National Institute for Health and Care Excellence

External Assessment Centre correspondence

Sherlock 3CG Tip Confirmation System

The purpose of this log is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the sponsors' original submission. This is normally where the External Assessment Centre:

a) become aware of additional relevant evidence not submitted by the sponsor,
b) need to check "real world" assumptions with NICE's expert advisers
c) need to ask the sponsor for additional information or data not included in the original submission, or
d) need to correspond with an organisation or individual outside of NICE.

These events are recorded in these tables to ensure that all information relevant to the assessment of the topic is made available to MTAC. These tables are presented to MTAC in the Assessment Report Overview, and are made available at public consultation.

Table 1. Correspondence with sponsor
Table 2. Collated responses from expert advisers to EAC questions
Table 3. Other correspondence

In the interests of conciseness and accessibility, please include only relevant text relating to the original question in the comment tables below. Additional text, e.g. introductions and signatures, need not be included in the log.
Please ensure at submission to NICE that the log is accompanied by an archive file format (.**ZIP file**) containing full copies of all correspondence.

Table 1. Correspondence with sponsor

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	Questions to sponsor for initial meeting (1-9): 1) Request for information on trial NCT01275430 that was stopped early.	The trial is being conducted in the USA. Patients (unknown number) have been recruited to phase 1. A report is expected and Bard will forward this when it is released. Phase 2 has not started and is going through approvals.	Sponsor to forward study phase 1 report if it becomes available within the timescale of the assessment process
	2) Have the sponsors contacted the authors of any of the papers?	Yes. Two have responded – Barton and Stewart. One has provided data and the other should provide it on Monday 21st July. No response has been received from Adams or Parikh; Bard was not involved in these trials. This additional information may be considered part of the clinical evidence in the same way as if Cedar had obtained it. Cedar may contact the authors directly following this.	Sponsor to forward additional data to Cedar and author contact details. Cedar to follow up remaining authors for additional data.
	3) NHS audit data	This was recently forwarded to Cedar. The questionnaire was sent to all NHS hospitals that were using Sherlock and the sponsor has forwarded all the responses that they have received. This data was not included in the clinical evidence analysis due to initial confusion about where it should be entered and was later omitted in error.	Bard to confirm to Cedar the response rate for the questionnaires, who was contacted and when.
	4) Difference between technology versions.	This documents conversation on Friday 18th July, however the information is not now complete. New information will be added to the version table, and this will supersede	Bard to provide details of when versions were

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		information in these minutes. All devices are USA only, apart from Sherlock 3CG TCS, which is the only one available in Europe. Sherlock (2006) – showed direction of tip only. Sherlock II – as above, with some improvements) Sapiens – tablet device attached to a drip stand, included ECG, name is now obsolete. Sherlock 3CG TCS was added to the Site~Rite ultrasound system in the US. The system available in the UK is a standalone notebook version, plus sensor and printer (the Site~Rite system will be available from 2015). Clinical evidence from previous versions that include ECG could be included in the critical analysis – the use of ECG in determining optimum position is a requirement for comparability. Some previous versions e.g. Sherlock TPS may have had capability for ecg, but without it being implemented widely. This would not be comparable.	released. AC (Cedar) to draft a table of the different versions, including any missing information that Cedar requires. To be reviewed by Bard.
	5) What are the compatible catheters?	There are two catheters available in the UK that allow for the use of ECG to assist with tip positioning: Power PICC and PowerPICC SOLO (includes a proximal one-way valve). PowerGroshong catheters (Groshong TLS) can be used but do not allow for ECG use. These have a distal valve and are made of silicone, rather than polyurethane (as for the PowerPICCs). PowerGroshong catheters compatible with	

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		Sherlock have only just been launched in the UK. For all catheters once placement is confirmed then the stylet and wire are removed from the catheter.	
	6) Clarification of Site~Rite and standalone systems.	Site~Rite is available in the UK, but not linked to Sherlock. In the UK the system is always standalone, with ultrasound for venous access being whatever hospital already using. Imaging is on a netbook. In USA Sherlock can plug into Site~Rite via a USB connection. The combined system will be available in the UK in 2016.	Contribute to table of product versions.
	7) CE marking documentation	Declarations of Conformity and supporting ISO13485 Quality Management Systems certificates have been received for the catheters and the Sherlock system. Two QMS certificates that were supplied but were surplus to requirements were noted to be out of date.	Cedar now have documents that we require.
	8) Clarification of length of availability of Sherlock in the US.	The first Sherlock device was available in 2006 and in the UK in April 2013.	See Q4 above.
	9) Johnston 2014 paper	The very recent availability of this paper was noted. It will be included in Cedar's critical appraisal. The same centre have published an audit of malposition before using Sherlock. RS noted that this NHS centre was unique in the UK, using Sherlock in intensive care patients (standard and neurological) – such patients are not able to lie supine as for other insertions.	

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		The paper notes differences between recommended placements in USA and UK. There are settings that are more common than others.Can be in or outpatients. Most patients would be seen in a treatment room or radiology suite, and brought there for PICC placement – they could be in or out patients, but treated by same staff in same location. Some PICCs are placed at bedside.	
	Meeting with Sponsor at Cedar to demonstrate device.	Notes attached in Appendix A	
	Thank you for your offer to let us see the Sherlock system. For your visit on Tuesday, Cedar (postcode CF144UJ) is located in the Cardiff Medicentre at the University Hospital of Wales (UHW). In the attached map……(travel info)	Chengetayi and I will look forward to meeting with you all at 10.00 on Tuesday next week. We will have the SherLock 3CG TCS system and Piccs with us so we can demonstrate the operation of the system.	
	I have created an early draft of a table, intended to show the characteristics of the Sherlock 3CG TCS and its predecessor devices. The aim is to reflect all of the key developmental changes and to enable Cedar to make a judgement on whether evidence on previous device versions is applicable to the Sherlock 3CG TCS. Can you please check the draft table for factual accuracy? I suspect that I have not captured the full complexity of the devices and I may have made	Many thanks to you and the team for meeting with Rachel and I this morning and affording us the opportunity to demonstrate how Sherlock 3CG works. Following on from our discussions this morning, please find attached the following:- The data pertaining to the Symington Study The information regarding the NHS Clinical Audit	

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	errors. I'd be grateful if you could respond with tracked changes.	As agreed I will forward the following as it becomes available:- Confirmation of the various Sherlock versions Data for the Barton and Stewart abstracts Any additional information pertaining to the STAT-PICC study	
	Thank you for your visit to Cedar. • I have attached some notes to document the discussion we had, please let me know if there are any inaccuracies or amendments you would like to make. • We also discussed the various versions of the device that are available and Andy has shared an initial table listing them. Since then I have looked at the FDA 510(K) database and added additional information. I would be grateful if you could check and correct this as necessary. • Could you also please forward contact details for the authors that you have been in touch with. • In addition, on the Bard website, there is mention of a clinical study:	Please find below the answers (in red) to the queries raised in your emails received on 24/07/2014 1. I have attached some notes to document the discussion we had, please let me know if there are any inaccuracies or amendments you would like to make. I have checked the notes and I can confirm that there are no inaccuracies or amendments to be made. 2. We also discussed the various versions of the device that are available and Andy has shared an initial table listing them. Since then I have looked at the FDA 510(K) database and added additional information. I would be grateful if you could check and correct this as necessary. Please find attached the corrected version of the table.	

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	In a clinical study, 99.1% of 114 PICCs were placed at the CAJ or within +/- 1 cm using Bard® Tip Confirmation Technology. †Data on File (Bard Access Systems, Inc., Salt Lake City, Utah) http://www.bardaccess.com/imaging-sherlock-3cg.php?section=Clinical Study accessed 24/7/2014 Do you know if this is publically available, and do you have further information on it?	3. Could you also please forward contact details for the authors that you have been in touch with. ***Details were provided, and have been redacted.*** I have already forwarded the details from Ken Symington. Please find attached the data from Andrew Barton. I have not heard back from Fiona Stewart. 4. In addition, on the Bard website, there is mention of a clinical study: "In a clinical study, 99.1% of 114 PICCs were placed at the CAJ or within +/- 1 cm using Bard® Tip Confirmation Technology. †Data on File (Bard Access Systems, Inc., Salt Lake City, Utah) http://www.bardaccess.com/imaging-sherlock-3cg.php?section=Clinical Study accessed 24/7/2014". Do you know if this is publically available, and do you have further information on it? Due to the misunderstanding that I only had to submit data relating to Sherlock 3CG TCS and not its similar predecessors, I had this study in the Clinical Evidence Submission as excluded. The study was done by Pittiruti et al, 2012 (The intracavitary ECG method for	

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		positioning the tip of central venous catheters: results of an Italian multicenter study. Pittiruti M, Bertollo D, Briglia E, Buononato M, Capozzoli G, De Simone L, La Greca A, Pelagatti C and Sandro Sette P. Journal of Vascular Access. 13(3):357-65) and Bard were able to obtain subgroup data from the authors which is what is referred to on the Bard website. I have attached the study. 5. Looking at the summary of Audit data submitted by Rachel and Chengetayi there should be 6 sets of questionnaires returned, however in the email from Ailish on 17th July there were only 5 sets, the one from Oxford seems to be missing. Could either NICE or Bard please check that we have received the complete information? My apologies for the omission. Please find the Oxford questionnaire attached.	
	Thank you for providing your responses and the attached documents. Megan is on planned leave and I'm trying to catch up with regard to which attachments relate to which issue. I've managed most of this but I can't work out exactly what the pdf titled 'Sherlock Trial' relates to. Is it for example a particular centre's case load in a 12 month period for PICC placement? Can you please	Many thanks for your email. That PDF data together with the word document titled database summary relates to the Barton 2014 abstract. Those are the PICCs he has placed using Sherlock 3CG	PDF file of data not used by EAC as not possible to interpret in context of abstract. EAC contacted Andrew Barton separately.

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	clarify?		
	did you intend to contact Nurse Consultant Fiona Stewart to request further data related to her abstract? If so did you have any luck? The abstract alone does not provide much information. I can't seem to find an email address for her but I note that Professor Peter Klineberg may be easier to track down.	Yes we did try to contact Fiona Stewart for additional information on her abstract, but unfortunately she did not get back to me. I had sent her contact details in the email I sent through on the 25th of July. ***Details were provided, and have been redacted.***	EAC sent email to Fiona Stewart and Peter Klineberg, but no responses.
	Regarding the audit data can you tell me if the response from the Royal Marsden is for both sites (Sutton and London)? Do you have contact details for the hospital sites not included in your survey? We have the following questions for them: • How long has Sherlock 3CG TCS been used at your site? • Has training been completed for staff who use Sherlock 3CG TCS? • Approximately how many PICC procedures (in-patient and out-patient) have been	We can confirm that the data collected from the Royal Marsden included both sites. Chengetayi is away until 1st September and she would be the person to confirm if we did in fact receive information from Oxford. The main contact at Oxford is Nicola York ***(email was provided and redacted)*** should you want to contact her directly regarding the questions below. I shall be away myself next week and have added David Dawson to the mail should you need any information urgently.	

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	carried out at your site? • Are chest x-rays routinely used with Sherlock 3CG TCS to confirm PICC placement at your site? • Do you have any comments to make about Sherlock 3CG TCS and your experience of using it?		
	We would like to contact the hospital sites that use Sherlock 3CG TCS and were not included in the Bard survey. Please could you send Cedar contact details for the appropriate people at the following sites: • Cambridge University Hospitals NHS Foundation Trust (Addenbrookes) • Heart of England NHS Foundation Trust (Good Hope Hospital) • King's College Hospital NHS Foundation Trust (King's College Hospital) • Maidstone and Tunbridge Wells NHS Trusts (Maidstone Hospital) • Medway NHS Foundation Trust (Medway	Please see the following table for the requested contact details: (these were provided to EAC in full with contact name and email, except Heart of England NHS Foundation Trust (Good Hope Hospital) were the post was currently vacant.	EAC contacted the centres, response included in assessment report.

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	Maritime Hospital) • Royal Liverpool and Broadgreen University Hospitals NHS Trust (Royal Liverpool) • University Hospitals Birmingham NHS Foundation Trust (Queen Elizabeth Hospital) • Belfast Health and Social Care Trust (Belfast City Hospital, Belfast) • Western Health and Social Care Trust (Altnagelvin Area Hospital, Derry) For your information, the brief questions that we will be asking are: • How long has Sherlock 3CG TCS been used at your site? • Has training been completed for staff who use Sherlock 3CG TCS? • Approximately how many PICC procedures (in-patient and out-patient) have been carried out at your site? • Are chest x-rays routinely used with Sherlock 3CG TCS to confirm PICC placement at your site? • Do you have any comments to make about Sherlock 3CG TCS and your experience of using it?		

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	We would like to include a couple of images of Sherlock 3CG TCS. The ones below are both in the instructions for use. Are you happy to give permission for Cedar to use these in the report, and ideally if you have a good clean version of them, rather than what I have gleaned off the internet, that would be great. I would of course acknowledge them as Bard's images.	Please find the requested images attached – png's with transparent BG and standard jpg's. They are not high resolution so I will aim to source these but they may take a while so if these are acceptable then please proceed. I attach a short form that we require in conjunction for using any of our images which includes our required correct terminology. I sincerely hope this is not an inconvenience.	Images included in report
	Thank you for the images, I have attached the completed permission for use form. Could I please confirm that were it says: *b. For a one year term beginning on the date of the last signature below (including the lifetime of the publication if applicable)* that this means that once placed in the current report, the permission remains in place for it to stay in that report for the duration of the time that	That is certainly my understanding.	

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	it is on NICE's website?		
	Could you please let me know if there is any of the information that you have passed to Cedar (eg from authors, or NHS sites) that should be marked as confidential in the assessment report?	Thank you for your email. Please could you treat all the questionnaires provided by NHS sites and the additional data for the abstract by Andrew Barton as confidential.	
	Would it be acceptable not to redact the questionnaire data if it was annonymised and centres weren't identified?	Yes that's acceptable.	Tables annonymised in report
		Further to your recent emails to David Dawson regarding use of Bard images - please now find attached for your records the signed permission request form.	

Expert Advisers

Name of Expert Adviser	Job Title	Professional Organisation/ Specialist Society	Nominated by	Ratified
Mr Andrew Barton	Clinical Nurse Specialist in Vascular Access, IV Therapy and OPAT Lead	Nursing and Midwifery Council		
Dr Andrew Bodenham	Consultant in Anaesthesia and Intensive Care Medicine	National Infusion and Vascular Access Society		

Dr Lisa Dougherty	Nurse Consultant	National Infusion and Vascular Access Society		
Dr Richard Leech	Nurse Consultant	National Infusion and Vascular Access Society		
Dr Andrew Johnston	Consultant Anaesthetist	Royal College of Anaesthetists		
Dr Tim Jackson	Consultant in Intensive Care. Medical Lead Vascular team	Royal College of Anaesthetists		
Ms Dympna McParlan	Consultant Anaesthetist	National Infusion and Vascular Access Society		
Ms Elizabeth Efleet	Infusion Services Coordinator	Nursing and Midwifery Council		

Table 2. Collated responses from expert advisers to EAC questions

Question 1: Sherlock 3CG TCS instructions for use state that ECG tip location is not reliable where the p-wave is unclear. At what point would this be identified? Would Sherlock be used anyway making use of the magnetic tip location facility and then be followed by a chest x-ray for confirmation?	
Expert Adviser	**Response / Comment**
Dr Richard Leech	Unless the patient had already been identified as being in Atrial fibrillation (most inpatients are), this would only be identified once the equipment had been attached to the patient. Patients who in Atrial Fibrillation do not have an identifiable p wave so the Sherlock 3CG TCS would not be able to confirm the correct position of the catheter tip. The Sherlock would be able to identify if the catheter tip was advancing in the jugular vein. rather than towards the SVC. However operator experience and ultrasound can also give some warning of malposition before Xray confirmation. In these patients the PICC could either be placed without the Sherlock and adjusted after XRay if necessary or under fluoroscopy. There is no real advantage using this technology just for the Sherlock without the 3CG confirmation of tip position. In patients who are paced, I would recommend that the PICC is placed under fluoroscopy because it can be very difficult to indentify catheter tip position on a plain Xray when there are so many other wires in the same location. Often movement of the PICC catheter in real time is the only way to correctly identify the tip position.

Dr Andrew Bodenham	It may clear before starting if patient known to be in Atrial fibrillation or evident when ECG monitor set up. Yes electromagnetic element would still work.
Dr Tim Jackson	The absence of a P-wave would be clear if the patient had already had an ECG performed. The most common clinical situation in which this would be the case would be atrial fibrillation. In common with other ECG-based tip-location systems, this is the standard caveat to their use. I am aware that some authors recommend using alternative methods for tip location in patients who are known to have abnormal ECG rhythms which would adversely affect recognition of the P-wave, however others describe experience with ECG tip-location technology even in patients with atrial fibrillation, although I am not familiar with the precise basis for their clinical experience. The magnetic element of Sherlock's guidance could theoretically be used to provide guidance on correct direction, and precise tip location could be verified by chest x-ray as you have mentioned, although I am unsure as to whether Sherlock requires a valid P-wave to be verified before it will proceed to the real-time tracking of the magnietic tip. There will be a minority of patients who have *unknown* atrial fibrillation, and this will only be discovered during the process of setting up the Sherlock probe for use. I would expect this would be an unusual situation, as most patients are likely to have coincidentally had an ECG at some stage before a PICC line is inserted, but there will be occasions when either a patient has no coincident indication for an ECG (young patient with no comorbidity and not systemically unwell) or those in whom atrial fibrillation has developed recently prior to using Sherlock, and in whom such rhythm disturbances will have been missed by their previously normal ECG. In my view, the maximum benefit of a device such as Sherlock is that it brings an extra modality (magnetic tip tracking) to the consept of ECG tip location. This allows the practitioner to both follow the progress of the PICC as it passes through the central veins, but also provides greater precision in final tip positioning. It also allows those practitioners who may not be as confident at ECG interpretation (as is often reported by non-cardiac trained nurses, for example) to have an extra guidance modality to improve their confidence in such a technique. Therein lies an alternative interpretation of the term "when the P-wave is unclear" which might also include a P-wave which is perfectly present, but the practitioner is less confident in that interpretation, and again, chest x-ray would always be used as a back-up option. There are those practitioners who use x-ray fluroscopy to guide their PICC placements (although I believe this is less common) and in a unit where this technique has been removed by the use of a device such as the Sherlock, then the logistical implications of the occasional need for fluroscopy in a patient in whom the P-wave was indistinct would be expected to be more complicated than merely obtaining a plain chest x-ray after the procedure.
Dr Lisa Dougherty	Identified: When ECG leads attached. Use Sherlock anyway: Yes that is what we would do

Ms Dympna McParlan	We would still use Sherlock for tracking and check if the p-wave is clear. If not, a chest x-ray would be performed for confirmation?
Question 2: We are unaware of current evidence on the number of PICCs placed annually in the NHS. Hospital Episode Statistics data is available for the number of PICCs placed for inpatients, but not for outpatients. What approximate proportion of the total PICCs placed within the NHS are likely to be inpatients? (an educated guess is fine). Are there other data sources we should use?	
Expert Adviser	Response / Comment
Dr Richard Leech	The number of PICCs placed in inpatients in our Trust is a relatively small number. Currently these patients are booked on a CEPOD list and the PICC is placed on an ad hoc basis. The main indication in this patient population is for prolonged antibiotic therapy (4-6 weeks plus), treating conditions such as cellulitis, osteomyelitis, endocarditis etc. The vast majority of PICCs placed in our Trust (and probably the UK) are for out patient chemotherapy for the treatment of cancer. If the Trust is coding this properly the OPCS code for a PICC is L99.7.
Dr Andrew Bodenham	Numbers large and increasing at present vast majority inserted in hospital setting, but increasingly used outside. Uncertain of data sources.
Dr Tim Jackson	I can only give you an educated guess, I would expect that in excess of 80% of PICCs are placed as inpatients. Many of those would possibly be sent home once their PICC was sited, but their treatment would continue on an outpatient basis. My experience is that most of the outpatient PICC insertions are likely to be performed in oncology patients, and as such I wonder if cancer networks have access to data which might further describe the total number. Failing that, there should be procurement data to describe how many PICCs are used in the NHS, which I would view as a surrogate estimate of the number of PICC insertions. One of the selling points of this technology is that it should reduce the number of failed insertion attempts, and I suspect the total number of PICCs used vs the number of patients having PICCs would be a crude reflection of the excess required due to failed insertions.
Dr Lisa Dougherty	really haven't a clue – for us it is 80% outpatients but it might be 50/50 in acute trusts. Don't know of other data sources.
Ms Dympna McParlan	Approximately 30% of PICCs placed within the NHS are likely to be inpatients. I am unaware of other data sources that could be used.
Question 3: Some studies have a small percentage of patients where the Sherlock procedure stated that the catheter tip was placed correctly, but the chest x-ray found it was malpositioned. Once x-rays were no longer being carried out, what would the likely consequences be to these patients? Would the malposition be detected clinically?	
Expert Adviser	Response / Comment

Dr Richard Leech	Studies have shown that there is a marked variance in the interpretation of catheter tip position on Chest Xray depending on which doctor or radiologist is reviewing the Xray. The main difficulty is the due to the fact the Superior Vena Cava (SVC) joins the right atrium posteriorly. There are other cardiac structures superimposed over this area which can make Xray interpretation difficult. The 3CG technology identifies where the Sino-atrial node is by the electrical signal generated by this specialised cardiac tissue. Theoretically this is a much more accurate method of correctly placing the catheter tip. Other long term vascular access catheters such as renal dialysis catheters are deliberately placed in the right atrium to ensure adequate blood flow during dialysis. Even if the PICC catheter tip was positioned in the right atrium it is unlikely to cause a major issue - it is a soft catheter. Malposition of the PICC so that the tip lies in the upper third of the SVC is more of an issue as this has been shown to increase infection and thrombosis risk. As far as I am aware PICCs placed with the Sherlock system are more likely to be "deemed" too long than too short on the confirmatory Chest Xray.
Dr Andrew Bodenham	Catheters can move on standing or later in days weeks ahead causing malfunction clinically or continue to work ok. This is problem irrespective of how catheter sited originally.
Dr Tim Jackson	I would be suspicious of the logical basis of this statement. IF the assertion is that a chest x-ray RELIABLY concluded that the PICC tip was malpositioned this is a potentially significant conslusion, however published evidence suggests that ECG tip location technology is more reliable than plain x-ray confirmation, as there are more errors inherent in the interpretation of what are merely surrogate landmarks on a chets x-ray, therefore my initial interpretation of this comment is that (assuming the PICC inserter had used the Sherlock correctly) then I would doubt the significance of the chest x-ray finding. Alternatively, assuming the chest x-ray findings are valid, then the precise clinical significance of tip malposition would depend on various factors, from the degree of malposition - some authors use very tight criteria for tip positioning precision, others are more conservative; the more proximally a PICC tip is placed, the more the risk of luminal thrombosis, which is also associated with infection and subsequent occlusion of the central venous anatomy. These malpositions are unlikely to be detected clinically, unless the tip is positioned too far in (eg: inside the heart itself) in which case cardiac dysrhythmias can occur, and these may be detectable. Too proximal, and the formation of intraluminal thrombosis may be detectable if the patient had further ultrasound scanning to facilitate alternative intravenous access into a central vein. This problem is often clinically unapparent, and as such it is well recognised is under-diagnosed so that many clinicians do not fully appreciate the potential effects of catheter tip related thrombosis.
Dr Lisa Dougherty	Once x-rays were no longer being carried out, what would the likely consequences be to these patients? Would depend on where it was – could increase risk of DVT Would the malposition be detected clinically? Would be if it was in jugular as might get aural sensation, if too far then might get palpitations

Ms Dympna McParlan	The likely consequence to a patient if the Sherlock procedure stated that the catheter tip was placed correctly, but the chest x-ray found it was malpositioned is delivery of infusate to the incorrect vein or increased risk of thrombosis. The outcome would depend on the type of infusate. The malposition may be detected through no venous return, discomfort expressed by the patient or chang in length of the device externally.
Question 4: Do you feel that clinicians have confidence to abandon routine use of confirmatory chest x-rays if Sherlock 3CG TCS indicates that the PICC is correctly located?	
Expert Adviser	Response / Comment
Dr Richard Leech	Like most advances in medicine there will be a period of scepticism when any new technology is introduced. Clinicians will soon realise that this is a more accurate method of placing all central venous catheters rather than using the ambiguity of the Chest Xray. In certain groups of patients with musculoskeletal abnormalities such as Kyphosis and Scoliosis where it can be impossible to interpret the Chest Xray it has a distinct advantage.
Dr Andrew Bodenham	Yes over time already happening.
Dr Tim Jackson	I believe that many clinicians will have confidence to change their practice to Sherlock-guided PICC placement, and indeed other forms of ECG-based tip-location technology. I believe the generic technology should be the way forward in improving precision in tip positioning. Nevertheles, our traditional reliance on the chest x-ray as the standard technique for confirming tip location will make this a leap of faith for many practitioners, and I have heard many place over-reliance on chest x-ray. I beleive there are the enlightened adopters of this (and similar) technology, but I also perceive there will be many who will take some convincing.
Dr Lisa Dougherty	Yes
Ms Dympna McParlan	Yes, I do feel that clinicians have confidence to abandon routine use of confirmatory chest x-rays when Sherlock 3CG TCS indicates that the PICC is correctly located if the method is properly evaluated. A thorough evaluation was performed using both methods in our department prior to abandoning routine chest x-rays. The results were demonstrated to clinicians and a decision was made to abandon routine chest x-rays based on the outcome of this evaluation.
Question 5: How is the ECG trace from the external electrodes used during catheter placement?	
Expert Adviser	Response / Comment

Dr Richard Leech	This is used as a reference ECG. The p wave can then be compared with the p wave obtained as the catheter is advanced. When the p wave is maximal, the catheter tip is adjacent to the Sinoatrial node (SAN). It is becomes biphasic the catheter tip has advanced into the right atrium. Usually the operator will advance the catheter tip until the trace has become biphasic and then pull back to identify the point at which the p wave is maximal.
Dr Andrew Bodenham	Multiple electrodes needed to generate ECG trace
Dr Tim Jackson	This is an area that I have less knowledge of, having yet to have the chance to us ethe device "hands-on" but I believe they are used for comparison with the intra-catheter ECG electrode. This is analagous to the standard 3-lead electrode placement used for basic rhythm recognition on sick patients, instead one internal electrode is compared with 2 external ones.
Dr Lisa Dougherty	As a comparator for the internal trace
Ms Dympna McParlan	The ECG trace from the external electrodes is used during catheter placement to determine a baseline pre insertion and presence of a P-wave. It is used post placement to compare with the internal P-wave?

Question 6: If a patient comes to a service that routinely uses Sherlock 3CG TCS who is known to have an unclear p-wave and be unsuitable for ECG tip confirmation using Sherlock 3CG TCS would you expect the PICC to be inserted using:

- **blind insertion plus chest x-ray**
- **Sherlock insertion (using magnetic tip location) plus chest x-ray**
- **fluoroscopy**
- **other**

Expert Adviser	**Response / Comment**
Dr Lisa Dougherty	Sherlock insertion (using magnetic tip location) plus chest x-ray
Dr Andrew Bodenham	Any of the first three would be acceptable options. Most centres are evolving and have mixed practice of theatre, ward and angio suite procedures. Hospitals have not invested in staff or infrastructure to maximise efficiency of practices.
Dr Andrew Johnston	If it is a Power PICC, we would normally just use the Solo part of the technology. For patients who don’t need a Power PICC we insert blindly. All patients currently get a CXR after the procedure.
Mr Andrew Barton	Sherlock insertion (using magnetic tip location) plus chest x-ray

Dr Tim Jackson	I do not work in a service that currently uses any form of ECG-based tip location technology, but I am familiar with the practice in some of the units that do, and my answer is based purely on that "second-hand" knowledge, and that of presentations on the subject at world conferences. I understand that there is variation in practice, but most units would tend to revert to their prior standard technique - this may include blind insertion plus CXR or fluoroscopy, the preference for which largely depends on historical practice and clinical skills. However there are a minority of units who have developed the skills to interpret the ECG in cases where the p-wave is indistinct (atrial fibrillation, for example) and can allegedly still use such technology even in these more challenging of cases. I do not know whether Sherlock units would use the magnetic element of Sherlock alone, and ignore the ECG element in such cases.
Ms Dympna McParlan	Sherlock insertion (using magnetic tip location) plus chest x-ray

Question 7: Do you know your consumable equipment cost for blind insertion (without Sherlock) – not including ultrasound or x-ray. Preferably a complete cost for catheter, drapes, gown, dressings, lidocaine etc, but if this is unknown (don't spend hours finding it), please give a cost for the PICC catheter that you use, if possible.

Expert Adviser	**Response / Comment**
Dr Lisa Dougherty	Based on costings done for evaluation in 2013 Old system (blind insertion) 5Fr PICC at £80, MST at £36 and pack at £21 excluding VAT = £137 4Fr PICC at £65, MST at £36 and pack at £21 excluding VAT = £122 Sherlock 5Fr SOLO PICC kit - contains full tray, MST, 3CG leads at £155.00 each excluding VAT 4Fr SOLO PICC kit - contains full tray, MST, 3CG leads at £140.00 each excluding VAT Chloroprep (would need to be added to Bard packs) at 92p each We now add more as we don't like certain items in the Bard pack
Dr Andrew Bodenham	I have no idea the procurement departments like to keep clinicians away from bidding processes as we might be considered biased.
Mr Andrew Barton	Previously to using Sherlock with SOLO PICCs the cost of the PICC I used which was a Bard Groshong PICC was about £65 and the PICC insertion pack which I had made by Vygon was around £18.00 plus gloves and chloraprep the cost was approximately £95.
Dr Tim Jackson	I'll check this out and get back to you.

Ms Dympna McParlan	The consumable equipment cost for blind insertion (without Sherlock) – not including ultrasound or x-ray was approximately £120.00
Question 8: For the purposes of costing nurse time, how long would you *estimate* PICC insertion takes from opening the pack at the start of the procedure to fixing the catheter in place at the insertion point ready for use (with Sherlock) or x-ray.	
Expert Adviser	**Response / Comment**
Dr Lisa Dougherty	• Using Sherlock 3CG TCS 20 minutes • Using blind placement 15 – 20 minutes
Dr Andrew Bodenham	Slightly more for Sherlock due to increasing set up time. Our PICC nurses can do 4-5 procedures in a day to include all elements, depending on assistance available. On half day list in theatre with full assistance one operator could to 8-10 cases if all set up, clean up etc done by others. The insertion bit say 30 minutes is the quickest bit overall compared to setting up, cleaning up, admin, booking, discharge etc etc.
Mr Andrew Barton	• Using Sherlock 3CG TCS – 40mins • Using blind placement – 40mins - 1 hour

Dr Tim Jackson	This can be very variable, however for a "typical" patient I would envisage a successful first-pass insertion to take less than an hour, but at least half an hour - including time for the XRay to be performed, developed and interpreted before the PICC is pronounced fit for use. assuming that such an easy insertion is similarly easy with Sherlock (and I see no reason why it shouldn't be) then I would envisage Sherlock would reduce that time by approximately 15 minutes in my clinical setting. It should be borne in mind that (as expanded in my answer to 6 below) that I practice in a unit which is largely Dr-led PICC insertion, performed in an operating theatre environment, and with the portable XRay machine coming to the patient within minutes of the completion of the insertion process. For many nurse-led procedures, the insertion occurs at the patient's bedside, and in this context radiation safety and logistics dictate that the patient is usually transferred to the Xray department to receive their Xray; anecdotally this can introduce a significant extra delay before the line is pronounced ready for use, and in this context the Sherlock poses potentially significant time-saving benefits. In terms of the "difficult" patient, I have known PICC insertion to take up to 2 hours of repeated attempts to insert, and thereafter it is possible that the Xray reveals malposition requiring a new attempt at insertion. The benefit of a device such as Sherlock in this situation is that Sherlock should alert the practitioner to the malposition before they resort to Xray, and hence those further attempts can be made at the same time. Sherlock doesn't make the procedure any easier in a difficult patient, it merely gives the practitioner more real-time information as to what the nature of the difficulty is, which should improve success and minimise time. I have no experience of how much time Sherlock could save in such situations, but it could well be significant in certain patients.
Ms Dympna McParlan	• Using Sherlock 3CG TCS – approx. 25mins • Using blind placement - N/A
Question 9: If a PICC is identified as malpositioned (eg during chest x-ray), what method would be used to insert a new PICC: • blind insertion plus chest x-ray • Sherlock insertion (using magnetic tip location) plus chest x-ray • fluoroscopy • other	
Expert Adviser	Response / Comment
Dr Lisa Dougherty	Sherlock insertion (using magnetic tip location) plus chest x-ray – if I had used it to insert the PICC I would reuse to do a guide wire exchange or place a new one
Dr Andrew Bodenham	All of the above suitable plus flushing and changing patient position sometimes works.

Dr Andrew Johnston	IF IT IS IN TOO FAR THEN IT IS SIMPLY A QUESTION OF PULLING THE PICC BACK. IF IT NEEDS COMPLETELY REVISING THEN THE DECISION REGARDING BLIND VS FLUROSCOPIC VS SHERLOCK 3CG WOULD DEPEND ON THE PATIENT.
Mr Andrew Barton	• If the PICC was placed without Sherlock in the first place, blind insertion plus chest x-ray would be used. • If the PICC was placed with Sherlock it would not be malpositioned.
Dr Tim Jackson	4 Unfortunately, in my unit (blind insertion & CXR) there is little available alternative. First-pass success is related to the skill and experience of the practitioner, and therefore my general approach would be as follows: a) in certain specific cases of malposition (eg: internal jugular) attempt "power flush" technique then allow time for the patient's blood flow to re-position the line b) further attempt with more experienced practitioner at a 2nd sitting c) fluoroscopy in particularly challenging cases I assume that as your question presupposes a blind CXR technique, then I wouldn't be in a setting that is using Sherlock anyway, hence I have not included it in my answer. Clearly if I had used an ECG-based tip location device such as Sherlock, then I wouldn't routinely be performing the CXR that you mention unless there had been a failure of insertion in some way, and in that case, I would probably resort to fluoroscopy as I believe it is the gold standard to help define the precise nature of the obstruction to PICC advancement.
Ms Dympna McParlan	Sherlock 3CG TCS if the patient has a clear p-wave. Sherlock insertion (using magnetic tip location) plus chest x-ray would be used if the p-wave was not clear
Question 10: When would you use fluoroscopy for PICC insertions at your site? Does this reflect wider NHS practice?	
Expert Adviser	Response / Comment
Dr Lisa Dougherty	Don’t use at all. In UK may be used if PICCs inserted in a radiology department
Dr Andrew Bodenham	Either when routinely available on set piece list or when difficulties have arisen with blind placement or anticipated difficult. Yes see above discussion re organisation in hospitals.
Dr Andrew Johnston	IF WE KNEW THERE WERE VASCULAR ANATOMOY ABNORMALITIES OR IF WE CAN HAD A PREVIOUS MALPOSITION THEN WE MIGHT USE FLUOROSCOPY +- VENOGRAM. DEPENDS ON THE PATIENT

Mr Andrew Barton	If the patient had difficult veins with a stenosis or such like, fluoroscopy would be used to visually guide the PICC into the correct vein using guide wires. This is common practice in the NHS and fluoroscopy is used in my Trust as a final resort when other techniques have been tried. In my Trust we place virtually no PICCs with Fluoroscopy.
Dr Tim Jackson	At my site, there are 2 circumstances in which fluroscopy would be used. 1 colleague routinely uses fluoroscopy as part of her standard practice. Although she acknowledges this is more costly and more complicated, she feels that it is the only way we currently have at our disposal of guaranteeing adequate tip location, and allows surveillance of catheter passage during the procedure. Otherwise, I personally reserve fluoroscopy for specific patients who are anticipated to be particularly difficult to pass the PICC, either due to known vascular anatomical abnormalities (rare) or if another practitioner has previously failed to successfully insert a PICC. As I am often referred the latter group of patients and my success rate is good without recourse to fluoroscopy, I rarely use this and my standard approach is ultrasound-guided venepuncture in the mid-arm, Seldinger technique and blind insertion followed by CXR. Overall, our unit's service is relatively in its infancy, and as such many of my colleagues are still on the learning curve. A recent audit has shown that tip-location accuracy is acceptable in approximately 50% of cases, and I aim to introduce some form of ECG tip-location technology to improve this situation in due course.
Ms Dympna McParlan	We never use fluoroscopy for PICC insertions at our site. I am unsure if this is reflective of wider NHS practice

Question 11: Who normally carries out PICC insertion at your site? Does this reflect wider NHS practice?

Expert Adviser	**Response / Comment**
Dr Lisa Dougherty	Nurses, yes mostly nurses in UK
Dr Andrew Bodenham	in oncology majority by picc nurses 15-20 per week in ward without ecg or flourscopy guidance. Other specialities patients in theatre or angios by medical/nursing staff with fluoroscopy. If organisation invested in staff and service would likely to become largely ward based procedure for all specialities. Similar issues across NHS I think, some hospitals much better organised with formal team etc than others
Dr Andrew Johnston	A TEAM OF SPECIALIST NURSES.
Mr Andrew Barton	Nurse led vascular access team.

Dr Tim Jackson	PICC insertion is carried out by 2 groups of practitioners at my site - in our oncology outpatient unit it is carried out by a handful of experienced nursing staff. The service provided to all non-oncology patients in the organisation is provided by a group of consultant anaesthetists on an ad-hoc basis, in an operating theatre environment. I do not know exactly how reflective this is of wider NHS practice, however I believe that there is wide variety in the models of service provision around the country. I am not aware of any data to support this answer (although I am aware of audits that may be in progress to answer the question) and therefore my hunch (based on links with NIVAS and the general professional backgrounds of those attending specialist vascular access courses & conferences) would be that most dediacted PICC-placement services in the UK are provided by nurses, with a relative minority being anaesthetists, and an even smaller minority being interventional radiologists and specialist services (eg: nutrition teams etc)
Ms Dympna McParlan	The Infusional Services nurse always performs the PICC insertion at our site. This is reflective of the majority of wider NHS practice.

Question 12: When searching the FDA (MAUDE) database of reported adverse events for Sherlock in the USA, we have found the following:

- **29 reports of the wire, wire tip or stylet being broken or damaged during use**
- **23 reports of adverse patient reactions, usually involving shortness of breath and a flushed face, and resolved with minimal intervention and a brief delay to treatment.**

The FDA (MAUDE) database lists all reported events as entered by the reporting person, and are normally not verified, or with additional information available. The version of the device is not always known.

Have you any experience of these or other adverse events using Sherlock 3CG TCS?

Would you consider that they raise significant safety concerns for the device?

Expert Adviser	**Response / Comment**
Dr Andrew Bodenham	I have limited experience with kit. Can I send this to colleagues who use it routinely for input? (EAC: I think it is better not to circulate the questions, we have also asked other expert advisors and had some response. Thank you for your willingness to help though.) Ok I am meeting with folk tomorrow on teaching day who use the devices and will just ask general questions re reliability for some informal feedback.
Mr Andrew Barton	I can't say I have experienced any adverse reactions using the Sherlock system but I did have 6 failed ECG leads during the initial trail
Ms Dympna McParlan	No reports of the below or any other adverse events have been experienced in our department while using Sherlock 3CG TCS.

Dr Lisa Dougherty	we haven't had any adverse events involving the Sherlock and was surprised to read the reports. I would consider the device to be very safe and all PICCs have a wire in so not sure what reported incidents PICCs have as a whole?
Question 13: (to Dr Lisa Doughty only) Can I just check about the wire in all PICCs - do all (non-Sherlock) PICCs have a guidewire along their entire length for the whole procedure process?	
Expert Adviser	**Response / Comment**
Dr Lisa Dougherty	Yes they do
Question 14: (to Dr Lisa Doughty, Andrew Barton, Dympna McParlan only, sent 12/9/2014) For the patient, there is likely to be a longer time from the start of PICC insertion to tip confirmation if an x-ray is required, than if Sherlock 3CG TCS is used to confirm tip position at bedside. **Would the PICC nurse be involved in the x-ray procedure at all (including accompanying the patient etc)?**	
Expert Adviser	**Response / Comment**
Dr Lisa Dougherty	Would depend – I verify my own x rays but many nurses would need to seek a doctor to verify tip
Mr Andrew Barton	In my Trust I have accompanied the patient for a chest x-ray if I want to speed up the process but usually a porter is sent to bring the patient to radiology, the patient will placed in a queue and sent for when radiology are ready.
Ms Dympna McParlan	**The only involvement the PICC nurse** would have if an x-ray is required is interpreting the x-ray and signing off the patient.
Question 15: (to Dr Lisa Doughty, Andrew Barton, Dympna McParlan only, sent 12/9/2014) **Would the PICC nurse time be any different for a Sherlock 3CG TCS procedure where chest x-ray was still used for tip confirmation vs a Sherlock 3CG TCS procedure without chest x-ray?**	
Expert Adviser	**Response / Comment**
Dr Lisa Dougherty	Only the extra time waiting for x ray to be done – I use the time to do my documentation so slightly less time if no CXR
Mr Andrew Barton	If Sherlock TCS was used without the ECG component of the procedure than achest x-ray would be indicated and take time however time and money would be saved in the long run because the PICC would not need to repositioned from the IJ etc..
Ms Dympna McParlan	**The PICC nurse time would be increased** if a chest x-ray was used for tip confirmation vs Sherlock 3CG TCS as the patient would return to the department following x-ray for interpretation and signing off. While this usually happens quite quickly it is unpredictable depending on Radiology workload.

Table 3. Other Correspondence

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
Dr Andrew Johnston (Johnston et al. 2013, 2014)			
	In your paper you report various malposition rates for PICC based on retrospective review of chest radiographs by two independent observers. Do you have any data regarding the number of PICCs in the cohort that were actually re-positioned or the number that were removed and a second PICC inserted due to malpositioning?	We only looked at primary malposition immediately post insertion and therefore I don't know the number that were repositioned. Most of the malpositions were because they were too far and so only needed a simple 'pull back'.	
	We have been reading the paper further and would be very grateful for some clarification of the tables 2 and 3. In particular • is the category high right atrium, a subset of right atrium (total), • in table 3, are all right atrium placements included as a correct placement for the second criteria, and • how are the figures for placements that were too far and too short calculated in the paragraph after table 3? There seem to be some differences with how the positions are categorised compared with the previous paper "Defining peripherally inserted central catheter	I've answered the questions below – you have correctly identified some mistakes in the manuscript which have now been corrected – the overall malposition rates are correct. We have been reading the paper further and would be very grateful for some clarification of the tables 2 and 3. In particular • is the category high right atrium, a subset of right atrium (total), • Unfortunately, a mistake has crept in to Table 2 - I have contacted the Editor to make the change • Right Atrium (total) should read High Right Atrium (upper 2 cm) (the values are still correct i.e. 63)	Corrected in assessment report

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	tip position and an evaluation of insertions in one unit" published in 2013. In the 2013 paper, table 2 figures add up to give the total number of PICC placement only if the high right atrium figure is excluded, in the 2014 paper the high right atrium placements must be included in the summation to give the total number of PICC placements. I am concerned that I may not be correctly interpreting what was found in your paper, and would appreciate your input.	• High right atrium (upper 2 cm) should read Low Right Atrium (below 2 cm) (the value is correct i.e. 39). • All the malpositon calculations are correct • in table 3, are all right atrium placements included as a correct placement for the second criteria, and Table 3 is correct given the above information – only high RA positioning is deemed as adequate • how are the figures for placements that were too far and too short calculated in the paragraph after table 3? These figures should read: If a catheter was misplaced with the Sherlock 3CG, it was significantly more likely to have been inserted too far as opposed to left short (too far vs too short: 40/239 vs 9/239, $p < 0.0001$). Again, the Editor has been informed of this There seem to be some differences with how the positions are categorised compared with the previous paper "Defining peripherally inserted central catheter tip position and an evaluation of insertions in one unit" published in 2013. In the 2013 paper, table 2 figures add	

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
		up to give the total number of PICC placement only if the high right atrium figure is excluded, in the 2014 paper the high right atrium placements must be included in the summation to give the total number of PICC placements. I am concerned that I may not be correctly interpreting what was found in your paper, and would appreciate your input. Hopefully this is now clearer given the above corrections	
Mr Andrew Barton (Barton, 2014)			
	I have read your abstract from WoCoVA 2014, Berlin and in addition the sponsor, Bard, has forwarded some additional data that you have collected (attached). So that we may properly understand the data and present it correctly to NICE can you please help me with a few queries? Sorry for presenting you with a list of tedious questions, but it's probably a sensible way to do it, as I have applied a degree of guesswork: 1. Your abstract is clear that you evaluated 65 procedures in the study, then continued to 225 before routine x-ray was discontinued. In the additional data (attached) does this represent a total series of 415 procedures (though the sum of	1. From the 29/3/13 to 13/1/14 282 lines were placed. 37 of these lines were 3fr midlines or other vascular access devices. 225 we PICCs all placed with the Sherlock device. Of the 225 PICC placed with the Sherlock device all were x-rayed and were in the correct position. From the 13/1/14 we went x-ray free. 2. fr = the French of the catheter of the diameter. 3. Tun = tunnelled line, not related to the Sherlock technology.	

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	the cells above is 418)? If so does this represent a failure rate (tip cannot be located in the SVC) as follows? (1+11)/418 = 2.9% (i.e. 12 failures) I suppose we can't derive a 'success rate' for the 418 (or 415) procedures as only 225 of them had a confirmatory x-ray. Is this correct? 2. Do the terms 3fr – 6fr simply refer to the PICC diameter (French / Charriere system)? 3. Does 'tun' refer to a failed Sherlock attempt such that you then instead inserted a tunnelled central venous line (i.e. not a PICC)? 4. Are there 11 cases where the PICC was located based on the magnetic tip sensor alone (no ECG)? Would these require confirmatory x-ray? 5. It looks as though there were 5 cases of atrial fibrillation. Were these patients with known AF in whom Sherlock procedures were attempted, or were they incident cases of AF during (or caused by) the procedure? 6. What do you class as failure of ECG electrodes (6 cases) is that they won't stick on / will fall off?	4. They would be x-rayed, this is because either the electrodes didn't work or the patient didn't have a p wave. 5 AF and 6 faulty electrodes = 11. 5. The patient already had existing AF, known or unknown, the procedure would not induce AF 6. The electrode connections were faulty.	
	Dear Andrew, As you know, we have read your abstract from	Dear Andrew, Thank you for the very helpful explanations yesterday. I	Clarified information in

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	WoCoVA 2014, Berlin. **Is there any other report on this work, either published or unpublished, or slides from the presentation that you would be able to share with us?** When necessary, information can be regarded as academic or commercial in confidence. This would be shared with the MTAC committee in private, but would be redacted from the published report. The abstract states that the confirmatory chest x-rays showed correct placement in 100% of the 65 trial PICCs and the subsequent 225 PICCs. I infer that these all PICCs where Sherlock 3CG TCS was used for placement, including use of ECG for confirmation of the tip position. We are also interested in the number of successful placements for total PICCS e.g. for all patients who had a PICC in that time period: • the number that were identified as unsuitable for Sherlock 3CG TCS (for instance unclear p-wave), • the number where Sherlock 3CG TCS was set up, but ECG confirmation was not possible The database summary notes 5 cases of AF and 6 of electrode failure, could you confirm if this is in addition to the 290 in the abstract and if there are other cases where Sherlock 3CG TCS was not used for ECG	will try to summarise the key points below, please let me know if there are any amendments you would like to make. There are a couple of queries in bold, where I'm afraid my notes didn't make complete sense. <u>Initial trial numbers:</u> 65 PICCs placed using Sherlock 3CG TCS for tip placement confirmation, 100% successful placement, judged by chest x-ray <u>Subsequent trial numbers:</u> Total of 225 PICCS placed (including initial 65) using Sherlock 3CG TCS for tip placement confirmation, 100% successful placement, judged by chest x-ray <u>Successful placement:</u> Acceptable tip position judged by chest x-ray, with not replacement, repositioning or pull-back of the catheter. <u>Acceptable tip position:</u> Lower third of Superior Vena Cave, or cavoatrial junction. Although the right atrium is not in the definition, it would not be a problematic placement, and in practice it is difficult to distinguish if the tip is in the right atrium, or the cavoatrial junction on the x-ray. <u>When Sherlock isn't used, or ECG is not possible for tip confirmation:</u> • Where Sherlock 3CG TCS is not used at all for placement, then protocol for PICC placement	abstract

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	confirmation of tip position during PICC placement? It might be easier to clarify this by telephone, if so please let me know when is a good time to contact you, or alternatively phone Cedar on the number below. Thank you for your assistance.	would now be using fluoroscopy. • During the complete (n=225) trial period, an additional 2 PICCs were placed using fluoroscopy, not using Sherlock 3CG TCS (giving n(Total PICCs) = 227). All other PICCs placed in this period used Sherlock 3CG TCS. • From the introduction of Sherlock 3CG TCS to the latest completion of the database, only 11 patients have required a chest x-ray due to failure of Sherlock 3CG TCS to confirm tip location. 5 were due to AF which was detected during the PICC procedure, 6 were due to faults in the electrode connections. For these patients Sherlock 3CG TCS was used for magnetic tip placement, and a chest x-ray was used for tip location confirmation. **They did not require placement with fluoroscopy?** • Sherlock 3CG TCS was used on two paediatric patients, outside the scope of Instructions for Use, and therefore these required a chest x-ray. **Are these additional to the 11 above?** Previous to using Sherlock 3CG TCS it was common practice to intentionally insert the catheter slightly	

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		further than required and then pull back to the correct position after the chest x-ray. Pull back would have been performed in about 80% of cases, but now is not required. Very few patients are seen with AF in this location, it will vary from site to site, some may have much higher number of patients where ECG tip confirmation is not possible. Cedar will not use the additional information provided by Bard in the form of the database and database summary, as it does not cover exactly the same time frame as the trial, includes additional catheter insertions and does not give tip location outcomes. The change in the p-wave on the ECG trace is due to the position of the catheter tip relative to the sinoatrial node as the catheter enters the right atrium. There will be a difference between the two ECG traces on the monitor.	
Meinir Hughes			

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	We are aware of your paper **Reducing PICC migrations and improving patient outcomes** in the British Journal of Nursing that includes cost data for PICC placement. I would be very grateful if you could supply some additional information and cost breakdown for this statement under PICC migration in the cost analysis 'The cost of a single PICC placement (inclusive of staff and X-ray costs) is: £250.' Also, is there any other report on this work, either published or unpublished that you would be able to share with us.	Phone call to Meinir Hughes, resulting in sharing of costing for single PICC placement calculation, giving 2010 cost of £250 per PIOC.	Additonal information mentioned in assessment report.
Questions to NHS sites using Sherlock 3CG TCS			
	• How long has Sherlock 3CG TCS been used at your site? • Has training been completed yet for staff who use Sherlock 3CG TCS? • Approximately how many PICC procedures (in-patient and out-patient) have been carried out at your site using Sherlock 3CG TCS? • Are chest x-rays routinely used with Sherlock 3CG TCS to confirm PICC placement at your site?	Responses are included in full in external assessment report.	

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
	• Do you have any comments to make about Sherlock 3CG TCS and your experience of using it?		

MT 234 Sherlock 3CG TCS: Supplementary Correspondence Log

Late responses to a request for expert advice by the EAC – sent September 12 2014

Sent to: Andrew Barton

Dr Lisa Dougherty

Dympna McParlan

Question 14: (to Dr Lisa Doughty, Andrew Barton, Dympna McParlan For the patient, there is likely to be a longer time from the start of PICC insertion to tip confirmation if an x-ray is required, than if Sherlock 3CG TCS is used to confirm tip position at bedside. **Would the PICC nurse be involved in the x-ray procedure at all (including accompanying the patient etc.)?**	
Dr Lisa Dougherty	Would depend – I verify my own x rays but many nurses would need to seek a doctor to verify tip
Mr Andrew Barton	In my Trust I have accompanied the patient for a chest x-ray if I want to speed up the process but usually a porter is sent to bring the patient to radiology, the patient will placed in a queue and sent for when radiology are ready.
Ms Dympna McParlan	The only involvement the PICC nurse would have if an x-ray is required is interpreting the x-ray and signing off the patient.
Question 15: (to Dr Lisa Doughty, Andrew Barton, Dympna McParlan :Would the PICC nurse time be any different for a Sherlock 3CG TCS procedure where chest x-ray was still used for tip confirmation vs a Sherlock 3CG TCS procedure without chest x-ray?	
Expert Adviser	Response / Comment
Dr Lisa Dougherty	Only the extra time waiting for x ray to be done – I use the time to do my documentation so slightly less time if no CXR
Mr Andrew Barton	If Sherlock TCS was used without the ECG component of the procedure than achest x-ray would be indicated and take time however time and money would be saved in the long run because the PICC would not need to repositioned from the IJ etc..
Ms Dympna McParlan	The PICC nurse time would be increased if a chest x-ray was used for tip confirmation vs Sherlock 3CG TCS as the patient would return to the department following x-ray for interpretation and signing off. While this usually happens quite quickly it is unpredictable depending on Radiology workload.

Appendix 1

[MT 234 Sherlock 3CG TCS, Meeting with Bard
Tuesday 22nd July 2014

Cedar: Megan Dale, Andrew Cleves, Grace Carolan-Rees, Susan Peirce
Bard: Rachel Spiller, Chengetayi Pswarayi

These are notes from the informal discussion, organised into topic headings. There is not attempt to comprehensively cover each topic, merely record the information passed to Cedar.

When to use a PICC?

- when the infusion would damage the vein otherwise eg nutrition, chemotherapy and some antibiotics
- in intensive care where a lot of drugs need to go into the system quickly

PICCs have a lower infection rate than insertion at the jugular vein.

Insertion point is normally above the elbow, so arm movement doesn't cause too many problems. Ultrasound is needed for insertion at this site.

System components

The PICC comes as a full sterile tray with all the disposables required including gloves, drapes, tape measures etc. This includes safety needles and safety scalpels. (There is a non-safety pack for doctors for some catheters, but this is not available for Sherlock). EPIC 3 guidelines require full drapes

The stand, netbook, sensor and printer are available at a list price of £9,900 excl VAT. There is also a loan option, where the capital equipment is provided with a contract for consumables. Actual price paid will vary depending on volume and what other Bard products the Trust purchases. Many English Trusts buy such items via procurement Hubs.

The printer will produce an image of the ECG signal at the point of placement, or this can be saved and exported as an image file. The purpose of the external ECG was unclear to Cedar as the change in P-wave was described as occurring in both ECG signals simultaneously.

Training is included in the purchase price.

Sherlock 3CG TCS has also been introduced into Scandinavia, Italy, France and Spain at the same time as the UK.

Catheters

More lumens have a higher infection risk, as each lumen must be flushed even if only one is used for infusion.

PowerPICC catheters can be used for CECT imaging, where a better image is obtained if contrast medium is injected fast, and under pressure. Traditionally PICC catheters were unable to be used for this, as they were not strong enough, however PowerPICC type catheters can be used. Where there are single or double lumens, any lumen can be used. For triple lumen PowerPICC catheters only one lumen is suitable for power injection.

Using Sherlock 3CG TCS and system display

Ultrasound is used to visualise the vein for insertion (NICE guidelines). In the UK this will be whatever system the centre currently uses and is separate to the Sherlock system.

If there is no Sherlock the ultrasound can also be used on the jugular to check that the PICC has not gone here, but it will not always show up.

The external ECG electrodes and connecting fin are disposable and included in the procedure pack. The fin slides onto the Sherlock sensor. This is then placed in a bag and secured to keep the device clean, and the device placed on the patient and covered with a drape. The ECG connection from the catheter connects to the fin by piercing through the drape and bag, to maintain the sterile field.

The Sherlock display screen shows the position and orientation of the stylet relative to the external sensor and also, on a separate section of screen the depth of the stylet in the body. These positions are all relative to the sensor, so correct positioning is important. There is also an audio signal but most users turn this off. Depth may be misleading / difficult to interpret in morbidly obese patients. The device is for adult use only, however clinicians will make a clinical decision on how appropriate its use is, for example for a larger, older child.

Positioning the catheter

The positioning that they teach is 2 cm from the cavoatrial junction. If it is in too far it may cause arrhythmias, if it is too short then it can irritate the smaller vessels. The exact positioning may depend on the patient and the use of the catheter. For oncology it may be in situ for more than 6 months with damaging drugs infused and the position is more important. In ITU where it will be in place for a couple of weeks the accuracy may not be as critical.

Sometimes the catheter may double back on itself, for instance if it cannot pass through a valve, but still appear to feed into the vein.

Malposition rate is very variable between hospitals. There are two main types:

Gross malposition – the catheter may go into the jugular or contra-laterally. Techniques such as lying the patient's head to one side or the valsalva manoeuvre may avoid or correct malpositioning in the jugular. PICCs are mainly inserted on the right hand side as the anatomy is easier to position the catheter correctly.

Other – some teams will routinely place the PICC a bit longer, giving them the option of pulling out a small distance at X-ray. Some will expect to do this on up to 85% of PICCs, as this can be done easily. If the PICC is too short it would have to be removed and the procedure repeated.

When using Sherlock the advice is that if there is any doubt about the position always get an X-ray. Practice following malposition varies across Trusts. If PICC placement by radiologists is common then fluoroscopy may be used. A 'flip-down' procedure with fluoroscopy may be attempted in which the patient performs a Valsalva manouvre in order to push the PICC tip downward. In other Trusts where only nurses place PICCs it is likely that the PICC will be removed and a new insertion procedure used.

AP planar X-rays may not show catheter position unequivocally. Richard Williams at Liverpool has conducted a study evaluating the use of planar X-rays for checking catheter position. Without a system for checking the position, malposition may be identified by arrythmias, localised pain and difficulty withdrawing blood or infusing via the catheter.

Malposition may also occur due to movement once the PICC is in place. Symptoms may include not being able to infuse easily, or to take blood. In this case an X-ray is required to investigate. On placing the PICC the amount of catheter remaining outside the insertion site is recorded, and therefore movement of the catheter into or out of the body can be ascertained.

Training

In the UK it is mainly nurses who place PICCs. Some hospitals place around a 1000 PICCs annually.

Bard have been holding training workshops for 19 years.

On introducing Sherlock to a new setting the Bard trainer would be present over a two week period. they can also train new members of a team where Sherlock is already used. There is an online course, followed by a presentation including ECG interpretation, then practical demonstrations and training with patients. Different users will take different lengths of time before feeling confident with the Sherlock system and to stop using X-rays routinely.

Trusts may require annual re-training (to account for new staff) and capability assessment.

Training is included in the purchase of the Sherlock 3CG TCS system, including additional training for new staff members.

Information to be forwarded by Bard when available, but by Friday 25th July at the latest:

- information about the NHS audit – how and when the data was collected (done)
- data for Symington, Strewart and Barton studies (done)
  dates for FDA approval of different version (please check against my table)