NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

Assessment report overview

SecurAcath for securing percutaneous catheters

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the External Assessment Centre (EAC) report. It includes key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the committee may wish to discuss. It should be read along with the sponsor's submission of evidence and with the EAC report. The overview forms part of the information received by the committee when it develops its recommendations on the technology.

Key issues for consideration by the committee are described in section 6, following the summaries of the clinical and cost evidence.

This report contains information that has been supplied in confidence and will be redacted before publication. This information is highlighted in yellow. This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Comments from professional bodies
- Appendix C: Comments from patient organisations
- Appendix D: NICE adoption scoping report

1 The technology

SecurAcath is a single-use device to secure percutaneous catheters in place on the skin. There are 2 components, a base and cover. The base comprises 2 metal tips, which form an anchor in the skin incision, and 2 foldable arms. The cover holds the catheter shaft in place and clips into the base. The device remains in place as long as the catheter is needed, and can be lifted to allow 360º cleaning of the insertion site.

SecurAcath is available in 6 different sizes (3 F to 8 F) and the smallest possible size should be used. SecurAcath is latex-free and MRI-compatible (3 Tesla or less). It received a CE mark in December 2009 for subcutaneously securing implantable percutaneous medical devices.

2 Proposed use of the technology

2.1 Disease or condition

SecurAcath is intended for use in adults and children who need a catheter for central venous access (peripherally-inserted central catheter [PICC], non-tunnelled or tunnelled (e.g. Hickman) central venous catheter [CVC]).

2.2 Patient group

The technology is likely to be used when percutaneous catheters need to remain in place for a long time (such as in older, critically ill patients, in patients after major trauma, or in people who need long-term, ongoing therapy such as those with cancer).

In these individuals, catheters often need to remain in place for long periods of time, to deliver and remove blood, allow infusion of fluids and nutrition and medicines as well as to facilitate kidney dialysis. Securement methods used to fix catheters in place include securement devices, steristrips, tape or sutures (stitches). These often need to be removed to clean the skin underneath, risking infection. Removing them, or not properly securing the catheter in the

first place, can lead to the catheter moving and causing complications (such as catheter malfunction, incorrect pressure measurements, catheter erosion, and thrombophlebitis of large or central veins). In addition, the catheter may accidentally fall or be pulled out, leading to loss of venous access.

The company states that SecurAcath may be of particular benefit in patients for whom adhesive devices would not be suitable, such as people with skin burns or diaphoresis (excess sweating).

2.3 Current management

Current options include adhesive securement devices, such as StatLock and Grip-Lok, steristrips, tape and sutures (stitches).

NICE has not produced any guidance on securing catheters for central venous access.

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 the use of securing devices such as StatLock in preference to sutures, and discourage the suturing of catheters to the skin[1].

The US Centers for Disease Control and Prevention guidelines for the prevention of intravascular catheter-related infections (2011) recommend the use of a sutureless securement device to reduce the risk of infection. This is a category II recommendation, which is defined as 'those practices where there is only suggestive or less definitive evidence'[2].

A number of NHS trusts have produced local guidance on using catheter securement devices including SecurAcath. For example, the Royal Cornwall

[1] Bishop L, Dougherty L, Bodenham A et al (2007) Guidelines on the insertion and management of central venous access devices in adults; International Journal of Laboratory Hematology 29 (4) 261-278
[2] Grady, N.P. et al (2011). Guidelines for the prevention of intravascular catheter-related infections

NHS Trust has produced a clinical guideline for the use of intravascular catheters in adults. The guideline recommends that a securement device should be used to prevent catheter migration and dislodgement in patients with a PICC or midline catheter.

The NICE guideline on infection control recommends that the skin at and around the catheter insertion site should be 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.

The Infusion Standards of Practice (2016) produced by the US Infusion Nursing Society considers engineered stabilisation devices (ESD) such as SecurAcath and StatLock. While it makes no formal recommendations on their use because of a limited evidence base, it states that ESDs should be considered for vascular access devices (VAD) because of the consequences of inadequate stabilisation and securement. It further states that ESDs promote consistent practice among clinicians, reduce VAD motion that can lead to complications, reduce the number of interruptions needed for infusion therapy, and may decrease costs of care. The document recommends that tape or sutures should be avoided because, based on good quality evidence from randomised controlled trials, they are not as effective as ESDs. It also notes that there is low-level evidence (that is, case reports) that subcutaneous ESDs can successfully stabilise PICCs and vascular access devices inserted through the jugular vein in adults, and that favourable patient outcomes, and patient and practitioner satisfaction scores, have been reported. It considers that further comparative research is needed.

2.4 Proposed management with new technology

SecurAcath would be used in patients who need central venous access for extended periods of time, through either a PICC or a tunnelled or non-tunnelled CVC. It would be used instead of current securement methods

(steristrips, tape, sutures or other securement devices such as StatLock) to prevent the catheter moving or falling out. It should be used with an appropriate dressing to prevent catheter-related infection. SecurAcath can remain in place as long as the catheter is needed, and does not need to be replaced when dressings are changed.

2.5 Equality issues

Although SecurAcath is suitable for people of all ages, it will most likely be used in older patients with chronic conditions. These people may be considered to have a disability if their condition has a significant and long-term effect on their ability to do normal daily activities. Age and disability are protected characteristics under the 2010 Equality Act.

SecurAcath may also be used regularly in people with cancer, who are protected under the Act from the point of diagnosis.

SecurAcath is not suitable for people with an allergy to nickel.

3 Company's claimed benefits

The benefits to patients claimed 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).

The benefits to the healthcare system claimed by the company are:

- A decrease in catheter replacement costs.
- A reduction in overall treatment costs through the avoidance of delays and complications.

4 Decision problem

Table 1 Summary of the decision problem

Population	People who require an intravascular catheter* for central venous access
Intervention	The SecurAcath securement device
Comparator	• Adhesive catheter securement devices, such as StatLock or Grip-Lok, or other adhesives (such as steristrips) • Sutures (see also 'Cost analysis' below)
Outcomes	The outcome measures to consider include: • Rates of catheter migration and dislodgement • Rates of catheter-related infection, including catheter-related bloodstream infection (CRBSI), local infection/inflammation and thrombophlebitis • Number of unplanned catheter removals and reinsertions • Time taken to secure catheter • Patient and clinician satisfaction scores • Pain while in situ and on insertion and removal • Quality of life measures • Device-related adverse events eg. catheter malfunction, thrombosis and vessel erosion
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	• People who receive a PICC • People who receive a CVC • People with co-morbidities • Children and young people • People with a medium to long dwell time
Special considerations, including issues related to equality	The technology may be used by adults or children, but is most commonly used in older patients with chronic conditions who may be classed as disabled if their condition has a significant and long-standing adverse effect on activities of daily living. The technology may also be used regularly in people with cancer, who are protected under the Act from the point of diagnosis. The technology is not suitable for people with an allergy to nickel.
* includes peripherally inserted central catheter [PICC], non-tunnelled or tunnelled (for example Hickman) central venous catheter [CVC]	

5 The evidence

5.1 Summary of evidence of clinical benefit

The company conducted a literature search for evidence on SecurAcath which identified 20 studies: 3 published studies, 4 published commentaries and reviews on catheter securement devices generally, and 13 unpublished studies (12 conference abstracts and 1 unpublished report; see pages 25–52 of the company's submission).

The external assessment centre (EAC) could not replicate the company's searches and considered its search terms to be inadequate to capture the relevant literature. The EAC considered that the 4 published commentaries (Oliver [2016], Alpenberg [2016], Higginson [2015] and Egan [2012]) did not contain evidence which was relevant to the decision problem and excluded them. It also excluded 4 primary unpublished studies: Balance (2012/2013; considered a single piece of evidence) and Peveler (2013) because they were case reports with low patient numbers, and Pittiruti (2015) and Sandeluss (2013) because of issues in the reporting of their methodology and the use of additional securement. The EAC also did not assess the poster presentation by Janssens (2016a) after being provided with an updated manuscript by the study author. In total, the EAC accepted 10 of the company's submitted studies.

The EAC conducted its own evidence searches adding more keywords and including additional databases. This identified 2 additional studies on SecurAcath: Janssens (2016b), an unpublished draft manuscript arising from the same work reported in a more limited form in Janssens (2016a), and Sansivero (2011), an earlier iteration of the Egan (2013) study. It also identified 6 studies on comparator technologies. In total, the EAC evaluated 18 studies (tables 5 and 6 of the assessment report, pages 72–103), which are described below and in table 2.

Published studies

The 3 published studies on SecurAcath are all observational without a comparator.

Cordovani and Cooper (2013) investigated 74 adults who had CVCs with SecurAcath (mean indwell time 3.1 days). The primary outcome was device securement success reported in 72 patients (97%). Mean catheter securement time was 62.5 seconds. Discomfort scores were measured on a 1 to 10 scale: mean scores were 0.9 in situ and 1.6 at removal. Of the 15 patients who had previous experience of a sutured catheter, 14 found SecurAcath 'as or more comfortable'. Six out of 8 healthcare professionals found maintenance 'somewhat' or 'much easier' than sutures. The authors concluded that SecurAcath is 'safe and reliable'.

Egan et al. (2013, and its earlier iteration Sansivero [2011]) investigated PICCs with SecurAcath in 68 adult inpatients 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. The mean indwell 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. 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 in terms of overall satisfaction with SecurAcath. Use of SecurAcath did not influence placement or maintenance techniques. The authors concluded that SecurAcath performs favourably compared with StatLock (versus historical data reported by Yamamoto et al. 2002: respective migration and dislodgement rates of 6% and 12% for StatLock, 2.9% and 0% for SecurAcath).

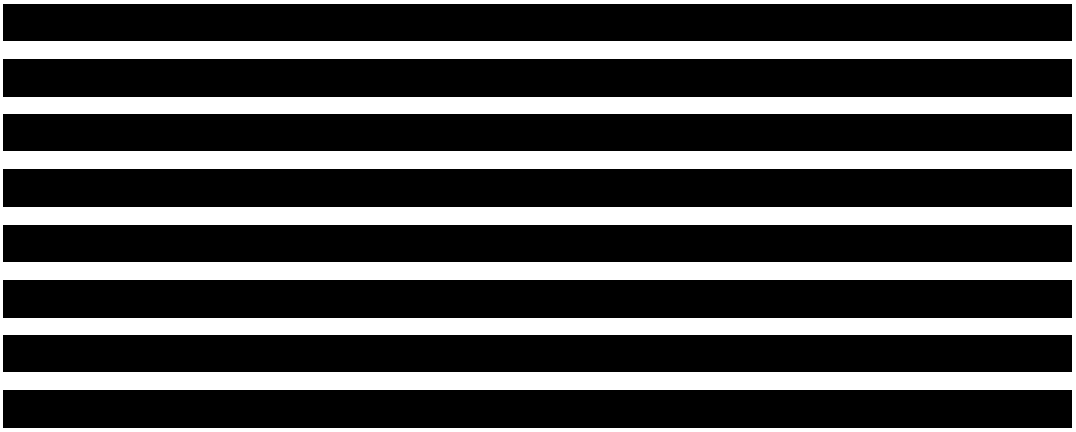
Hughes (2014) prospectively evaluated PICCs with SecurAcath in 31 adults. Mean indwell time was over 30 days in 45% of patients. The study reported

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 patients’ scores were over 5, and at removal over half of patients’ 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).

The EAC noted a number of limitations in these published studies, in addition to the lack of a comparator in each. None reported sample size calculations or measures of variance. For both Cordovani and Cooper (2013) and Egan (2013), protocols for catheter placement differed across centres and there was no reporting of patient characteristics.

Unpublished studies and conference abstracts

Janssens (2016b) is an unpublished manuscript provided by the author as academic in confidence. The study is a Belgian-based, single-centre, prospective, unblinded, randomised controlled trial comparing PICCs with SecurAcath and PICCs with StatLock in 105 adults [redacted]



The other 7 studies on SecurAcath were poster presentations, audit reports or oral presentations.

Djurcic-Jovan et al. (2016) is a single-centre retrospective, observational, comparative, longitudinal study in Canada comparing PICCs with and without SecurAcath in 54 patients needing complex continuing care. Mean indwell time was over 31 days. The primary outcome measure was unplanned catheter reinsertion. There were 60 unplanned catheter reinsertions without SecurAcath compared with 3 unplanned reinsertions with SecurAcath. There was no catheter migration. The authors reported substantial time savings for nurses and physicians following the introduction of SecurAcath. Qualitative outcomes were collected retrospectively. Catheter migration was rated ‘very good’ or ‘good’ in 88% of cases, and catheter stability during maintenance, ease of dressing, and overall use of the devices were rated as ‘very good’ or ‘good’ in 95% of cases.

Dougherty (2013) is a UK-based single-centre prospective study with no comparator which evaluated PICCs with SecurAcath over 1 month in 30 patients. Qualitative data was gathered from nurses and patients. There was a reduction in malposition and catheter damage and no skin reactions were seen. Nurses reported increased confidence in 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.

Hill (2014) is a Canadian-based single-centre pilot evaluation without a comparator of PICCs with SecurAcath in 60 patients. The author reported no malpositions but accidental dislodgement in 2 agitated patients. The author describes 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 describes successful use in patients with skin integrity issues, where the device was used without adhesive dressing. The author concludes that patients were satisfied overall.

Misericordia (2015, reported as Anonymous 2015 in the assessment report) is an unpublished, retrospective, comparative audit report from the parenteral therapy team at the Misericordia Community hospital in Canada, which evaluated 164 unanchored PICCs placed during 2013 and 542 PICCs with SecurAcath placed during 2014. The average indwell time was 29 days. The report also evaluated the use of a PICC designed to reduce catheter-related thrombosis. Six different operators took part in the evaluation. The primary outcomes were catheter-related thrombosis, PICC occlusions, 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 rates of catheter-related thrombosis decreased from 3.75% to 3.69%, PICC occlusions increased from 14.35% to 16.97%, and malpositions decreased from 10.98% to 1.66%. The authors concluded that without SecurAcath, around 60 of the 542 patients would have needed catheter replacements.

Zerla et al. (2016) is a single-centre prospective study with no comparator, which investigated 30 adults needing chemotherapy who had a PICC with SecurAcath in place for over 2 months. The median indwell time was 145 days. Skin integrity issues were seen in 32.17% of patients. Pain scores were measured on a 0 to 10 scale: at placement pain scores were ≤2 in 90% of patients, in situ ≤2 in 98.7% and at removal ≤2 in 66.7%. The authors report median maintenance time of 10 minutes for SecurAcath, which was compared

with a historical cohort which had a median of 20 minutes' maintenance time for an adhesive device. No catheters were dislodged. The authors concluded that, after effective training in its use, SecurAcath is comfortable for the patient, reduces catheter movement, and is safely indicated in patients with cancer who need long-term catheterisation and ambulatory maintenance.

Stone et al. (2013) is a prospective, single-centre study which included PICCs with SecurAcath in 42 children with previous skin issues or skin irritation/allergic reactions to standard dressings. The authors compared outcomes with historic data on 17 migrations in the same centre (undefined cohort). In the SecurAcath cohort, there were no migrations, complications or unplanned catheter removals. The authors concluded that further research is needed to optimise protocol for dressings in patients with skin integrity issues.

McParlan et al. (2016) is a single-centre, UK prospective cohort study comparing PICCs with SecurAcath and PICCs with StatLock in haematology and oncology patients. [redacted]

The EAC identified 6 studies on the comparator technology StatLock. The comparator, where present, was sutures or tape, and the studies involved patients having both PICCs and CVCs. Two of the studies were randomised controlled trials: Fang et al. (2011) and Teichgräber et al. (2011). The 6 studies all find StatLock to be superior in terms of catheter migration, removal and infection outcomes. For further details, see table 2 and the assessment report (pages 66 to 71).

Additional work by the EAC: meta-analysis

The EAC conducted pooled meta-analyses using data from 16 of the 18 included studies to generate results for the main outcomes on SecurAcath, StatLock and sutures, described on pages 104–109 of the assessment report). Dependent on the outcome, up to 9 studies were included in the meta-analyses. Because of the limits in the evidence base, it was not possible to look at subgroups or quality assure the data; this uncertainty was reflected in the wide confidence intervals of the results. For these reasons, the results did not inform the model parameters in the EAC's base case.

EAC conclusions on the clinical evidence

The EAC noted a lack of comparative evidence between SecurAcath and the comparators listed in the scope. It considered the unpublished study by Janssens (2016b) to be the most relevant evidence, and that its meta-analyses was supportive of the results (with the exception of dislodgement); that is, that the 2 devices are similar in terms of clinical outcomes. The EAC noted that the observational studies reported higher pain scores with SecurAcath at removal compared with placement and in situ, and that in Hughes (2014) device removal caused the most dissatisfaction among staff and pain among patients.

The EAC concluded that the evidence suggests that SecurAcath and StatLock are better than sutures for securing PICCs in terms of catheter migration, dislodgement and infection, but that this is not relevant to clinical practice because sutures are not used to secure PICCs. The EAC also concluded that there is insufficient evidence to determine that SecurAcath is clinically superior to StatLock in terms of effectiveness and adverse events, but there is some evidence to suggest it is non-inferior in terms of effectiveness and side-effect profiles to StatLock.

Table 2: Literature identified by EAC

Abbreviations used: RCT= randomised control trial; CVC = central venous catheter; PICC = peripherally inserted central catheter; CICC = centrally inserted CVC					
Study	**Study design (country)**	**Population**	**Intervention versus comparator**	**Outcomes considered**	**EAC comments on study**
Full, peer-reviewed articles					
Cordovani (2013)	Prospective cohort study, multi-centre (Canada)	74 adults requiring a 7Fr CVC in the internal jugular vein	SecurAcath No comparator	Device securement success (defined by device malfunction and adverse events) Securement time Patient comfort Ease of SecurAcath use	No detail is provided about population characteristics. There was no comparator. The dwell time appears to be short term, making it less relevant
Egan (2013)/ Sansivero (2011)	Prospective cohort study, multi-centre, (USA)	68 adults including medical and surgical inpatients, patients in ICU or transplant unit, and outpatients. PICCs 5Fr size	SecurAcath No comparator	Device securement success (defined by device malfunction and adverse events) Securement time Patient satisfaction Ease of PICC maintenance	This study is prospective and has a medium sample size. There was no within study comparator. It provides data on a number of relevant outcomes.
Hughes (2014)	Prospective cohort study, single-centre (UK)	31 adults diagnosed with cancer PICCs 4Fr (96%) and 5Fr (4%) size	SecurAcath No within study comparator	Ease of SecurAcath placement PICC migration Infection rate Securement time Patient comfort	Of medium usefulness to inform the decision problem- UK study. There was no within study comparator, however some results are compared with previous practice (securement involving wound closure strips and an

Abbreviations used: RCT= randomised control trial; CVC = central venous catheter; PICC = peripherally inserted central catheter; CICC = centrally inserted CVC					
Study	**Study design (country)**	**Population**	**Intervention versus comparator**	**Outcomes considered**	**EAC comments on study**
					adhesive securement device). The mean dwell time is unspecified, however, a figure in the publication indicates that most patients had an indwelling catheter > 30 days
Fang (2011)	Single-centre prospective RCT (China)	Inpatients (n=120) PICCs 4Fr size	StatLock (n=40) Suture (n=40) Tape (n=40)	Catheter migration, catheter dislodgement, catheter-related complications (cellulitis, phlebitis), skin injuries, patient satisfaction	The study provides data on a number of relevant outcomes, and is of medium usefulness in informing the decision problem
McMahon (2002)	Single-centre retrospective comparative cohort (USA)	Inpatients (n=1212) 5Fr size	StatLock (n=726) Suture (n=486)	Catheter dislodgement	Of low usefulness to the decision problem: only one relevant outcome is reported. The two cohorts were not studied concurrently.
Teichgräber (2011)	Single-centre prospective RCT (Germany)	Haemodialysis patients (n=72) CICC 14.5Fr size	StatLock (n=36) Suture (n=36)	Successful catheter placement, catheter-related complications	The outcomes data are poorly defined and the sample size is small, so this study is of limited use

Abbreviations used: RCT= randomised control trial; CVC = central venous catheter; PICC = peripherally inserted central catheter; CICC = centrally inserted CVC					
Study	**Study design (country)**	**Population**	**Intervention versus comparator**	**Outcomes considered**	**EAC comments on study**
Yamamoto (2002)	Single-centre prospective RCT (USA)	Adult inpatients and out patients (n=170) PICCs	StatLock (n=85) Suture (n=85)	Unplanned removal and catheter-related complications (catheter dislodgement, catheter migration, confirmed and suspected CRBSI, cellulitis, leak, occlusion, central venous thrombosis, securement detached or loose)	The study provides clear data for StatLock on a number of important variables
Zerla (2015)	Single-centre, retrospective observational cohort (Italy)	Adult oncology patients (n=1341) PICCs and midline catheters 4Fr size	StatLock No comparator	Catheter- related complications	This is a non-comparative study. Outcomes are not clearly defined and the main focus of the study is not securement
Abstracts/ posters/ presentations					
Djurcic-Jovan (2016)	Single-centre retrospective comparative cohort (Canada)	Single-centre retrospective comparative cohort (Canada) PICC	SecurAcath StatLock	Unplanned catheter reinsertion	The study compares SecurAcath and its main competitor (StatLock) but the outcomes are unclear. The study is published as a poster presentation
Dougherty (2013)	Single-centre prospective	Inpatients and outpatients (n=30)	SecurAcath No comparator	Nurse and patient satisfaction scores	This is a non-comparative study reporting only qualitative data. The sample size is very small

Abbreviations used: RCT= randomised control trial; CVC = central venous catheter; PICC = peripherally inserted central catheter; CICC = centrally inserted CVC					
Study	**Study design (country)**	**Population**	**Intervention versus comparator**	**Outcomes considered**	**EAC comments on study**
	evaluation (UK)	PICCs			
Hill (2014)	Single-centre prospective evaluation (Canada)	Inpatients (n=60) PICCs	SecurAcath No comparator	Catheter dislodgement, Unplanned removal	This is a non-comparative study reporting a limited number and unclear set of outcomes
Janssens (2016b) NCT02311127	RCT, single centre, (Belgium).	105 adults PICCs 4-6Fr size	SecurAcath StatLock	Primary endpoint: Time spent on dressing changes. Secondary endpoints: Catheter migration, Accidental dislodgement, CRBSI Pain scores	The only RCT, unpublished, non-peer reviewed. 
Misericordia (2015)	Audit report, single centre, (Canada).	706 patients PICCs	SecurAcath (n=542)	Catheter-related thrombosis PICC occlusions Catheter malposition	No methodology is described therefore study design is unclear. The comparator is not explicitly

Abbreviations used: RCT= randomised control trial; CVC = central venous catheter; PICC = peripherally inserted central catheter; CICC = centrally inserted CVC					
Study	**Study design (country)**	**Population**	**Intervention versus comparator**	**Outcomes considered**	**EAC comments on study**
			PICC with no subcutaneous anchor (n=164) (comparator is unclear).	CRBSI Local infection	mentioned. Though, relative to other studies included, the population size is large, there is no description of its characteristics.
McParlan (2016)	Single-centre prospective comparative cohort (UK)	Haematoncology patients (n=[redacted]) PICCs	SecurAcath (n=[redacted]) StatLock (n=[redacted]	Catheter dislodgement, unplanned removal	The study compares SecurAcath and its main competitor (StatLock) in a UK-based setting. [redacted]
Stone (2013)	Prospective cohort study, single centre, (USA)	42 children with previous skin issues or skin irritation/allergic reaction to standard dressing products PICCs	SecurAcath No within study comparator	PICC migration Complications associated with PICC Unplanned catheter removal	There is limited information to assess methodological quality. Dwell time was not reported and no definition of migration was provided, therefore it may be challenging to compare outcomes with other studies. An unclear comparison with historical data is made (it is unclear for example, which device was used and how many PICC insertions were carried out)

Abbreviations used: RCT= randomised control trial; CVC = central venous catheter; PICC = peripherally inserted central catheter; CICC = centrally inserted CVC					
Study	**Study design (country)**	**Population**	**Intervention versus comparator**	**Outcomes considered**	**EAC comments on study**
Zerla (2016)	Prospective cohort study, single centre (Italy)	30 adults diagnosed with cancer PICCs 4-5Fr size	SecurAcath No within study comparator	Skin integrity Pain scores	Limited information is available to assess methodological quality. There was no within study comparator, however, some historical comparisons were made with historical data for StatLock. However, this does not provide an appropriate comparison. The only outcomes measured a priori appear to be skin integrity and pain scores: it is unclear if other adverse events were unrecorded or omitted
Venturini (2011)	Single-centre prospective observational cohort (Italy)	212 Haematology patients CVC/CICC	StatLock No comparator	Successful catheter placement, catheter dislodgements, CRT	Many of the outcomes are not clearly defined, so this study is of limited usefulness

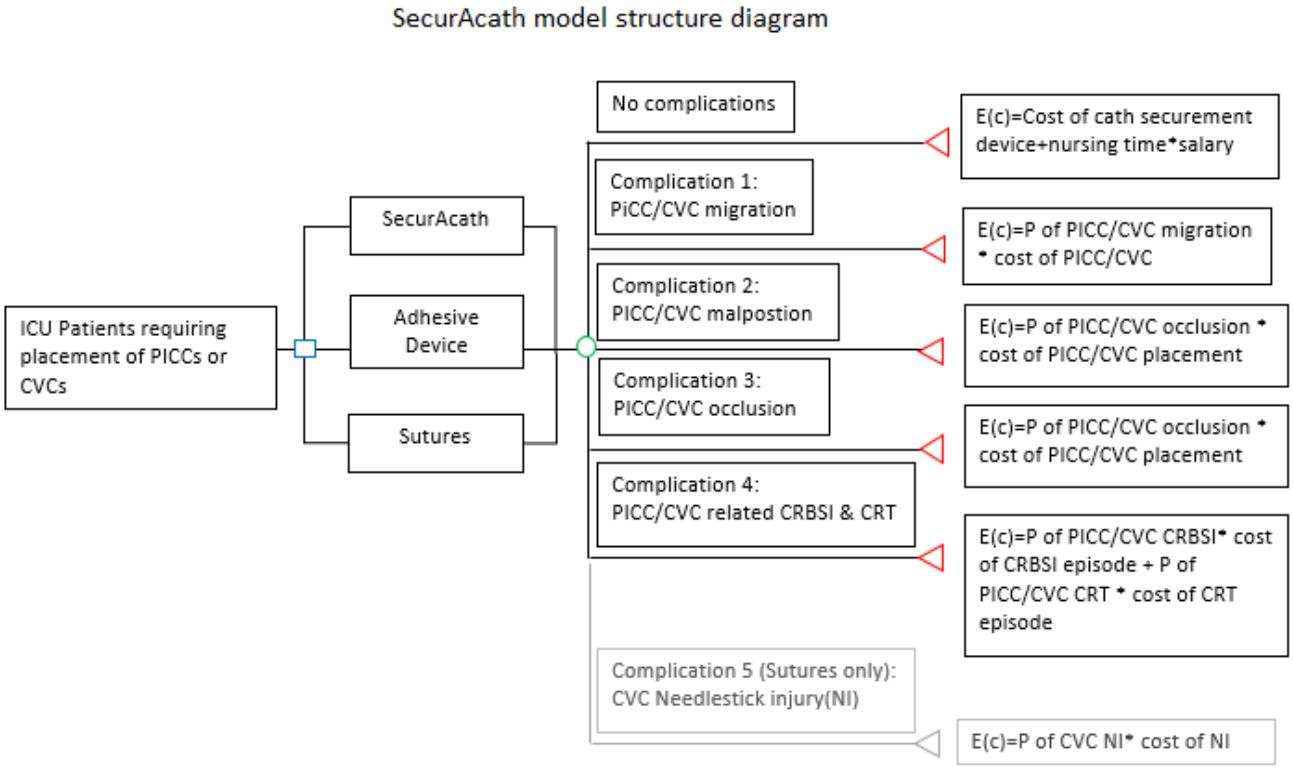
5.2 Summary of economic evidence

The company conducted a literature search for economic evidence on securement and stabilisation devices for CVCs and PICCs, identifying 3 studies. The EAC did not accept any of the studies because it did not consider their populations to be consistent with those specified in the scope. It reviewed the company's search strategy and found a number of deficiencies: only 2 databases were searched (PubMed and Embase), the search strategy was too narrow and risked missing studies on comparators, and the search terms were too limited. The EAC conducted its own searches to address these concerns, which identified no economic studies consistent with the scope.

The company's de novo analysis

The company presented 2 decision tree models: one for PICCs, comparing SecurAcath with StatLock, and one for CVCs, comparing SecurAcath with sutures (see figure 1). Both trees contained 5 outcomes following securement with SecurAcath or the comparator: 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 patient group having sutures.

Figure 1: Structure of the company's model



Model parameters

The company's models assumed indwell times of 25 days for PICCs and 3 days for CVCs. Values for the clinical parameters were informed from the literature. The company relied heavily on unpublished data, specifically the results provided by Misericordia (2015) in confidence. The values reported by the company are provided in table 3 below, and in table C5a in the company's submission.

Table 3: Clinical parameters used in the company's model

Variable	Base-case value	Source(s)
Probability of PICC migration	SecurAcath, [redacted] StatLock, [redacted]	[1], [3] [2], [3]
Probability of PICC malposition	SecurAcath, 0.0166 StatLock, 0.1098	[3]
Probability of PICC occlusion	SecurAcath, 0.1435 StatLock	[3] [4]
Probability of CRT	0.0369	[3]
Probability of CRBSI (PICC)	SecurAcath 0.0036	[3]

	StatLock, 0.00369	[5]
Probability of CVC migration	SecurAcath, 0 Sutures, 0	[1] [4]
Probability of CVC malposition	SecurAcath, 0.03 Sutures, 0.03	[1] [1], [6]
Probability of CVC occlusion	SecurAcath, 0 Sutures, 0.06	[1] [4]
Probability of CRBSI (CVC)	SecurAcath, 0.04 Sutures, 0.14	[4] [4]
Probability of needle stick injuries (sutures)	0.02	[4]
[1] Cordovani (2013); [2] McParlan (2016); [3] Misericordia (2015); [4] Frey (2001); [5] Cooper (2014); [6] Boland (2003)		

Costs and resource use

The company used its own internal data and consulted a number of sources for costs, presented in table 4 below and table C5a in its submission.

Table 4: Cost parameters used in the company's model

Variable	Value	Source(s)
SecurAcath device costs	£16	Hughes 2014 (11)
StatLock device costs	£3.47	Hughes (2014)
Suture costs	£5	Interrad report (2015)
Nurse cost per minute	£0.60	NHS Band 7 mid-point – NICE economic template
Doctor cost per minute	£1.47	NHS Band 9 midpoint-NICE economic template
PICC placement[1]	£250	Hughes 2014
CVC placement[2]	£450	Boland (2003)
CRBSI episode	£9,900	Hockenhull (2008), Tegaderm CHG guidance (2015)
Needle stick injury episode	£312	Won Chan Lee (2005)
SecurAcath nurse time	[redacted] mins	Janssens (2016b)
Adhesive nurse time	40.8 mins	Interrad report (2015)
Doctor time sutures	4.7 mins	Interrad report (2015)
CRT episode	£250	Tegaderm CHG guidance (2015), Saint (2000)
[1] Used for costing PICC migration, malposition and occlusion [2] Used for costing CVC migration, malposition, and occlusion		

Table 5: Company's base-case results

Technology	PICC (25 days)	CVC (3 days)
SecurAcath	£114.20	£447

StatLock	£155.60	-
Sutures	-	£1,425.60
Difference in costs: SecurAcath – comparator	–£41.40	–£1,005.60

Compared with StatLock, the company reported base-case cost savings of £41.40 per patient for PICCs with SecurAcath and £1,005.60 per patient for CVCs with SecurAcath (see table 5 above and page 36 of the submission). The main reasons for StatLock's greater costs were device costs and differences in catheter migration rates; for sutures, the main reasons were differences in the rates of catheter-related bloodstream infection or catheter-related thrombosis.

The company conducted a one-way deterministic sensitivity analysis, increasing SecurAcath device costs by up to 200%. It also conducted multiway deterministic sensitivity analyses, changing the values for each economic and clinical parameter simultaneously by ±20%. In all cases, SecurAcath remained cost saving compared with its comparator (see section 9.5.7 of the company's submission). When PICC indwell time was increased to 6 months (representing their use in patients with cancer), the cost saving with SecurAcath increased to £115.00 per patient.

EAC critique of the company's model

The EAC queried a number of assumptions in the company's model: indwell times; nurses' placement of SecurAcath and adhesive securement devices versus doctors to place sutures; and that no extra resources are needed to place securement devices or for the outcomes chosen.

The EAC noted that the grade of staff placing the securement device will vary by clinical environment, but in UK practice, this is most likely to be a nurse. It noted difficulties and a lack of clarity in defining the outcomes used by the company. It agreed that the company's estimate of indwell time was conservative, specifically 3 days for CVCs. It noted that the company assumed that event rates for outcomes were constant with respect to catheter

indwell times, when it is more likely the probability of these events increases the longer the catheter is in place.

Overall, the EAC considered the company's model to be appropriate given the limited evidence base, but noted a number of concerns in the parameters used and errors in the company's submission. These included figures wrongly quoted, applying probabilities as rates and a lack of clarity on some sources of evidence.

EAC revisions to the company's model

The EAC made changes to the model parameters as described in table 6. The EAC had concerns with the clinical data, particularly the absence of complication rates. The company's analyses made a significant assumption that outcomes were independent of time and were collected over similar indwell times. There was also a risk of study heterogeneity because of uncertainty about similarity in clinical practice and outcome measurements.

Table 6: EAC revisions to the company's model (adapted from pages 142 to 144 of the assessment report)

Parameter	Value (base case)	Value (sensitivity analysis)	Source
Routine placement and maintenance times			
SecurAcath placement	3 mins	0.5 mins	Interrad report (2015)
StatLock placement	3 mins		Interrad report (2015)
SecurAcath maintenance	[redacted] mins		Janssens (2016b)
StatLock maintenance	[redacted] mins		Janssens (2016b)
Suture maintenance	[redacted] mins	[redacted] mins	Janssens (2016b)
Hazard ratios (SecurAcath vs StatLock)			
Migration	0.8443		EAC meta-analysis
Dislodgement	0.1424		EAC meta-analysis
CRSBI	1.1441		EAC meta-analysis
Complication rates per 1000 catheter days			
SecurAcath migration	0	2.18	Yamamoto (2002), EAC meta-analysis
StatLock migration	0	1.8	Yamamoto (2002)
Suture migration	0	3.1	Yamamoto (2002)

SecurAcath dislodgement	0	0.4	Yamamoto (2002), EAC meta-analysis
StatLock dislodgement	0	3.6	Yamamoto (2002)
Suture dislodgement	0	4.1	Yamamoto (2002)
SecurAcath CRBSI	0	0.7	Yamamoto (2002), EAC meta-analysis
StatLock CRBSI	0	0.7	Yamamoto (2002)
Suture CRBSI	0	3.4	Yamamoto (2002)
Needlestick Injury (suture)*	1.2		Yamamoto (2002)
Unit costs			
Nurse time per minute	£2.08		PSSRU (2015)
Cost of migration of CVC line	£134		Boland (2003) inflation adjusted
Cost of migration of PICC line	£134		Boland (2003) inflation adjusted
Cost of dislodgement of CVC line	£440		Boland (2003) inflation adjusted
Cost of dislodgement of PICC line	£274		NICE MTG24, Sherlock 3CG

The EAC regarded Yamamoto (2002) as the best evidence for complications, because it was the only source that reported rates rather than probabilities. This allowed the EAC to explore the effect of catheter indwell time on the complications in the decision problem. Yamamoto reported no statistically significant difference in dislodgements or migrations between StatLock and sutures, but a significant reduction (p=0.04) in infections with StatLock.

Using this evidence for its base case, the EAC assumed clinical equivalence on all outcomes between SecurAcath and comparators, except needlestick injury, where a reduced risk without sutures was highly likely. Therefore, the base-case costs were based only on placement and maintenance costs over the relevant indwell time, with needlestick injury costs included where relevant. The EAC conducted sensitivity analyses for complications, which included differential risks of migration, dislodgement and catheter-related bloodstream infections, based on the figures reported in Yamamoto (2002) and in the EAC's meta-analysis.

For CVCs, the EAC's model compared SecurAcath with both StatLock and sutures. For PICCs, the EAC analysis was restricted to SecurAcath and StatLock, based on expert advice that suturing of PICC lines is no longer done. Three indwell times were considered for both CVCs and PICCs: 5 days (short), 25 days (medium), and 120 days (long). The sensitivity analysis included costs for migration, dislodgement and catheter-related bloodstream infection. These costs were estimated from the probability of the event over the indwell period and the unit cost of the event. These EAC-assumed complication rates were independent of whether the catheter was a PICC or CVC.

The EAC calculated the probability of complications over the relevant indwell time from a baseline event rate per day, multiplied by indwell time in days and converted to a probability. Event rates were derived from Yamamoto (2002). These rates were used to estimate the probability of complications for both CVCs and PICCs with StatLock and for CVCs with sutures. The catheter-related bloodstream infection rates for CVCs reported by Yamamoto (2002) is in agreement with the baseline rate of 1.48 per 1,000 catheter days for PICC catheters applied in NICE's medical technology guidance on the 3M Tegaderm CHG IV securement dressing.

The probability of complications using PICCs and CVCs with SecurAcath was estimated by multiplying the relevant rate for StatLock with a relative risk estimated from the EAC's meta-analysis comparing StatLock and SecurAcath. The EAC assumed an indwell time of 25 days and converted pooled event probabilities to rates on this basis. A relative risk for each complication with SecurAcath compared with StatLock was then derived as the ratio of the relevant rates. This relative risk was applied to the event rate for each complication with StatLock, to derive an event rate with SecurAcath.

The EAC assumed a 3-minute placement time for StatLock based on the company's submitted evidence (Interrad 2015), which agreed with Frey (2006). The company's submission reports a 30-second placement time for

SecurAcath. The EAC made a more conservative assumption that placement time would be the same as StatLock (3 minutes), with 30 seconds used in a sensitivity analysis. The EAC used 4.3 minutes for the dressing-change time for SecurAcath and 7.3 minutes for StatLock, taken from Janssen (2016). No evidence was available for dressing-change time with sutures, so the EAC assumed 4.3 minutes (as for SecurAcath) in the base case, and 7.3 minutes (as for StatLock) in a sensitivity analysis.

Other amendments made by the EAC included: reducing needlestick injury to 1.2% based on Yamamoto (2002); increasing the cost of nurse time per minute from £0.60 to £2.08, based on Health and Social Care (2015); and applying costs for PICC and CVC placement of £274 and £440 (after inflation) respectively from Boland (2003). Based on expert advice that catheter migration would lead to replacement only when the catheter had moved out of the superior vena cava, the EAC used a lower cost of £134 for catheter migration from Boland (2003). Finally, the EAC made other assumptions that suturing is done by a band 6 nurse; that sutures remain in place throughout the indwell time; and that occlusion and thrombosis rates are independent of securement device.

Results from the EAC revisions to the company's model

Table 7 shows the results of the EAC's revised model. The EAC's base case found that StatLock was the cheapest option for PICCs needing a short indwell time (5 days), but that SecurAcath became cost saving for medium to long dwell times (25 days or more). For CVCs, StatLock was the cheapest securement option for short catheter indwell times, and sutures was the cheapest for medium to long indwell times.

Table 7: Summary of EAC results

Scenario	[1]	[2]	[3]	[4]
	Cheapest device (cost saving for cheapest device)			
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)
[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				

The EAC conducted a one-way sensitivity analysis, reducing the placement time for SecurAcath to 30 seconds (as reported by the company). This made SecurAcath slightly more cost saving and sutures slightly less cost saving, but did not change the base-case results. A second one-way sensitivity analysis assumed a maintenance time of [redacted] 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 indwell time. The EAC did a multivariate sensitivity analysis using the figures shown in table 6. This found that for short-term catheter placement for both PICC and CVCs, StatLock was the cheapest securement option, but for the medium and long term, SecurAcath was the most cost saving.

The EAC conducted a threshold sensitivity analysis for indwell times, which 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 at indwell times of 8 days or more, but SecurAcath remained more expensive than sutures for securing CVCs over any indwell time. A probabilistic sensitivity analysis generated cost savings of £22 for SecurAcath compared with StatLock for securing PICCs for 25 days (95% confidence interval [CI]: –£128 to £438). For a CVC for 5 days, the analysis generated a cost saving of –£7 (95% CI: –£210 to £47) for SecurAcath compared with

StatLock and £137 (95% CI: –£31 to £574) compared with suturing. However, the EAC concluded that there was considerable uncertainty in the underlying evidence, reflected by the large 95% confidence intervals.

EAC conclusions on the economic evidence

For PICCs, the EAC agreed with the company's conclusion that SecurAcath appears to be cheaper than StatLock over medium and long indwell times (25 days and over). Cost savings arise from shorter maintenance times with SecurAcath and the need to replace StatLock weekly. The EAC concluded that these cost savings were robust: it found smaller savings in the base-case analysis which excluded complications, but similar results in a multiway sensitivity analysis including complications. As an additional analysis, the EAC explored the cost consequences of PICC securement devices for shorter indwell times (5 days) and found that StatLock was the cheapest option in all scenarios.

For CVCs, the EAC agreed with the company's conclusion that SecurAcath was cost saving compared with sutures over a short indwell time of 3 days, but to a lesser extent. However, the EAC disagreed with the exclusion of StatLock as a comparator for CVCs. Additional analysis by the EAC with StatLock as a comparator concluded that StatLock is the cheapest securement device for CVCs with short indwell times in all scenarios. For CVCs with medium to long indwell times, the EAC felt there was uncertainty in the cost case. In the base case (excluding complications), suturing was somewhat cheaper than SecurAcath or StatLock. However, evidence suggested an increased risk of infection with suturing, which is a costly complication. A multiway sensitivity analysis including differences in complications found SecurAcath to be cheaper than suturing and StatLock over 25- and 120-day indwell times. This led the EAC to conclude that SecurAcath is likely to be the cheapest option for securing CVCs over medium and long indwell times.

6 Ongoing research

The company and the EAC are not aware of any ongoing research on SecurAcath. The EAC recommends further research is done on SecurAcath, which is detailed on page 157 of the assessment report.

7 Issues for consideration by the committee

Clinical evidence

Limited evidence base

There is uncertainty as to whether SecurAcath is clinically superior or equivalent to StatLock. The evidence on SecurAcath is limited, being largely prospective, observational non-comparative studies. As the only randomised controlled trial, Janssens (2016b) represents the most robust study evidence, and is the only study that directly compares SecurAcath and StatLock.

Assumption of clinical equivalence

Because of the uncertainty in the evidence and meta-analysis, the EAC has assumed clinical equivalence between SecurAcath and StatLock. This means that in the EAC's base case, the comparison between SecurAcath and the comparators is based only on differences in device costs, time needed for placement and maintenance (with the exception of needlestick injury).

Experts' clinical experience with SecurAcath

Advice from clinical experts is summarised in appendix B and in the adoption scoping report in appendix D.

Cost evidence

What to include in costings

The EAC has presented: a base case with an assumption of clinical equivalence; 2 alternative costing scenarios where this assumption is

changed for different variables; and a 4th scenario where multiple variables are replaced with those in Yamamoto (2002) and Janssens (2016b).

Comparators for PICCs and CVCs

The company assumed that for PICCs, the comparator for was StatLock; for CVCs, the comparator was sutures only. The EAC disagreed with the absence of StatLock as a comparator for CVCs and included them.

Catheter indwell time

SecurAcath appears cost saving, but this is dependent on indwell times. The EAC considered a range of indwell times from 5 to 120 days, because it considered the company's estimates to be conservative, particularly for PICCs. As the catheter indwell time increases, the cost case for SecurAcath improves.

- What are typical indwell times for PICCs and CVCs in clinical practice?
- Are the indwell times used in the company's and EAC's models realistic?

8 Authors

Neil Hewitt, Lead Technical Analyst

Abigail Stevenson, Technical Analyst

Paul Dimmock, Senior Technical Analyst (evaluations)

NICE Medical Technologies Evaluation Programme

September 2016

Appendix A: Sources of evidence considered in the preparation of the overview

A Details of assessment report:

- Chalkidou A, Goddard K, Herz N et al. The SecurAcath device for securing percutaneous catheters. Kings Technology Evaluation Centre, September 2016

B Submissions from the following sponsors:

- Interrad Medical Inc.

C Related NICE guidance:

- The Sherlock 3CG Tip Confirmation System for placement of peripherally inserted central catheters (2015) NICE medical technologies guidance 24
- The 3M Tegaderm CHG IV securement dressing for central venous and arterial catheter insertion sites (2015) NICE medical technologies guidance 25
- Guidance on the use of ultrasound locating devices for placing central venous catheters (2002) NICE technology appraisal guidance 49
- Healthcare-associated infections: prevention and control in primary and community care (2012) NICE guideline CG139
- Healthcare-associated infections: prevention and control (2011) NICE guideline PH36
- Surgical site infections: prevention and treatment (2008) NICE guideline CG74
- Prevention and control of healthcare-associated infections (2015) NICE pathway
- Infection prevention and control (2014) NICE quality standard 61
- Surgical site infection (2013) NICE quality standard 49

- Infection: Evidence Update 64, September 2014. A summary of selected new evidence relevant to NICE clinical guideline 139 ‘Prevention and

control of healthcare-associated infections in primary and community care' (2012). Available from: https://www.nice.org.uk/media/default/About/what-we-do/Evidence%20Services/Evidence-Updates-list.pdf

- Surgical site infection: Evidence Update 43, June 2013. *A summary of selected new evidence relevant to NICE clinical guideline 74 'Prevention and treatment of surgical site infection' (2008).* Available from: https://www.nice.org.uk/media/default/About/what-we do/Evidence%20Services/Evidence-Updates-list.pdf.

D References

Ballance P (2012) "Evaluation of Products Promote Patient and Clinician with Positive Advancement in Vascular Access Care" Poster presentation

Cordovani, D. and R. M. Cooper (2013) "A prospective trial on a new sutureless securement device for central venous catheters." Canadian Journal of Anaesthesia 60(5): 504-505

Curtis Lesley, 2015. PSSRU: Unit Costs of Health and Social Care 2015

Djurcic-Jovan A, Eisener A, McDiarmid S et al. (2016) "Implementation of a Quality Improvement Initiative Reduces PICC Migrations in a Complex Continuing Care Hospital" Poster presentation for Canadian Vascular Access Association

Dougherty L (2016) "Securing a more stable PICC" Poster presentation for the Association for Vascular Access

Egan, G. M., G. P. Siskin, R. Weinmann, et al. (2013) "A prospective postmarket study to evaluate the safety and efficacy of a new peripherally inserted central catheter stabilization system." Journal of Infusion Nursing 36(3): 181-188

Hughes, E. M. (2014) "Reducing PICC migrations and improving patient outcomes." British Journal of Nursing 23(2): S12, S14-18

Fang, F., H. Y. Zhang, F. Wang, et al. (2011) "Comparison of three different fixation methods for peripherally inserted central catheter. [Chinese]." Chinese Journal of Clinical Nutrition 19(2): 119-123

Frey, A. M. and G. Schears (2001). "Dislodgment rates and impact of securement methods for peripherally inserted central catheters (PICCs) in children." Pediatr Nurs 27(2): 185-9, 93.

Frey AM, Schears GJ. Why are we stuck on tape and suture? A review of catheter securement devices. J Infus Nurs. 2006;29(1):34-8.

Hill, J. G. (2014) "Beyond the Dressing for PICCs - Strategy for Cost-Savings and Work Efficiency." Journal of Vascular Access 15 (3)(208

Interrad Medical CH. Misericordia Parenteral Therapy PICC/Outcomes. Clinical Outcomes summary 2014.

Interrad Medical. SecurAcath cost-effectiveness report. Interrad Medical 2015.

Janssens C, Jerome M, Grumiaux N et al. (2016a) “Securing PICCs, results of the SecurAstap study: RCT comparing SecurAcath and StatLock” Poster presentation

Janssens, C. (2016b). "pre-publication draft submitted as academic in confidence by the author." August 2016.

McMahon, D. D. (2002) "Evaluating new technology to improve patient outcomes: a quality improvement approach." Journal of Infusion Nursing 25(4): 250-255

McParlan D, Gault M, Gillespie R et al. (2016) “PICC migration – a problem of the past!” Poster presentation at the 4th World Congress of Vascular Access 2016

Misericordia (2015) [reported as Anonymous 2015 in the assessment report] Misericordia Parenteral Therapy PICC Statistics/Outcomes report. Report from Covenant Health, Canada

Peveler, S. and Curry, C. (2013) “Changing the Outcome: Securing the future of Vascular access.” Poster presentation

Pittiruti, M. (2015) “Defining the indications of subcutaneously anchored securement devices: a European point of view.” Poster presentation

Sandeluss, S., Price, N., Simcock, L., et al. (2013) “Introducing SecurAcath into a Haematology/Oncology setting” Poster presentation

Sansivero, G., G. Siskin, M. Tessier, et al. (2011) "SecurAcath subcutaneous securement in peripherally inserted central catheters: Results of a prospective 50 patient trial with an internal securement device." Journal of Vascular Access 12 (1)(81

Simcock, L., N. Price, S. Sandeluss, et al. (2014) "Effectiveness & Acceptability of a Novel Securement Device in Adult & Teenage Cancer Patients with PICCs." Journal of Vascular Access 15 (3)(204

Stone, L., Lamagna, P., Pratt, P. (2013) “Improving PICC care in the Pediatric Patient” Poster presentation

Teichgraber, U. K., M. de Bucourt, B. Gebauer, et al. (2011) "Effectiveness of sutureless percutaneous placement of cuffed tunneled hemodialysis catheters applying StatLock attachment devices." Journal of Vascular Access 12(1): 17-20

Appendix B: Comments from professional bodies

Expert advice was sought from experts who have been nominated or ratified by their Specialist Society, Royal College or Professional Body. The advice received is their individual opinion and does not represent the view of the society.

Mr Maurice Madeo
Deputy director for infection prevention and control, Infection Prevention Society

Ms Jackie Nicholson
Consultant nurse in vascular access, National Infusion and Vascular Access

Dr Lisa Dougherty
Nurse consultant, National Infusion and Vascular Access

Ms Meinir Hughes
Intravenous access nurse specialist, Royal College of Nursing

Mr Matthew Hobley
IV nurse practitioner, Royal College of Nursing

Ms Rachel Binks
Nurse consultant, digital and acute care, Royal College of Nursing

Ms Liz Simcock
Clinical nurse specialist, Royal College of Nursing

Ms Carol McCormick
Clinical interventions team manager, Royal College of Midwives

Ms Dympna McParlan
Infusion services coordinator, Nursing and Midwifery Council

Dr Andrew Johnson

Consultant in intensive care medicine and anaesthetics, Royal College of Anaesthetists

- 7 expert advisers had direct involvement with SecurAcath; the others would like to use it, but is not currently available to them.
- Experts stated other catheter securement products were available, but SecurAcath had a unique method of securement which made it novel with the potential to improve outcomes. Comparators identified were adhesive securement devices (StatLock, Grip-Lock, Vygon and Modulare) and sutures. It was noted that these devices all adhere to the skin, and no comparator technologies fixed the catheter in place beneath the skin.
- The experts agreed that the most appropriate use of SecurAcath was to secure PICC and central lines; one expert indicated its suitability for long-term central venous access devices, one for securing any indwelling intravenous device and 2 experts noted it would be most appropriate in patients where a line will be in place for over a week. 2 experts highlighted that it is unsuitable in patients with a nickel allergy. Another expert identified a potential for use in patients with burns or skin conditions where suturing is presently the only securement option.
- Potential patient benefits for SecurAcath included its ability to remain in situ for long periods, reducing catheter migration, avoiding adhesion to the skin, and allowing cleaning around the insertion point on the skin surface. Other benefits identified were reductions in allergic reactions, infections and skin damage, reduced need for X-rays to check catheter positioning, and increased patient confidence in their ability to move without dislodgement.
- Potential benefits for the healthcare system included reductions in catheter line-related infections, reduced dressing costs (changes), PICC placement and X-ray costs and line replacements.
- All experts considered specialist training in using SecurAcath to be necessary. Removal of the device was identified as the most important challenge in the use of the device.

Appendix C: Comments from patient organisations

The following patient organisations were contacted: no response was received.

- Critical Care Patient Liaison Committee (CritPaL)
- BME cancer.communities
- British Kidney Patient Association
- Cancer Black Care
- Cancer Equality
- Cancer of Unknown Primary (CUP) Foundation - Jo's Friends
- Cancer52
- Children with Cancer
- CLIC Sargent
- Crohn’s and Colitis UK
- HAWC
- Helen Rollason Cancer Charity
- ICU Steps
- Independent Cancer Patients' Voice
- Macmillan Cancer Support
- Maggie’s Centres
- Marie Curie Cancer Care
- MRSA Action UK
- National Kidney Federation (NKF)
- Kidney Research UK
- PINNT (Patients on Intravenous and Nasogastric Nutrition Therapy)
- Rare Disease UK
- Rarer Cancers Foundation
- Royal College of Surgeons of England (RCSeng) Patient Liaison Group
- Sue Ryder
- Tenovus Cancer Care
- Together for Short Lives
- Ulcerative Colitis UK.

Appendix D: NICE adoption scoping report

Adoption and Impact Programme

Adoption Scoping Report MTG 291: June 2016

The SecurAcath device for securing percutaneous catheters

1. Introduction

The adoption team has collated information from healthcare professionals working within NHS organisations all of whom have experience of using the SecurAcath device for securing percutaneous catheters.

This report includes some of the benefits and difficulties that may be faced by organisations when planning to adopt the technology into routine NHS use.

2. Contributors

The table below contains the details of individuals the adoption team liaised with during the scoping of the SecurAcath device for securing percutaneous catheters.

Name of individual	Job title	Organisation
Richard Barron & Christopher McManus	Senior Radiographer	Countess of Chester Hospital NHS Foundation Trust
Lisa Dougherty	Nurse Consultant, Intravenous Therapy Nursing, Rehabilitation & Quality Assurance	The Royal Marsden Hospital NHS Trust
Matthew Hobley	IV Nurse Practitioner	East Kent Hospitals University NHS Foundation Trust
Carol McCormick	Clinical Interventions team manager	The Clatterbridge Cancer Centre NHS Foundation Trust

Dympna McParlan	Infusional Services Coordinator	Belfast Health and Social Care Trust
Chris O'Loughlin	IV Access Specialist nurse	Aintree University Hospitals NHS Foundation Trust

3. Use of the device in practice

All contributors have been using the SecurAcath device in the NHS for between 1 and 4 years, inserting between 400 and 1100 IV lines per annum. Most are using it routinely with only one site still trialling it. If a patient has a metal or nickel allergy a StatLock or Grip-Lok device is used. Clinicians report that while the technology is used mainly in specialist cancer centres, some local general hospitals have begun adopting it. For more detailed indications for use please see patient selection and areas of application.

Placing the device

Insertion is generally undertaken in a clinical room either by an IV access specialist nurse or a senior interventional radiologist at the time of PICC line insertion. On very rare occasions it may be undertaken at the bedside for example if a patient is too unwell, unstable or nursed in isolation. Correct positioning of the device is vital to ensure patient comfort.

Reports on device placement time varied from an additional 20 seconds to a few minutes.

Techniques for ensuring the most comfortable placement include; placing a small pad underneath the device to hold it off the skin, ensuring sufficient depth (this may require a surgical nick), and directing and securing the dressed line towards the shoulder to prevent it hanging downwards and pulling on the site.

Changing the dressing

An adhesive transparent or hypo-allergenic dressing is used over the insertion site and device. Routine dressing changes occur weekly or more frequently if there are any problems with the exit site. This may be done by hospital or community staff and one expert advised they have started training carers and family members to do this. Contributors suggest that during dressing changes the device should be moved and cleaned to prevent granulation making removal difficult. Anecdotally they report that this has improved line infection rates.

Removing the device

Contributors advised that removal of the device has been the most difficult aspect of implementation as it can be painful if not done correctly. A short sharp tug with sufficient force is needed to decrease discomfort.

There is variation in the use of local anaesthetic (lignocaine available on Patient Group Directions (PDGs)) for removal in adults. Confidence in the technique means some users achieve pain free removal without local anaesthesia. Local anaesthetic is always used when removing the device in children.

Variation exists regarding the grade of staff (band 3 Healthcare assistant to consultant level nurse and ward doctor) and which team (hospital IV team, ward based nurses or community staff) removes the device. All contributors stressed the need for training in device removal. In one organisation the hospital IV team advise the community team not to remove the device if the length of the catheter is not documented in the notes.

The company originally advised folding the device back on itself for removal. Following feedback from users they now suggest "*cutting the anchor base completely in half lengthwise along the groove*". A preferred method is identified, taught and used in individual organisations.

4. Levers and barriers to adoption

Training

Contributors advise that it is necessary to identify the staff groups that will remove the devices and plan their training in advance of implementation. Failure to identify and train enough staff can lead to unnecessary increased demand on the IV access team.

All contributors reported that there is a learning curve in the use of the device both in insertion, but more critically, removal. Gaining competency and confidence in removing the device is a potential barrier to adoption. All received initial training from the company but report that their ongoing practical experience has enabled them to develop improved techniques to make it a more comfortable experience for the patient and have built this into local training.

Training from the company lasts 30-60 minutes and consists of a demonstration, followed by practicing on a dummy. The company trainer then observes the clinician placing the device. Contributors report that the

company website and app are useful adjuncts to training. The company will provide extra training sessions and in one organisation deliver training to final year doctors.

Training of other staff includes:

- watch one, do one
- 1:1 sessions
- group training for final year doctors
- use of a dummy for clinicians to practice on
- Infusional nurses training
- ward based link nurses to deliver training
- competency based training on removal of SecurAcath

Patient selection and area of use in the NHS

Criteria for patient selection varies therefore before implementation an agreed protocol for use should be developed.

- Patients receiving long term parenteral nutrition, long term antibiotics, chemotherapy, or where there is a risk of the PICC being pulled out (for example if the patient is confused).
- Settings include oncology, haematology, medical, surgical and rheumatology services, both inpatients (including ITU) and outpatients.
- One expert specified they use it where the line is needed for longer than 2 months.
- All contributors use the device for PICC lines but shared knowledge that staff in other hospitals choose not to place on PICC lines. There is variation on use for tunnelled and midline catheters (the latter was considered as not cost effective by one contributor). None of the sites reported current use on non-tunnelled catheters.
- The device is not used for patients with a nickel allergy.
- One expert uses the device for older children if they have had the PICC placed without general anaesthetic. This is of particular value to very active children who may require PICC lines to be more secure.
- One expert does not use the device for patients who receive follow-up out of area (for example Hospice care) if they are not certain that there are suitably trained staff available to remove it.

Governance

NHS use of the SecurAcath device has been predominantly in specialist centres and it remains a novel piece of technology in many general hospitals, and with community based staff. It is essential that a detailed record is kept

explaining what the device is, the length of catheter, when it was placed and when the dressings need to be changed, who can remove it and how it should be removed. One expert explained that they use a diary card with all the necessary detail placed in the patient's notes.

Clinician confidence / acceptance

Clinician reluctance to change current practice has been a barrier to implementation in some organisations. One expert also reported that they have not gained agreement from their anaesthetic team to use it with non-tunnelled catheters.

Patient experience

Contributors advise that when they first started using the device there was some discomfort (while in place and with removal) reported by patients. As users have become more experienced and identified ways to make placement more comfortable, the majority of patients have reported no pain or discomfort with it.

In one organisation where more than 1000 lines are placed per annum 5 patients have requested it to be removed due to discomfort, over 4 years. This low figure appears representative of reports from other sites.

Resource impact

Introducing SecurAcath is reported to be cost saving with the following examples given:

Organisation 1:

- Replacing a migrated PICC £150 -£200 (excluding staff costs)
- Migration rates pre-implementation of SecurAcath = 40-60%
- Migration rates post implementation of SecurAcath = 0%

Organisation 2:

- Statlock = £3 per weekly dressing-change over 6 months = £78 (per patient)
- SecurAcath = £24 per patient (one off cost)
- Approximately 1100 lines placed
- Total for all patients when using StatLock = £86,000
- Total for all patients when using SecurAcath = £27,000

Organisation 3:

- Place approximately 1000 PICC lines per annum.
- Calculate the device to be cost effective compared with Grip-Lok if used for longer than 2 weeks.

Other issues reported
One expert reported that the insertion site tends to bleed more when SecurAcath is used and that it is harder to stop the bleeding with the device in situ. They are considering using surgical glue to deal with this issue.

5. Comparators

If the SecurAcath is not appropriate to use, for example in patients with a nickel allergy, or if a patient has found it uncomfortable or declines it, the comparators reported are either Grip-Lok or StatLock (adhesive catheter securement devices).

6. Reported benefits

The benefits of adopting the SecurAcath device for securing percutaneous catheters, as reported to adoption team by the healthcare professionals using the technology are:

1. Increased patient satisfaction due to more efficient dressing changes, reduced risk of line migration and subsequent need to replace lines.
2. Reduction, and in most cases elimination, of migration of lines.
3. Increased staff confidence when changing dressings, and improved dressing procedure.
4. Financial benefit of only doing a single placement.
5. Appropriate to use device if patient has an allergy or reaction to dressings and are therefore unable to have Grip-Lok and StatLock applied.
6. Reduced thrombosis and infection rates – anecdotally reported, but no data collected.
7. PICC placement teams have been able to meet the demand for service as no longer having to re-insert lines following migration.
8. No delays to treatment as a result of lines needing to be replaced.