. Three SecurAcath studies were published as peer-reviewed journal articles (Cordovani and Cooper 2013; Egan et al. 2013; Hughes et al. 2014), the remaining 8 studies were unpublished manuscripts, poster presentations, audit reports or conference abstracts (Janssens et al. 2016b; Djurcic-Jovan et al. 2016; Dougherty et al. 2013; Hill et al. 2014; Misericordia et al. 2015; Zerla et al. 2016; Stone et al. 2013; McParlan et al. 2016). The external assessment centre also identified, in addition to those presented in the company's submission 6 studies on a comparator, StatLock (Fang et al. 2011; Teichgräber et al. 2011; McMahon et

al. 2002; Yamamoto et al. 2002; Zerla et al. 2015; Venturini et al. 2011).

Published studies with SecurAcath

- 3.3 Cordovani and Cooper (2013) is a prospective multicentre cohort study done in Canada, which investigated 74 adults who had central venous catheters (CVCs) secured with SecurAcath. The primary outcome was device securement success, which was reported in 72 patients (97%). Mean catheter securement time was 62.5 seconds and the mean dwell time was 3.1 days. Discomfort was measured on a 1 to 10 scale (with 10 being most discomfort): mean scores were 0.9 in situ and 1.6 at removal. Of the 15 patients who had previously had a sutured catheter, 14 found SecurAcath 'as or more comfortable'. Six out of 8 healthcare professionals found maintenance 'somewhat' or 'much easier' than sutures.
- 3.4 Egan et al. (2013, and its earlier iteration Sansivero [2011]) investigated peripherally inserted central catheters (PICCs) secured with SecurAcath in 68 adults in intensive care units, transplant units or outpatient clinics. The primary end point was device securement success, defined by the absence of device-related malfunctions and adverse events. Secondary end points included securement time, patient comfort and ease of maintenance. Mean dwell time was 22.6 days and mean securement time was 31 seconds. Securement-related malfunctions were seen in 6 patients (8.8%), with 20 (22.1%) adverse events reported. Pain scores were measured on a 0 to 10 scale: immediately after device removal, the mean pain score was 1.5. In situ mean pain score was 0.7 and 91.2% of patients were either neutral, satisfied or very satisfied with SecurAcath. Use of SecurAcath did not influence placement or maintenance techniques. The authors concluded that SecurAcath performed favourably when compared with StatLock (on the basis of historical data for Statlock reported by Yamamoto et al. [2002]: respective

rates of migration and dislodgement of 2.9% and 0% for SecurAcath and 6% and 12% for StatLock).

- 3.5 Hughes et al. (2014) prospectively evaluated PICCs with SecurAcath in 31 adults. Mean dwell time was over 30 days in 45% of patients. The study reported 100% successful device placement; 11% were placed with 'difficulty' and 19% with 'slight difficulty'. Staff reported difficulty with removal 'fairly frequently'. One patient experienced catheter migration of 1 cm. Pain scores were measured on a 0 to 10 scale. At placement, pain scores were 0 in all patients; in situ, 5 patient's scores were over 5, and at removal over half of patient's scores were over 3. PICCs were removed in 3 patients because of severe or unresolved pain. The study reported a PICC-related infection rate of 12% (n=31), which was reduced to 2% in a subsequent cohort (n=100).

Unpublished studies and conference abstracts with SecurAcath

- 3.6 Janssens (2016b) is a Belgian-based, single-centre, prospective, unblinded, randomised controlled trial comparing PICCs secured with SecurAcath and PICCs secured with StatLock in adults. The outcomes included time spent on dressing changes, catheter migration, accidental dislodgement and laboratory-confirmed catheter-related bloodstream infection. The study was submitted as an unpublished manuscript which was available to the committee as academic in confidence.
- 3.7 Djurcic-Jovan et al. (2016) is a single-centre retrospective, observational, comparative, longitudinal study done in Canada comparing PICCs placed with and without SecurAcath in 54 patients needing complex continuing care. The primary outcome measure was unplanned catheter reinsertion. Mean dwell time was over 31 days. There were 60 unplanned catheter reinsertions reported without using SecurAcath compared with 3 unplanned reinsertions with SecurAcath. There was no catheter migration

reported. The authors observed substantial time savings for nurses and physicians after the introduction of SecurAcath. Qualitative outcomes were collected retrospectively. For SecurAcath, catheter migration was rated 'very good' or 'good' in 88% of cases, and catheter stability while doing insertion site maintenance, ease of dressing, and overall use of the device were rated as 'very good' or 'good' in 95% of cases.

- 3.8 Dougherty et al. (2013) is a UK-based single-centre prospective study with no comparator which evaluated PICCs secured with SecurAcath over 1 month in 30 patients. Qualitative data were gathered from nurses and patients. There was a reduction in malposition and catheter damage compared with previous practice and no skin reactions were seen. Nurses reported increased confidence in doing insertion site maintenance but also reported some difficulty removing the device. Patients reported pain at insertion ('if incorrectly placed and the anchor was too superficial') and pain at removal.
- 3.9 Hill (2014) is a Canadian-based single-centre pilot evaluation of PICCs secured with SecurAcath in 60 patients without a comparator. The author reported no malpositions but accidental dislodgement in 2 agitated patients. The author described dressing changes as being done by 'general unit staff, not IV team staff': SecurAcath gave staff increased confidence, fewer anxieties and increased efficiencies. The author described the successful use of SecurAcath in patients with skin integrity issues, when the device was used without adhesive dressing. The author concluded that overall patient satisfaction was achieved.
- 3.10 Misericordia et al. (2015, reported as Anonymous 2015 in the assessment report) is an unpublished report provided by the company. This is a retrospective, comparative audit done by the parenteral therapy team at the Misericordia Community hospital in

Canada which evaluated 164 unanchored PICCs placed during 2013 and 542 PICCs placed during 2014 and secured with SecurAcath. The average dwell time was 29 days. The report also evaluated using a PICC designed to reduce catheter-related thrombosis. Six different operators took part in the evaluation. The primary outcomes were catheter-related thrombosis, PICC occlusion, catheter malposition, local infection and catheter-related bloodstream infection. In the SecurAcath cohort, there were no confirmed catheter-related bloodstream infections. From 2013 to 2014, the rate of catheter-related thrombosis decreased from 3.75% to 3.69%, PICC occlusion increased from 14.35% to 16.97%, and malposition decreased from 10.98% to 1.66%. The authors concluded that without using SecurAcath, around 60 of the 542 patients would have otherwise needed catheter replacements.

3.11 Zerla et al. (2016) is a single-centre prospective study with no comparator, which investigated 30 adults needing chemotherapy who had a PICC in place for over 2 months secured with SecurAcath. The median dwell time was 145 days. Skin integrity issues were reported in 32.2% of patients. Pain scores were measured on a 0 to 10 scale: at placement pain scores were less than or equal to 2 in 90% of patients, in situ they were less than or equal to 2 in 98.7% of patients and at removal they were less than or equal to 2 in 66.7% of patients. The authors report a median insertion site maintenance time of 10 minutes for SecurAcath, which compared favourably with a median of 20 minutes maintenance time for an adhesive device in a historical cohort of patients. No catheters were dislodged. The authors concluded that, after effective training, SecurAcath can be safely used in patients with cancer who need long-term catheterisation and ambulatory maintenance. It is comfortable and reduces catheter movement.

3.12 Stone et al. (2013) is a prospective, single-centre study which included PICCs secured with SecurAcath in 42 children with

previous skin problems, irritation or allergic reactions to standard dressings. The authors compared outcomes with historical data on 17 patients with catheter migration in the same centre (undefined cohort). In the SecurAcath cohort, there were no catheter migrations, complications or unplanned catheter removals. The authors concluded that further research was needed to optimise dressings in patients with skin integrity issues.

- 3.13 McParlan et al. (2016) is a single-centre, UK prospective cohort study comparing PICCs secured with SecurAcath and with StatLock in haematology and oncology patients, published as a conference abstract. The full study was submitted as an unpublished poster which was available to the committee as academic in confidence. The abstract states that, during the study, there were no reported incidences of migration or PICC removal. This was associated with a reduction in chest x-rays to verify the location of migrated catheter tips, a reduced need for re-insertions, decreased patients' exposure to radiation and reduced delays to therapy. The study reported significant financial benefits due to fewer PICC re-insertions and more efficient dressing changes. Additional benefits include reduced skin reactions, improved cleansing of the catheter site and greater user satisfaction. The abstract authors concluded that using SecurAcath had prevented PICC migration and improved patient outcomes.

Additional work by the external assessment centre

- 3.14 The external assessment centre noted the lack of comparative published evidence between SecurAcath and its comparators. It considered the unpublished randomised controlled trial (Janssens et al. 2016b) to be the most relevant evidence to inform the decision problem.
- 3.15 The external assessment centre conducted a meta-analysis using data from 16 studies on 5 clinical outcomes that it considered

appropriate: migration, dislodgement, catheter-related infection, catheter-related bloodstream infection and unplanned removals/reinsertions. Because of the limited evidence base, there was significant uncertainty in the results, reflected in wide 95% confidence intervals (95% CI). The meta-analysis reported the following results comparing SecurAcath and StatLock: migration: 4.00% (95% CI: 1.48 to 8.50) and 4.72% (95% CI: 2.28 to 8.50); dislodgment: 0.59% (95% CI: 0.3 to 1.03) and 4.07% (95% CI: 3.29 to 4.97); catheter-related infection: 0.77% (95% CI: 0.28 to 1.66) and 1.64% (95% CI: 1.10 to 2.35); catheter-related bloodstream infection: 1.68% (95% CI: 0.20 to 5.94) and 1.47% (95% CI: 0.18 to 5.21). The external assessment centre considered the meta-analysis to be supportive of the results of Janssens et al. 2016b (with the exception of dislodgement, where the meta-analysis showed a difference in dislodgement rates), with similar clinical outcomes between devices.

Committee considerations

- 3.16 The committee considered that the available evidence, despite its limitations, was sufficient to conclude that SecurAcath was associated with a high rate of successful device placement, a low incidence of catheter-related complications and does not usually need replacing while the catheter is in place. The committee also considered that the emerging comparative evidence suggested that SecurAcath is at least as effective as other securement devices for securing PICCs, with the added benefit of not needing to be replaced at weekly dressing changes.
- 3.17 The committee received advice from experts who use SecurAcath to secure PICCs in haematology and oncology patients in both inpatient and outpatient settings. The experts highlighted that PICCs in these patients have long dwell-times of at least 6 months, and can be in place for up to 1 year.

- 3.18 The committee was advised by the experts that SecurAcath is well tolerated by patients when placed by an experienced healthcare professional. Pain is rare on insertion, as local anaesthetic is used anyway during the initial PICC placement. Pain is also rare while the device is in place, provided that it has been placed correctly. SecurAcath removal involves using scissors to cut the device in half and local anaesthetic administration is very rarely needed. One expert stated that with regard to patient satisfaction, any discomfort patients experienced with using SecurAcath was countered by a reduction in anxiety associated with a lower likelihood of catheter displacement during dressing changes.
- 3.19 The committee was informed by the experts that it is routine practice to anticipate the likely dwell time of PICCs at the time of insertion, based on the individual patient and clinical circumstances. It is possible that this consideration would inform the specific line-securement method selected in normal clinical practice. Although PICCs are sometimes in place for less time than anticipated, this is usually because of unexpected complications that necessitate early line removal or replacement.

4 NHS considerations

System impact

- 4.1 The company claimed that SecurAcath could lower costs by avoiding delays in treatment and reducing catheter-related complications.
- 4.2 Experts considered that specialist training was needed for the insertion and removal of SecurAcath. Removal of the device was identified as the most challenging element in using the device.
- 4.3 NICE has produced an adoption and impact scoping report on SecurAcath, which describes the barriers and levers to using

SecurAcath for the securement of peripherally inserted central catheters in 6 NHS organisations.

Committee considerations

- 4.4 The committee was advised by experts that dressing changes are needed at the catheter insertion site on a weekly basis and that a considerable amount of time is saved by using SecurAcath compared with StatLock for the maintenance of long-term PICCs. Dressing changes are much quicker and easier and there is a reduced risk of catheter dislodgement with SecurAcath.
- 4.5 The committee concluded that training was essential for the correct use of SecurAcath and experts advised that there is a learning period of about 1 month of regular use before becoming proficient. Training is provided free of charge by the company and consists of face-to-face instruction by clinical nurse advisers as well as online support from a downloadable application.
- 4.6 SecurAcath is contraindicated in people with nickel allergy. One expert stated that in their experience, true nickel allergy is rare and they had not encountered an allergic reaction to SecurAcath in their practice. It was also stated by the experts that patients may experience sensitivity to adhesive dressings.
- 4.7 The experts stated that they had no experience of using SecurAcath in young children (who tend to have tunnelled central venous catheters), but 1 had used it successfully with older children (aged 12 years and over) having chemotherapy.
- 4.8 One expert highlighted that bleeding after SecurAcath placement can happen, so additional dressings may be needed.

5 Cost considerations

Cost evidence

- 5.1 The company identified 3 published economic studies, but the external assessment centre considered them to be outside the scope. It did not identify any further economic studies.
- 5.2 The company presented a de novo cost model that compared the cost consequences of using SecurAcath in people with peripherally inserted central catheters (PICCs) compared with StatLock, and in people with central venous catheters (CVCs) compared with sutures.
- 5.3 The model used a decision-tree structure where people entered the model at the point of having a securement device (either SecurAcath, StatLock or sutures). Both trees contained 5 outcomes after securement: no complications; catheter migration; catheter malposition; catheter occlusion; or catheter-related infection (catheter-related bloodstream infection or catheter-related thrombosis). There was an additional outcome of needlestick injuries for health professionals in the suture group.
- 5.4 The model was constructed with a time horizon of 25 days for PICCs and 3 days for CVCs. Other clinical parameters such as the probability of migration, malposition, occlusion, infection and thrombosis were derived from published and unpublished literature. Device and resource costs relating to the cost of placement (such as nurse time) and complications were also from published and unpublished sources.
- 5.5 The results of the company's base case found cost savings with SecurAcath of £41.40 per patient for PICCs compared with StatLock and £1,005.60 per patient for SecurAcath with other CVCs compared with sutures. The main reasons for StatLock's greater costs as compared with SecurAcath were device costs and

differences in catheter migration rates. For sutures, the main reasons for the greater costs were differences in the rates of catheter-related bloodstream infection or catheter-related thrombosis.

- 5.6 The company did a 1-way deterministic sensitivity analysis, increasing SecurAcath device costs by up to 200%. It also did multiway deterministic sensitivity analyses, changing the values for each economic and clinical parameter simultaneously by $\pm 20\%$. In all cases, SecurAcath remained cost saving compared with its comparator. When PICC dwell time was increased to 6 months (reflecting a typical clinical situation of a patient having cancer treatment), the cost saving with SecurAcath increased to £115.00 per patient.
- 5.7 The NICE adoption and impact scoping report (included in the assessment report overview) describes real-world total cost savings of up to £59,000 when compared with StatLock at a single site placing 1,100 PICCs placed over 6 months.
- 5.8 NICE is developing a resource impact report on SecurAcath. The estimated annual cost saving across the NHS in England ranges from £0.5 million to £4 million, based on hospital episode statistics for the number of PICCs inserted.

Additional work by the external assessment centre

- 5.9 Overall, the external assessment centre considered the company's model to be appropriate given the limited evidence base available, but noted some errors in the model. These included figures wrongly quoted, applying probabilities as rates and a lack of clarity on some sources of evidence. It queried a number of assumptions in the model: dwell times; the differential impact of securement device placement by nurses or doctors; that no extra resources are needed to place securement devices and the clinical outcomes chosen. It also queried the significant assumption in the model that

outcomes were independent of time and were collected over similar dwell times. It noted there was a risk of study heterogeneity and uncertainty about variations in clinical practice and outcome measurements.

- 5.10 The external assessment centre regarded Yamamoto et al. (2002) as the best evidence available to inform the issue of the incidence of complications, since it reported rates rather than probabilities. Yamamoto et al. (2002) is a single-centre, US-based, prospective randomised controlled trial, comparing Statlock with sutures in patients with PICCs (n=170). The primary endpoint was catheter-related complications. Mean dwell times were 33 days for Statlock and 35 days for sutures. Total complication rates were 49.4% and 71.7% for Statlock and sutures, respectively (p=not significant). There was no statistically significant difference in dislodgement or migration rates between the 2 groups, but a significant reduction in infections with StatLock was observed (p=0.032).
- 5.11 Using this evidence, the external assessment centre revised the model base case, assuming clinical equivalence for all outcomes between SecurAcath and comparators, except for needlestick injury, where a reduced risk without sutures was highly likely. Therefore, base-case costs related to placement and maintenance costs over the relevant dwell time only, with needlestick injury costs included where relevant. It also considered 3 dwell times for both CVCs and PICCs: 5 days (short), 25 days (medium), and 120 days (long). Other amendments included: adding StatLock as a comparator for CVCs; varying placement and maintenance times; suturing being done by a band 6 nurse; sutures remaining throughout the dwell time and updating resource costs.
- 5.12 The revised base case (see [table 1](#)) found that StatLock was the cheapest option for PICCs for short dwell times (5 days), but that SecurAcath was cost saving for medium to long dwell times

(25 days and over). For CVCs, StatLock was the cheapest securement option for short dwell times and sutures was the cheapest for medium to long dwell times.

- 5.13 A one-way sensitivity analysis, reducing SecurAcath placement time to 30 seconds (as reported by the company), made SecurAcath slightly more cost saving and sutures slightly less cost saving, but did not change the base-case results (see [table 1](#)). Another one-way sensitivity analysis assumed an insertion site maintenance time of 7.3 minutes for sutures, equivalent to the time reported for StatLock in Janssens (2016b). This changed the results for CVCs such that SecurAcath was cheaper than sutures for both PICCs and CVCs with a medium and long dwell time (see table 1).
- 5.14 The external assessment centre conducted a multivariate sensitivity analysis including differential risks of migration, dislodgement and catheter-related bloodstream infections, based on the figures reported in Yamamoto et al. (2002) and its meta-analysis. This found that StatLock was the cheapest option for short dwell times for both PICCs and CVCs, but for medium and long dwell times, SecurAcath was the most cost saving (see table 1).

Table 1 Summary of external assessment centre results

Scenario	[1]	[2]	[3]	[4]
	Cheapest device (cost saving)			
CVC line for 5 days	StatLock (£5)	StatLock (£5)	StatLock (£5)	StatLock (£11)
PICC line for 5 days	StatLock (£12)	StatLock (£7)	StatLock (£12)	StatLock (£14)
CVC line for 25 days	Sutures (£7)	Sutures (£2)	SecurAcath (£12)	SecurAcath (£25)
PICC line for 25 days	SecurAcath (£17)	SecurAcath (£22)	SecurAcath (£17)	SecurAcath (£13)
CVC line for 120 days*	Sutures (£7)	Sutures (£2)	SecurAcath (£94)	SecurAcath (£116)

PICC line for 120 days	SecurAcath (£94)	SecurAcath (£99)	SecurAcath (£94)	SecurAcath (£68)
<p>[1] Base case (placement and maintenance costs only; no differences in complication rates across devices); [2] One-way sensitivity analysis: assumes a SecurAcath placement time of 30 seconds; [3] One-way sensitivity analysis: assumes a suture maintenance time of 7.3 minutes; [4] Multiway sensitivity analysis including complication rates</p> <p>*Experts stated that this situation was not clinically relevant as non-tunnelled CVCs are only used on a short-term basis.</p>				

- 5.15 A threshold sensitivity analysis for dwell times using the base case indicated that SecurAcath was the cheapest option for securing PICCs for 15 days or more. For CVCs, the costs of sutures dropped below those of StatLock for dwell times of 8 days or more, but SecurAcath remained more expensive than sutures for securing CVCs over any dwell time.
- 5.16 For PICCs, the external assessment centre agreed with the company's conclusion that SecurAcath appears to be cheaper than StatLock over medium and long dwell times (25 days and over). Cost savings arise from shorter maintenance times with SecurAcath and the need to replace StatLock weekly. It concluded that these cost savings were robust: it found smaller savings in the base case excluding complications, but similar results in sensitivity analyses including complications.
- 5.17 For CVCs, the external assessment centre agreed with the company's conclusion that SecurAcath was cost saving compared with sutures over short dwell times, but disagreed with the exclusion of StatLock as a comparator. Additional analysis including StatLock concluded that it was the cheapest for CVCs with short dwell times in all scenarios. For medium to long dwell times, suturing was cheaper than SecurAcath or StatLock in the base case (excluding complications). However, evidence suggested an increased risk of infection with suturing. Sensitivity analyses including complications found SecurAcath to be cheaper than suturing and StatLock over 25- and 120-day dwell times. This led the external assessment centre to conclude that SecurAcath is

likely to be the cheapest option for securing CVCs over medium and long dwell times.

Committee considerations

- 5.18 The committee noted that the experts disagreed with the external assessment centre's assumption that nurses would place sutures in the NHS, as they considered it would usually be done by a doctor in an operating theatre environment. Furthermore, the committee noted that when the external assessment centre had recalculated the CVC costs for using a consultant anaesthetist to place sutures, there were only minor differences in the results of the cost modelling, with sutures becoming slightly less cost saving compared with SecurAcath in the base case (£2 saving), and SecurAcath becoming the cheapest device over sutures in a one-way sensitivity analysis (£3 saving).
- 5.19 The committee were advised by the experts that a 25-day dwell time for PICCs was an underestimate of routine clinical practice, since haematology and oncology patients usually have PICCs in place for 4 to 6 months, and even up to 1 year.
- 5.20 The committee concluded that while SecurAcath may take a few minutes longer than StatLock to place and remove, (although the experts indicated that this differential reduces with increased experience), maintenance times with SecurAcath are considerably shorter than with StatLock.
- 5.21 The committee concluded that SecurAcath would not usually be used for tunnelled (Hickman) CVCs or implanted ports, but may be used for non-tunnelled CVCs. However, the committee also noted that non-tunnelled CVCs are used for short-term vascular access (usually less than 10 days) Furthermore, if SecurAcath is used for non-tunnelled CVCs, experts advised that in their experience, an adhesive device would also be placed on top of SecurAcath as an additional measure to prevent potential dislodgement. For all these

reasons, the committee concluded that the cost modelling results for non-PICC CVCs (with dwell times for up to 120 days) are unlikely to be clinically relevant.

6 Conclusions

- 6.1 The committee concluded that there is evidence that SecurAcath is effective for securing peripherally inserted central catheters (PICCs). Using SecurAcath avoids the need for securement device replacement and is associated with a low incidence of catheter-associated complications, such as migration, occlusion, thrombosis and infection.
- 6.2 The committee concluded that SecurAcath is easy to use and is well tolerated by people with PICCs provided that device placement is done by staff with appropriate training and experience.
- 6.3 The committee concluded that the adoption of SecurAcath for the securement of PICCs is likely to be cost saving compared to StatLock, with cost savings resulting from a reduction in the time taken during weekly dressing changes and from the avoidance of securement device replacement. Cost savings are therefore greater with longer PICC dwell times with cost modelling indicating that using SecurAcath becomes cost saving when the catheter is expected to be in place for more than 15 days.

Peter Groves
Chair, medical technologies advisory committee
January 2017

7 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 technology guidance topic is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal) and a senior technical lead. Other key contributors are listed in the Assessment Report Overview.

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