National Institute for Health and Care Excellence

Medical Technologies Evaluation Programme

MT291 SecurAcath for securing percutaneous catheters

Consultation Comments table

MTAC date: 17 March 2017

There were 22 consultation comments from 7 consultees (3 manufacturers, 1 US private professional, 2 professional societies and 1 other). The comments are reproduced in full, arranged in the following groups – recommendations, clinical evidence, cost considerations and general. The draft responses to the 22 comments are based mainly on expert advice.

Com #	Consultee number and organisation	Sec. no.	Theme	Comments	Response
1	Manufacturer 1	1.1 Page 2	Recs	The statement “does not usually need replacing while the catheter is in place” is confusing. Should state “does not need to be replaced when the catheter is in place”.	Thank you for your comment. This statement reflects the fact that although SecurAcath does not usually need replacing, it may sometimes need to be removed due to rare complications. Expert advice was sought on this comment and is collated in Appendix 1. **The committee decided to reword section 1.1 in response to this comment and expert advice and changed replacing to ‘removing’.**
2	Manufacturer 1	1.2 Page 2	Recs	SecurAcath should be used on all patients receiving a CVC (PICC or short dwell CVC). It should be the standard of care for securing these catheters, replacing adhesive-based securement devices and sutures, and standardizing the protocol for catheter securement. All patients should receive the	Thank you for your comment. The committee’s considerations on the specific circumstances in which SecurAcath should be considered are summarised in Sections 3.17-3.20, 4.4-4.9 and 5.21-5.24. Expert advice was sought on this comment and is collated in Appendix 1.

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				same level of care regarding catheter securement.	**The committee considered this comment and expert advice but decided not to change its recommendations in light of the uncertainty in the evidence base for the use of SecurAcath for people receiving non-PICC CVCs.**
3	Manufacturer 2	1.1 Page 2	Clinical evidence	It's unfortunate that the most relevant quality evidence supporting SecurAcath has been redacted from the report. In these circumstances it is very difficult for the independent observer to have any understanding of whether the recommendation made in this report is supported by the available evidence. However, it's our view that the Recommendations of the report are modified to reflect the situation that there is a paucity of direct evidence supporting the clinical use and cost effectiveness of this device as stated in section 3.14. We recommend rewording 1.1 as follows:1.1 The case for adopting SecurAcath for securing peripherally inserted central catheters (PICCs) is supported by the limited evidence available. This together with expert opinion supports the conclusion that 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.	Thank you for your comment. To ensure that the process is as transparent as possible, NICE considers it essential that evidence on which the committee's decisions are based is publicly available. Confidential information is accepted using the process described in section 5.4 of the MTEP Process Guide. Unpublished evidence is accepted under agreement of confidentiality and is not made available to the public. Such evidence includes certain data that are awaiting publication ('academic-in-confidence'). The most relevant evidence (Janssens 2016b) is currently submitted awaiting acceptance by a peer-reviewed journal. The full manuscript was available for critical appraisal by the external assessment centre on an academic in confidence basis. Data from academic-in-confidence studies are discussed in the public parts of MTAC meetings and thus are open for public scrutiny to stakeholders who attend in person. In this case, the full protocol and a published abstract and poster presentation were in the public domain and the company relied on these in its submission. The EAC sought further information from the authors of the study for the assessment of the submission. The information contained in the publically available publications contains summary findings. **The committee considered this comment and decided not to change the guidance. Summary information on the academic in confidence material is available in the**

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					public domain. If the study is published before the guidance, appropriate changes will be made.
4	Manufacturer 1	2.2 Page 3	Clinical evidence	Tunneled CVCs may not need additional securing after the cuff has healed. However, the amount of time it takes for cuff to heal is variable and securement is needed until the cuff heals. In some patients the cuff never fully adheres. Stability helps the cuff heal properly.	Thank you for your comment. This part of section 2.2 is based on a published nursing manual and expert advice. Expert advice was sought on this comment and is collated in Appendix 1. **The committee decided to add some additional wording in the 3rd bullet of section 2.2 to reflect the need for securement of tunneled CVCs before healing.**
5	Manufacturer 1	2.3 Page 4	Clinical evidence	Tunneled CVCs should not be excluded from this guidance. Use of SecurAcath on tunneled catheters provides improved stability to allow the cuff to heal in place more quickly and completely.	Thank you for your comment. Please refer to the response to comment 2. Expert advice was sought on this comment and is collated in Appendix 1.
6	Manufacturer 1	2.4 Page 4	Clinical evidence	Description terminology should be modified. The base is made up of 2 foldable metal legs and 2 securement feet. The feet are inserted under the skin at the catheter insertion site, and are unfolded to form a subcutaneous anchor.	Thank you for your comment. Expert advice was sought on this comment and is collated in Appendix 1. **The committee decided to change section 2.3 to reflect the wording suggested by the consultee.**
7	Manufacturer 1	2.5 Page 4	Clinical evidence	The statement, “The smallest possible size should be used, depending on the size of the catheter” is confusing. Restate as, “The SecurAcath device is size specific should be matched to the size of the catheter.	Thank you for your comment. **The committee decided to change section 2.4 to reflect the wording suggested by the consultee.**
8	Manufacturer 1	2.11 Page 5-6	Clinical evidence	The Infusion Therapy Standards of Practice also include a caution to be aware of the risk of medical adhesive-related skin injury (MARSI) associated with the use of adhesive-based Engineered Stabilization Devices (Statlock).	Thank you for your comment. **The committee decided to change section 2.10 to reflect the wording suggested by the consultee.**
9	Manufacturer 1	5.21 Page 20-21	Clinical evidence	The SecurAcath can and should be used on tunneled CVCs. Use of SecurAcath on tunneled catheters provides improved stability	Thank you for your comment. Please also see the responses to comment 2.

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				to allow the cuff to heal in place more quickly and completely. Use of SecurAcath on a short dwell, non-tunneled CVC does not require the use of an additional adhesive device to prevent dislodgement. The catheter should be completely under the site dressing with only the extension tubes outside the dressing. When the dressing is placed properly additional securement of the catheter hub with and adhesive device is not necessary.	Expert advice was sought on this comment and is collated in Appendix 1. **The committee carefully considered this comment and decided not to change section 5.24, as using an adhesive device on top of a SecurAcath device for short-term non-tunnelled CVCs was considered standard practice in the NHS.**
10	Manufacturer 2	1.3 Page 2	Costs	The EAC cost model is largely populated by extrapolating rates of complications from Yamamoto et al 2002, a paper that compared complications between an adhesive securement device (Statlock) and sutures. The results for Statlock seem to have been assumed to be the same as what might be expected from using Securacath and with no reasoning for this assumption. Since the two devices have completely different ways of anchoring devices (Statlock, topical adhesive; Securacath, invasive)this assumption would seem to be misplaced. We suggest the following change to 1.3: Cost modelling based largely on clinical evidence for adhesive catheter securement devices, indicates that SecurAcath leads to cost savings if the PICC remains in place for 15 days or longer	Thank you for your comment. The external assessment centre notes that the evidence on differential complication rates was very weak. It was insufficient to conclude with any certainty that SecurAcath was associated with lower complication rates than StatLock, as described in section 3.15. The largest observational study indicated substantially lower migration rates for SecurAcath compared with the only RCT. This indicated heterogeneity in the definition of migration which compromised the pooling of evidence. For this reason, we assumed the same complication rates for SecurAcath and StatLock in the base case analysis and examined the impact of the evidence of different complication rates in a sensitivity analysis, as described in sections 5.10 and 5.14. **The committee carefully considered the assumption of clinical equivalence between SecurAcath and StatLock used in the cost modelling and agreed with the EAC that there was insufficient evidence to determine that SecurAcath was clinically superior in effectiveness and adverse events to StatLock, so concluded it was non-inferior in terms of effectiveness and side effect profiles, which was added to section 3.15.**

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11	Manufacturer 1	2.6 Page 4	Costs	The list price of the SecurAcath is £20 (£200 for a box of 10 devices). The £16 was a specific customer sale price stated in the Hughes article from the British Journal of Nursing. £16 is not the list price for the SecurAcath in the U.K.	Thank you for your comment. The list price of SecurAcath stated in 9.3.5 of the company submission and used in the cost modelling was £16. This was also stated in the assessment report, which was sent to the company to check for factual accuracy. The external assessment centre re-ran the model using the updated price of £20 and reported that raising the cost of SecurAcath by £4 in all analyses did not affect the ranking of SecurAcath in any of the base case or deterministic sensitivity analysis for placement times of 5, 25 and 120 days. StatLock remains the cheapest option for placement times of 5 days. SecurAcath remains cheaper than StatLock for placements of 25 or 120 days. Sutures remain the cheapest option for 25 and 120 day placement times assuming these are placed by a nurse. The change in price will impact on the additional analysis we undertook in which we assumed that sutures were placed by a doctor. At a price of £16 and assuming both that suturing is undertaken by a doctor and that placement of SecurAcath takes only 30 seconds (base case assumed 3 minutes), SecurAcath is £3 cheaper than sutures for indwell times of 25 and 120 days. A price rise of £20 would change that result – sutures would now be £1 cheaper than SecurAcath. Fundamentally, the impact of the price change is minimal. Assuming suturing is to be avoided, StatLock is the cheapest option for short indwell times and SecurAcath is cheaper for medium and long indwell times (as before). **The committee considered the updated list price and updated modelling results and decided to update sections 2.5 and 5.12-5.13, 5.16 and Table 1 accordingly.**
12	Manufacturer 1	3.16	Costs	The statement, “does not usually need replacing while the catheter is in place” is confusing.	Thank you for your comment. Please see the response to comment 1.

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		Page 12		Should state, “does not need to be replaced when the catheter is in place”	
13	Manufacturer 1	3.19 Page13	Costs	SecurAcath should be used on all patients receiving a CVC (PICC or short dwell CVC). It should be the standard of care for securing these catheters, replacing adhesive-based securement devices and sutures, and standardizing the protocol for catheter securement. All patients should receive the same level of care regarding catheter securement.	Thank you for your comment. Please see the response to comment 2.
14	Manufacturer 2	5.1.1 – 5.1.5 Page 17	Costs	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..." Evidently the EAC has made the unsupported assumption of the equivalence of complications associated with adhesive securement devices and Securacath without providing a reasoned justification of this premise. It would seem that a reduction in overall costs associated with a decrease in infection with Securacath has been included in the EAC model with no published evidence to support this factor. The economic model is optimistic about the probability of Securacath providing cost savings through extrapolation of data from a competing product and a redacted unpublished study. These factors cast some doubt on the output of the model. This requires fuller explanation in the reports and the associated limitations acknowledged in the recommendations.	Thank you for your comment. Please see the response to comment 10. The external assessment centre noted that the conclusions drawn from the evidence included in the assessment report are based not only on the numbers reported in the individual studies, but also the clinical and statistical significance and the methodological quality of the assessed studies. The EAC considered the results of the meta-analysis in comparison with the results reported by the unpublished RCT by Janssens (2016b) which did not show any superiority of SecurAcath in respect to catheter related infection rates (2% for SecurAcath and 2% for StatLock). This was similar to the previous rate of catheter related infections reported by Yamamoto 2002 (1.2%). The same study provided evidence of an increased rate of infection for sutures compared to StatLock. Based on the above reasoning the EAC concluded that there is insufficient evidence that SecurAcath is clinically superior in effectiveness and adverse events to StatLock. The EAC did however, considered the differences in complications rates in a sensitivity analysis, as it regarded the differences in complication rates to be weak and conflicting.

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					The committee carefully considered the assumption of clinical equivalence between SecurAcath and StatLock used in the cost modelling and agreed with the EAC that there was insufficient evidence to determine that SecurAcath was clinically superior in effectiveness and adverse events to StatLock, so concluded it was non-inferior in terms of side effect profiles, which was added to section 3.15.
15	Manufacturer 1	5.11 Page 17	Costs	Suturing is not performed by nurses in the UK. Nurses who place PICCs will use adhesive-based securement device or Securacath. Sutures are used by physicians who place short-dwell CVCs.	Thank you for your comment. The committee's considerations on this point are summarised in section 5.18.
16	Manufacturer 1	5.17 Page 19-20	Costs	Over 90% of short dwell CVCs (typically central lines placed in the internal jugular vein in the neck) are secured with sutures. Statlock may be the cheapest securement option, however, it has not been clinically accepted by physicians for securing these short dwell CVCs due to issues with hair, skin oils, moisture, or skin folds preventing the adhesive device from adhering to the skin properly. Therefore, physicians have continued to use sutures for securing short-dwell CVCs even though they have an increased risk of infection, create additional punctures in the skin, do not allow for complete cleaning of the catheter insertion site, and put the clinician at risk for a suture needle stick injury.	Thank you for your comment. Expert advice was sought on this comment and is collated in Appendix 1. **The committee considered this comment and expert advice and decided not to change the guidance as experts stated that StatLock rather than sutures is used for securing short-term CVCs in current practice.**

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17	Manufacturer 2	general	Costs	The cost modelling is based on clinical evidence for adhesive catheter securement devices which may not necessarily be translated to the costs associated with a more invasive device such as SecurAcath which may have a different cost profile. In our opinion this should be more clearly stated.	Thank you for your comment. The external assessment centre (EAC) noted that the cost modelling in the base case analysis is based on the component and time costs to place and maintain the relevant securement device. These data were taken predominantly from the Janssen RCT which was powered to compare placement and maintenance times for StatLock and SecurAcath along with component costs for SecurAcath (£16) taken from the manufacturer's cost submission. Please see the responses to comments 10 and 14.
18	Manufacturer 1	4.2 Page 13	General	Removal proficiency improves quickly with experience.	Thank you for your comment. **The committee decided to change section 4.5 to reflect the wording suggested by the consultee and further clarification on training from experts.**
19	Private Sector Professional	general	General	Thank you for this opportunity to comment and for your efforts. I have no conflict/ disclaimer. I am not in a position to determine the dollar (or British Pound) value of SecurAcath , but I am perhaps in the best position of all to comment on the short comings of other presently available securement devices. I am a private practice interventional radiologist (IR) in the USA. I am an " in the trenches" stakeholder regarding various types of catheter securement problems. We see them all, fix the problems created by them and as such are greatly affected by all of them. I bear witness that we have a huge replacement, repositioning and re-start tube problem in modern medicine. I read your guidance therefore with great interest.	Thank you for your comments. In developing the guidance, we have consulted with experts with a wide variety of experience of vascular access in UK NHS settings. NICE medical technologies guidance reflects the cost consequences of adopting a device in a UK NHS setting, so insurance costs are not included in our cost modelling. As described in the Medical Technologies Evaluation Programme (MTEP) process and methods guides, costs are modelled from an NHS and personal social services perspective only, so any costs from loss of productivity are not taken into account. Regarding soft costs, any impacts a technology has on patient or carer's quality of life can be considered, but will not be considered in the cost analysis as cost consequence analysis is used rather than cost effectiveness, so costs per QALY are not calculated. The EAC noted that costs of migration of a CVC or PICC line and the cost of dislodgement of a CVC line were taken from a health technology assessment published in the UK.

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				All other present securement devices have significant problems, that include ineffectiveness, additional risk and transiency. Your study appropriately focused on costs, but I think severely underestimated their number and their severity. What is the total or true cost? These can be broken down into hard and soft costs- the soft ones being much more subjective and/or difficult to measure. Let me state some. First the hard costs: 1. Dislodgement or mal-positioning of any tube or drainage device is either a failure or at a minimum a postponement of appropriate therapy. Particularly "specialty devices" that are special order/ not readily available for replacement. 2. In the USA- unnecessary ER, followed by IR , followed by hospital, followed by Insurance costs. 3. MARSI. 4. Lost work - patient, family and/ or caregivers. 5. Transportation, lodging, ambulance. Where I live in the winter transportation is more dangerous than many of my procedures , including many tube malfunction issues. 6. Work flow perturbation- busy ER's having to deal with non- emergent issues, busy referring	The data were collected as part of a randomised controlled trial of the clinical and cost-effectiveness of Hickman line insertions by nurses in adult cancer patients. The cost of dislodgement of a PICC line was taken from an evaluation underpinning guidance issued by NICE on the placement of PICC lines (MTG24). We considered these sources the most authoritative estimate of the true cost to the NHS. Costs borne to other organisations such as patients or employers have not been considered. This perspective follows guidance for technology assessment issued by NICE which recommends a health and personal social services perspective. We would also like to highlight 2 further points. Firstly, our cost estimates are similar to the values used in the manufacturer's cost submission. Second, in the base case analysis dislodgement rates are assumed the same across adhesive devices and hence the cost of these episodes are irrelevant – they will have the same impact across comparators regardless of their magnitude. Differences in rates of migration, dislodgement and catheter related infection were considered only in a sensitivity analysis. Expert advice was sought on this comment and is collated in Appendix 1. **The committee considered the points raised in this comment carefully but, because several of the points relate to issues outside of our processes and methods, especially those relating to non-UK NHS practice and costs incurred or saved outside of a cost consequences approach, decided not to change the guidance.**

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				clinicians hassled, IR scheduling issues including unnecessary overtime and weekend expenses. Now the soft costs: 1. Patient: concern, anxiety, worry, inconvenience, frustration. 2. Loved ones- concern, anxiety, worry, inconvenience, frustration. 3. Caregivers-concern, anxiety, worry, inconvenience, frustration. Clearly, we would all agree that our goal as health care providers and patient advocates is to have a durable, reliable, easy to place and remove, well-tolerated securement device that allows easy access to and visibility of the access skin entrance site. In other words- something that does not prevent or delay the tube from doing its' intended job. Now the SecurAcath device has shown great ability to answer all of these needs as well as promise to address needs that extend well beyond the scope of your present guidance regarding PICCs and CVC's. I would also state that not all access can be regained and all repeat access has repeat risk. This is especially pertinent to the litigious nature of US health care.	

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				I am not a marketer nor a salesperson, - but for all of it's ability it's price would seem to be reasonable, particularly when TOTAL COSTS, such as the ones above, are taken into account. I would encourage additional effort toward an accounting of these total costs vs. total capabilities of the device. Subcutaneous securement is in its' infancy and offers a completely new paradigm. I think it is incumbent upon us to fairly assess its' total value.	
20	6. Department of Health	general	General	Thank you for the opportunity to comment on the evaluation documents for the above medical technology. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment.
21	Professional society	General	General	Experts within the RCoA are not familiar specifically with this device. The lack of an illustration was highlighted as a particular deficiency in this document. The body of evidence was felt to be about what one would expect for such a device at this stage in its life cycle. There did not appear to be specific controversies highlighted related to clinical aspects. That said, there was a consensus view from the RCoA that it would seem more helpful for NICE to produce generic recommendations on the best way to secure catheters, rather than just considering a single product for doing that. This was not felt to be a very useful way forward, and is potentially misleading as it was not at all	Thank you for your comment. NICE medical technologies guidance provides recommendations on a single technology notified to NICE. Please see the MTEP Process Guide for further details.The guidance is developed by a committee which reviews the available evidence and obtains advice from clinical experts and patient organisations and decides if the company's claimed patient and healthcare system benefits are plausible. The MTEP programme use a cost consequences approach to calculate costs rather than cost effectiveness. The committee heard advice from clinical experts who stated that dwell time is routinely anticipated in practice, especially for PICCs, and this reflected in section 3.19. The MTEP Process Guide (section 3.7) describes the way in which expert advisers are identified and engaged. The Royal College of Anaesthetists (RCoA) was approached to nominate

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				highlighted which aspects of the specific device were felt beneficial and which not (all devices being ultimately and inevitably a mix of these things). Moreover, the recommendations so far are based on only three published studies (with another study comparing SecurAcath with StatLock still ongoing), some unpublished data and a meta-analysis of other studies, most of which were not comparative. There seems to be a lot of dependence on the views of experts, but not all of these have actually used SecurAcath. It was noted (and of some potential concern) that there was a preponderance of sponsor-nominated assessors (notwithstanding any conflicts that were declared). The financial calculations are quite complicated and opaque, and these suggest cost effectiveness of the different products depends on how long the catheter will be in place. This may be impossible to know from the start, when the catheter is first inserted. In summary, the RCoA feels that while on the one hand there is unlikely to be controversy around the specific device, the evidence so far does not appear particularly robust and would probably not, for example, be publishable as peer-reviewed literature. The whole topic would benefit from deferring the recommendation or reviewing it when more information is available, and then to consider a broader recommendation around key principles rather than comments on specific devices in the absence of a full evidence base."	experts for this evaluation, however no nominations were received. 10 experts, 1 of whom is a member of the RCoA and 3 of whom were not sponsor-nominated, provided expert advice. We do not routinely include illustrations as NICE guidance is intended to make recommendations about the use of a device, not describe the device itself. It's part of our content strategy that we don't repeat content or information that is available publically elsewhere. Further information about the treatment, condition or device is available online and we link to this from the guidance. The EAC has stated: "The lack of high-quality evidence was highlighted in the assessment report with the exception the unpublished RCT by Janssens (2016b). The conclusions drawn from the evidence included in the assessment report are based not only on the numbers reported in the individual studies, but also the clinical and statistical significance and the methodological quality of the assessed studies. The EAC considered the results of the meta-analysis in comparison with the results reported by the unpublished RCT by Janssens (2016b) and concluded that there is insufficient evidence that SecurAcath is clinically superior in effectiveness and adverse events to StatLock, despite the fact that few individual before and after studies have shown superiority of SecurAcath for some of the outcomes. However, there were some evidence to support equivalence between SecurAcath and StatLock. The EAC would also like to note that most current and ongoing research on these devices is largely nurse-led. As a result, most of the evidence exist in the form of audits and service evaluation, namely real-world data. Despite the apparent lower quality in comparison with RCTs real-world evidence can still provide valuable information that can be used to

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					support an MTEP decision as long as the results reported are handled with caution. For example, from the 8 outcome categories included in the scope, our meta-analysis was deemed appropriate for only 5 outcomes that were considered to be objective and hence valuable information could still be extracted from abstracts and conference proceedings. These were migration, dislodgement, catheter-related infection, CRBSI, unplanned removals/reinsertions. In addition, we know that observational studies are likely to overestimate the size of the effect which we took into consideration during our assessment to assume non-superiority of SecurAcath over adhesive devices. Finally, we would like to note that it is not unusual for MTEP assessment reports to consider both unpublished data from RCTs but also data from observational non-comparative studies as long as all the limitations are outlined and taken into consideration as the EAC did in the case of SecurAcath. Expert advice was sought on this comment and is collated in Appendix 1. **The committee considered the points raised in this comment carefully but as several of the points conflict with MTEP published processes and methods, decided not to change the guidance**
22	Professional society	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with the Renal Association and would like to make the following comments: 1. It is a device to hold lines in place by securing under the skin and preventing migration in lines that would otherwise by permanently sutured or held in place by an adhesive device	Thank you for your comment. Expert advice was sought on this comment and is collated in Appendix 1. The company states they are not aware of use of SecurAcath on dialysis catheters but that it does plan to release 9F, 10F and 12F SecurAcath sizes by the end of

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				2. There is no mention in the document of it being used for dialysis catheters; it's main use appears to be PICCS lines and ITU CVC 3. It only comes in a largest size of 8F. A Permcath is 14F. 4. The main issue is in lines more likely to migrate; assuming that we all used tunnelled cuffed lines and that in some they do move but not a huge issue in most. We also only suture for the first couple of weeks then take them out so risk of infection and cost associated with regular suturing not a huge issue.	the year which could be used on some dialysis catheters and drainage catheters. **The committee considered this comment and added an additional consideration in section 4.9 regarding its use for dialysis catheters and the larger sizes of SecurAcath.**

Appendix 1: Expert advice in response to consultation comments

Com #	Query from consultation comment	Expert response
1	The statement “does not usually need replacing while the catheter is in place” is confusing. Should state “does not need to be replaced when the catheter is in place”.	Ex1: Not sure how this would be done as if it has been a few days after PICC inserted there is tissue growth around the exit site and would make it very hard to reinsert. Ex2: ‘does not need to be replaced during the dwell time of the catheter unless a complication occurs’
2	SecurAcath should be used on all patients receiving a CVC (PICC or short dwell CVC). It should be the standard of care for securing these catheters, replacing adhesive-based securement devices and sutures, and standardizing the protocol for catheter securement. All patients should receive the same level of care regarding catheter securement.	Ex1: Agree with the recommendations that its only for PICCs – at this stage there is not enough experience or data to recommend it for short term CVCs Ex2: We in N.I. only use the device with PICCs. We currently do not use it with short-term CVCs but I am aware that some hospitals are changing their practice to do so. This is because suturing can increase the risk of infection, particularly considering the location of the catheter, prove difficult to cleanse, it can cause scarring and has associated risks of needle stick injury. Suturing is increasingly being considered as ‘old practice’. If access has been difficult and essential, the catheter continues to be displaced then securacath may be justified and considered cost effective.
4	Tunneled CVCs may not need additional securing after the cuff has healed. However, the amount of time it takes for cuff to heal is variable and securement is needed until the cuff heals. In some patients the cuff never fully adheres. Stability helps the cuff heal properly.	Ex1: Yes it would need to be retained for same time as the sutures currently are left insitu – cuff usually secured in tunnel in 3 – 4 weeks Ex2: I don’t use them with CVCs but the cuff needs time to granulate as opposed to heal. The sutures remain insitu for 21 days to allow tissue granulation but it is thought that this process takes approximately 14 days. Ex3: I don’t insert tunnelled cuffed lines myself at the moment but yes I think this SecurAcath would be a good idea if available in the right sizes. It would have two advantages over the current practice at our hospital of stitching the line in place: a) better from an infection point of view, and b) eliminates the risk of accidentally making a hole in the line with the stitch cutter when removing the stitch which we do at 21 days. I have known this happen a few times and when it does, not only is there a risk of air embolism and infection but the whole line needs to be

Com #	Query from consultation comment	Expert response
		removed because the hole in the catheter is almost always too close to the exit site for the line to be repaired.
5	Tunneled CVCs should not be excluded from this guidance. Use of SecurAcath on tunneled catheters provides improved stability to allow the cuff to heal in place more quickly and completely.	Ex1: I think we only have PICC experience but it could still be used for others – not sure we should restrict its use though Ex2: SecurAcath is only manufactured to size 8F and tunnelled catheters used in the UK are predominantly 10-12F therefore the SecurAcath is too small to accommodate a tunnelled catheter. Paediatric tunnelled catheters are smaller and may accommodate the SecurAcath. It would be beneficial to use a SecurAcath with a tunnelled catheter if it was manufactured to the required size. Ex3: I have used SecurAcath with non-tunnelled NON-CUFFED CVCs. In this case the SecurAcath replaces the cuff as a means of keeping the line in place and would stay in for as long as the line was needed. This not currently standard practice as you correctly state but I think it has the potential to remove one of the big disadvantages of tunnelled CUFFED catheters: ie the fact that removal of the catheter requires minor surgical skills whereas removal of the SecurAcath does not.
6	Description terminology should be modified. The base is made up of 2 foldable metal legs and 2 securement feet. The feet are inserted under the skin at the catheter insertion site, and are unfolded to form a subcutaneous anchor.	Ex2: I think this is an excellent analogy and should be reworded as suggested.
9	Use of SecurAcath on a short dwell, non-tunneled CVC does not require the use of an additional adhesive device to prevent dislodgement.	Ex1: In the one centre that uses it successfully they did use an adhesive too – without having any experience using it for short term CVCs I would not like to categorically say the adhesive dressing was not required. Ex2: I have no experience with using a SecurAcath on a non-tunnelled CVC but I would agree that if used that additional adhesives should not be required to prevent dislodgement. Ex3: No I don't agree. I wouldn't like to risk this.
16	Over 90% of short dwell CVCs (typically central lines placed in the internal jugular vein in the neck) are secured with sutures. Statlock may be the cheapest securement option, however, it has not been clinically accepted by physicians for	Ex1: StatLock is used in some centres but not all Ex2: StatLock is not used in our establishment. I agree that it would not be clinically acceptable given the stated reasons and the use of a SecurAcath would be much more suitable.

Com #	Query from consultation comment	Expert response
	securing these short dwell CVCs due to issues with hair, skin oils, moisture, or skin folds preventing the adhesive device from adhering to the skin properly.	Ex3: In my hospital Statlock has completely replaced sutures which are not allowed by infection control. In my opinion if it is true that physicians at other hospitals need to be encouraged to stop using sutures I would rather put my energies into persuading them to use Statlock rather than SecurAcath.
19	Your study appropriately focused on costs, but I think severely underestimated their number and their severity. What is the total or true cost?	Ex1: Think there could be more discussion re the other savings from not having dislodgement and replacement etc Ex2: The loss of a catheter can be very costly in many aspects but it is difficult to assess if these are captured accurately in the guidance. Ex3: I'm not sure sorry.
21	The financial calculations are quite complicated and opaque, and these suggest cost effectiveness of the different products depends on how long the catheter will be in place. This may be impossible to know from the start, when the catheter is first inserted	Ex1: In some instances that may be true – when antibiotics are started they may need to be given for longer than first anticipated but in most other settings that would be clear eg. Chemotherapy or home TPN. Ex2: When catheters are requested they are usually for a specific period of time i.e. x no. of cycles of treatment, however, in many cases this period can increase/decrease if treatment plans change or complications occur. When inserted for supportive therapy i.e. fluids/blood products the time period can be difficult to predict. However, the predicted dwell time of the vast majority of catheter insertions can
22	There is no mention in the document of it being used for dialysis catheters; it's main use appears to be PICCS lines and ITU CVC	Ex1: Sorry I know nothing about renal catheters

Appendix 2: EAC critique on new published evidence on SecurAcath

Zerla 2017

(PICC)

Clinical evidence

Zerla et al. (2017) investigated adult oncology patients requiring chemotherapy with a PICC in place for more than 2 months, secured with SecurAcath (N=30). The authors regularly collected data on catheter securement, maintenance and complications (thrombotic and catheter-related infection episodes). The median dwell time was 145 days. Skin integrity issues were seen in 32.17% of patients. Pain scores were measured on a 0-10 scale: pain scores were ≤2 at placement in 90% of patients, ≤2 in situ in 95% of patients, and ≤2 at removal in 43.33% of patients. However, it is noted by the authors that in 12 cases they could not evaluate pain during removal because the patients either had the catheter still in-situ or they died with the catheter in-situ. No cases of dislodgment, infection and thrombotic episodes were reported. Authors report a median maintenance time of 10 minutes for SecurAcath which was compared to a historical cohort that had a median of 20 minutes maintenance time for an adhesive device. The authors conclude that, after effective training, SecurAcath is comfortable for the patient, reduces catheter movements, and is more effective in comparison to adhesive devices in oncology patients with long-term catheterisation and ambulatory (outpatient) maintenance.

Critical appraisal

This single-centre prospective study in Italy, previously published as a conference abstract (Zerla et al. 2015), has no comparator and is probably too small to derive any meaningful data for future comparison. The authors provide their method in detail for PICC insertion and SecurAcath placement, along with a detailed maintenance protocol. The manufacturer's protocol was used for SecurAcath insertion and removal. They have used photographic documentation for recording local complications including dislocation rates which enhances the methodological quality of data collection. The authors report some baseline characteristics (such as age, dwell time and BMI) and the cohort is homogenous. The study uses the visual analogue scale for pain scores and the visual exit-site (VES) score for infection, which is generalisable to future studies. Patients reported as pain-sensitive received administration of a local anaesthetic during removal, which may have affected the pain scores reported by the study. Sample size calculations and CIs are not reported.

The full text publication (Zerla et al. 2017) reports the same results as the conference abstract with the exception of higher pain scores during removal (43.33% vs. 66.7% in Zerla

et al. 2016) and the unplanned removals (2 cases vs. 0 cases in Zerla et al. 2017). The pain score results from Zerla et al. (2017) have no impact in our clinical and economic evidence conclusions as for the former we have already highlighted in our assessment report the higher rates of pain during removal with SecurAcath vs. adhesive devices. For unplanned removals the total number reported from all available studies increases from 25 to 27, which is already absorbed by our wide confidence intervals reported for this outcome into the meta-analysis (10.31% to 22.06%).

Economic Analysis

Zerla et al. (2017) provide a cost comparison of SecurAcath with StatLock which includes only the cost of the devices. Few details on the analysis are given but it appears that the 30 patients receiving SecurAcath were compared with a historic control population (Zerla et al. 2015) using StatLock. Devices were assumed to cost €30 for SecurAcath and €6 for StatLock generating total device costs of €900 for SecurAcath and €4,254 for StatLock. The authors conclude that SecurAcath is cost saving.

The authors report shorter maintenance for SecurAcath than StatLock but do not include this in their cost comparison. They report a median time of 10 minutes for SecurAcath compared to 20 minutes for StatLock. The quality of data recording that underpins these estimates is unclear. Although the times reported in Zerla et al. (2017) are longer than the estimates of 4.3 minutes for SecurAcath and 7.3 minutes for StatLock reported by Janssen and used in the cost analysis undertaken by the EAC, they are approximately in the same order magnitude 1:2. The authors also report no dislodgments with SecurAcath and compare this with results from Zerla et al. (2015) of 793 PICCs secured with adhesive devices in which 63 dislodgements were observed. An overall cost for reinsertion for all 63 dislodgements of €18,710 is estimated.

The inference from the cost analysis is consistent with the EAC's conclusion that SecurAcath is cost saving when compared with StatLock over medium and long indwell times. The authors report longer maintenance times than those reported by Janssen and used in the analysis by the EAC. The EAC regards the Janssen study, which was an RCT powered to compare placement and maintenance times, as providing higher quality evidence on maintenance times. The EAC notes that the use of maintenance times from this study in place of those by Janssen would not change the conclusions of the EAC cost comparison that StatLock is cheaper than SecurAcath over short indwell times and SecurAcath is cheaper than StatLock over medium and long indwell times. The EAC further notes that the estimate of the cost of reinsertion of 63 PICC lines at €18,710, or €297 per PICC line is similar to the cost of dislodgement of a PICC line of £274 used in the EAC cost analysis.

In summary, the EAC does not believe that this study challenges the findings of the cost analysis already undertaken.

References

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