NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

Assessment report overview

MT 234 Sherlock 3CG Tip Confirmation System for placement of peripherally inserted central catheters

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

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

This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Comments from professional bodies
- Appendix C: Comments from patient organisations

1 The technology

The Sherlock 3CG Tip Confirmation System (C.R. Bard) is designed to confirm the correct tip placement of a peripherally inserted central catheter (PICC; that is, a catheter inserted through a large vein in or near the arm rather than the neck or chest). By using magnetic and electrocardiographic real-time tracking of the PICC tip, the device is intended to allow the person placing the PICC to immediately detect and correct any error in tip positioning. It removes the need for a chest X-ray usually used with the insertion of a PICC.

The Sherlock 3CG Tip Confirmation System (TCS) is intended for use in any indication in adults where therapy means accessing a vein through a PICC. This technology should be used with caution in patients with altered cardiac rhythms, specifically those in whom an electrocardiography (ECG) P-wave is not easily detectable, due to atrial fibrillation, atrial flutter, rapid tachycardia and paced rhythm. Although the Sherlock 3CG TCS can be used in these patients, a chest X-ray will still be needed to confirm PICC tip location.

The Sherlock 3CG TCS comprises: a system console, including a control processor with display interface; a tip location sensor; a PowerPICC SOLO catheter with Sherlock 3CG Tip Positioning System (TPS) stylet; a remote control; and an optional miniature wireless printer to create a paper record of the ECG.

Ultrasound is used to identify a suitable vein in the upper arm before the Sherlock 3CG TCS is used. The sensor is positioned on the patient's sternum with 2 leads placed to pick up external ECG waveforms. The catheter is then inserted with the stylet, which has permanent, passive magnets in its tip. During insertion, when tip location mode is active, the magnets generate a field that is detected by the sensor. This enables clinicians to track the PICC on the display interface in real time, allowing them to see if the PICC is tracking into the internal jugular vein or contralateral vein, or if it is taking the correct path towards the cavoatrial junction. The display interface also shows

real-time ECG waveforms received from the patient's skin (baseline) and from the tip of the catheter (intravascular). Intravascular ECG is acquired from a column of saline injected into the PICC prior to placement. The P-wave changes on the ECG as the PICC tip moves towards the right atrium and right ventricle. By observing the P-wave, a clinician can determine the PICC tip location as it travels through the superior vena cava to the right atrial junction.

The Sherlock 3CG TCS is a fifth-generation device that was launched in the UK in April 2013. Previous versions available in the USA include the following:

- The Sherlock I TLS (2006) was solely a tip positioning system, with no ECG component.
- The Sherlock II TLS (2006) included a Y-shaped metal field sensor for tip location, and was the first version to be compatible with the PowerPICC catheter.
- The Sherlock 3CG TPS (2009) featured ECG confirmation using a single channel ECG device, but did not claim to eliminate the need for a chest X-ray. The catheter along with the Sherlock 3CG TPS stylet received a class III CE mark in February 2012.
- The Sapiens TCS (2009) also featured a single ECG channel, and claimed that it replaced the need for a chest X-ray. It does not use magnetic tracking.

2 Proposed use of the technology

2.1 Disease or condition

The Sherlock 3CG TCS is indicated for use in any adult who needs a PICC as part of treatment for any disease or condition. Limiting (but not contraindicated) situations for the device are patients in whom alterations of cardiac rhythm change the presentation of the P-wave, for example atrial fibrillation, atrial flutter, severe tachycardia and pacemaker-driven rhythm. In such patients, who can usually be identified before PICC insertion, the use of

the Sherlock tip location sensor will track the catheter into the correct position but a chest X-ray is needed to confirm tip placement.

The length of time a PICC is fixed in a patient (called the indwelling time) can range from a few days to over a year. On average, however, PICCs tend to be in situ for 1 week to 3 months, with the most frequent indwelling time being 3 weeks.

PICCs have a wide range of applications and are commonly used for both intravenous access for drugs and fluids (infusion of irritant drugs, such as in chemotherapy; total parenteral nutrition; or long-term administration of drugs such as antibiotics) and monitoring or interventions (such as central venous pressure, repeated blood sampling, or where there is poor peripheral access).

2.2 Patient group

PICCs are used in a variety of clinical scenarios and for this reason there is no single source for the average annual number of insertions. A 1994 review, quoted in NICE technology appraisal guidance on the use of ultrasound locating devices for placing central venous catheters, estimated that more than 200,000 central venous catheters (including PICCs) were inserted in the UK annually. This figure does not refer exclusively to PICCs and includes other types of central venous access devices. A report submitted by the sponsor shows that PICC sales in the UK for 2013 were approximately 74,490 (iData, 2014). Hospital Episode Statistics for England (2012–13) recorded 31,427 inpatient procedures. An unknown, but thought to be substantial, proportion of PICCS are placed in outpatient settings. Based on a brief literature search, the EAC concluded that the sponsor's estimate of approximately 74,490 was reasonable in the context of the available data (appendix 2 of the assessment report, page 87).

2.3 Current management

There is substantial variation in PICC insertion between different sites in current NHS clinical practice. Catheters may be inserted by nurse-led or consultant-led vascular access teams. More generally, PICCs may be inserted

by clinicians including nurse specialists, intensive care consultants, anaesthetists, general physicians, radiologists and radiographers. Clinical settings include operating theatres, emergency rooms, oncology, orthopaedic and other wards, radiology departments, intensive care, high dependency units and outpatient clinics. A sterile environment is needed, but can be achieved using a maximum barrier sterile field at the bedside.

Ultrasound is used to identify a suitable vein in the upper arm. The PICC is then inserted using a modified Seldinger technique, which involves inserting a small gauge needle into the vein followed by a wire. A sheath and dilator are used for the catheter to gain access to the vein before the wire is removed. The PICC is advanced to a suitable point using a measurement of the distance between the insertion site and a suitable anatomical landmark (for example, the third right intercostal space below the right clavicular head). The position of the PICC is confirmed by chest X-ray. Fluoroscopy may also be used to position the PICC, especially where this is difficult, such as in patients with narrow vessels.

2.3.1 Correct PICC placement

Different guidelines recommend different catheter tip positions. The European Society for Clinical Nutrition and Metabolism guidelines on parenteral nutrition state that the best position is in the lower third of the superior vena cava, at the cavoatrial junction, or in the upper portion of the right atrium within 2 cm of the cavoatrial junction (Pittiruti et al., 2009). US guidelines (Funaki, 2002) use more specific criteria, specifying the low superior vena cava or cavoatrial junction.

The British Committee for Standards in Haematology and current NHS local practice guidelines and policies recommend a chest X-ray to confirm the location of the PICC before it can be used. Once the chest X-ray has been taken, the guidelines state that no PICC should be used unless the X-ray has been checked and it has been documented that the line is in the correct position.

2.4 Proposed management with new technology

The new pathway of care would involve using the Sherlock 3CG TCS to confirm tip location at the bedside in all cases for which the technology is indicated. This would allow intravenous therapy to begin immediately after PICC insertion. In cases where a PICC is needed for venous access therapy, the Sherlock 3CG TCS could replace X-ray confirmation in most cases. A minority of patients would still require a confirmatory chest X-ray due to a number of medical factors that limit the use of the Sherlock 3CG TCS for tip location. Bedside placement could be used in an inpatient, outpatient or community-based setting. If the need for an X-ray were removed, PICCs could potentially be used in community settings. PICCS could also be used in patients for whom a confirmatory X-ray is contraindicated, such as pregnant women. PICC placement could ultimately be moved from radiology suites to less costly outpatient departments.

2.5 Equality issues

No equality issues were identified.

3 Sponsor's claimed benefits

The benefits to patients claimed by the sponsor are as follows:

- Better accuracy of PICC placement (reducing the need for repositioning after surgery).
- It removes the need for a chest X-ray or fluoroscopy to confirm tip location after PICC insertion.
- Intraprocedural verification of the PICC tip position allows the PICC to be used immediately after insertion. This reduces treatment delays, which may be up to 48 hours after PICC insertion.
- It is a safe method for PICC tip placement with no associated adverse events or complications.
- PICC placement and tip confirmation happen during the same clinical procedure.

- It increases the patient's confidence in whoever is placing the PICC, because the rate of malpositioning and repositioning is reduced.

The benefits to the health system claimed by the sponsor are as follows:

- A reduced and more efficient care pathway because no confirmation X-ray is needed.
- Lower staff requirements (radiologists/radiology nurses/radiographers/ radiology healthcare support workers) because the need for an X-ray to confirm PICC placement is reduced or eliminated. All staff who are freed by the use of the Sherlock 3CG can be redirected to other areas of need.
- Potential reduction of bed occupancy due to reductions in treatment delays post-PICC insertion and delays caused by repositioning. This may lead to earlier discharge of hospital patients having intravenous therapy, enabling management in the community.
- Reduced costs of consequences of incorrect PICC placement.
- Reduced costs of using resource-intensive departments such as radiology.

4 Decision problem

Table 1 Summary of the decision problem

Population	Adult patients undergoing PICC insertion
Intervention	Sherlock 3CG Tip Confirmation System
Comparators	•PICC insertion followed by chest X-ray to confirm tip placement •Fluoroscopy to guide PICC insertion and confirm tip placement
Outcomes	Outcome measures to be considered include: •accuracy of catheter tip placement •incidence of catheter malposition •need for catheter repositioning •effect of malposition-related complications such as infection or thrombosis •treatment delay following catheter placement •reduced staff time •shorter hospital stay •need for confirmatory chest X-ray •need for fluoroscopy to correctly place the PICC tip •time taken to insert PICC •PICC failure/re-insertion rates •patient experience measures •quality of life •device-related adverse events.
Cost analysis	The cost analysis will include both the standard method of PICC placement and the fluoroscopic method as comparators. The use in different care settings (for example secondary or tertiary care) should be considered. This includes considering the difference between inpatient and outpatient costs. Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficient to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analyses will be done to address uncertainties in the model parameters, which will include scenarios where the use of the Sherlock device removes the need for post-insertion confirmatory chest X-ray.
Special considerations, including issues related to equality	Although many patients needing a PICC would be considered disabled under the Equality Act 2010, there are no equality issues directly related to the use of the Sherlock 3CG TCS.

The sponsor's submission did not contain any stated deviation from the scope.

5 The evidence

5.1 Summary of evidence of clinical benefit

The sponsor identified 13 studies from its literature search. It excluded 9 of these and presented 4 published abstracts as supporting clinical evidence. It also identified a study which was about to be published but was not yet available (Johnston et al. 2014).The External Assessment Centre (EAC) agreed with the study selection and included the study by Johnston et al. As a result of the lack of evidence – in terms of both quantity and quality – the EAC did a literature search with a wider scope to include any previous model of the device which included both magnetic tracking and ECG tip confirmation components. One additional presentation of low quality was identified (Symmington et al, 2013). This had also been identified by the sponsor, but excluded as it did not related specifically to the Sherlock 3CG TCS. Full details of the methodologies and outcomes of clinical studies are outlined in pages 23–39 of the assessment report. A summary of all the studies considered is in table 1.

The sponsor also submitted responses to questionnaires from 6 of the 14 NHS hospitals currently using the Sherlock 3CG TCS (page 32 of the assessment report).

Table 1. Studies related to clinical benefit identified by the sponsor and the EAC

Study	Study design (country)	Population	Intervention versus comparator	Outcomes considered	EAC comments on study
Full, peer-reviewed articles					
Johnston, 2014	Consecutive, retrospective case series (UK)	ICU patients needing PICC insertion, excluding those not in sinus rhythm [n=239]	Intervention was the Sherlock 3CG TCS. No comparator.	Malposition rates of PICCs placed in patients in ICU using the Sherlock 3CG TCS.	Aims, methods, patient population, results and exclusion criteria are fully reported. Chest X-rays were reviewed by at least 2 of 3 authors. The EAC undertook an analysis using patient data from the same patient population in the same hospital treated with blind bedside insertion (Johnston et al. 2013).
Other evidence: abstracts, posters and presentations					
Adams, 2013	Case series (USA) [poster]	People needing PICC insertion, excluding those with no identifiable P-wave [n=333]	Intervention was the Sherlock 3CG TCS. No comparator. Previously, the Sherlock TPS was used to aid tip positioning, which was then verified with confirmatory chest X-ray.	Tip location accuracy, time until PICC available for infusion, cost of insertion.	Full critical appraisal was not possible. The publication was not peer-reviewed. It was reported that accurate tip position needed to be separately verified by 2 radiologists.
Barton, 2014	Case series (UK) [abstract]	Adult patients with no AF needing a PICC insertion [n=225]	Intervention was Sherlock 3CG TCS. No comparator. Previously, tip position was confirmed with X-ray.	Accuracy of tip placement	Only minimal information was available. The publication was not peer-reviewed. Full critical appraisal was not possible.

Study	Study design (country)	Population	Intervention versus comparator	Outcomes considered	EAC comments on study
					Chest X-rays were reviewed by an independent physician. The author was contacted and provided additional information on the patient population and acceptable tip position.
Parikh, 2012	Prospective case series (USA) [poster]	People needing a PICC insertion, excluding those with AF, atrial flutter, no discernible P-wave and those at increased risk of bleeding [n=209 in original study, n=437 in follow-up]	Intervention was the Sherlock 3CG TCS. No comparator. Previously, the Sherlock II TLS was used aid tip positioning, which was then verified with confirmatory chest X-ray.	Accuracy of tip placement.	A detailed poster containing sufficient information for some critical analysis. Clearly defined patient population and statement of acceptable tip placement, which was separately assessed by 2 independent observers. Clearly stated patient exclusion criteria. The publication was not peer-reviewed.
Stewart, 2013	Case series (Australia) [poster]	Not reported [n= >65]	Intervention was the Sherlock 3CG TCS. No comparator. Previously, tip position was confirmed with X-ray.	Accuracy and proficiency of ECG technology for PICC insertion with respect to cost savings, time saved, and minimised radiation.	Only minimal information was available. The publication was not peer-reviewed. Full critical appraisal was not possible. Information should be treated very cautiously; even the number of patients recruited was not accurately reported.

Study	Study design (country)	Population	Intervention versus comparator	Outcomes considered	EAC comments on study
Symington, 2011	Prospective case series (USA) [presentation]	Patients needing a PICC insertion [n=63]	Intervention is the Sapiens TCS in conjunction with the Sherlock II TLS. Previously, the Sherlock II TLS was used to aid tip positioning, which was then verified using confirmatory X-ray.	Success and accuracy of PICC placement [not clearly reported]	Only minimal information was available. The presentation was not peer-reviewed. Full critical appraisal was not possible.
Abbreviations used: AF, atrial fibrillation; EAC, external assessment centre; ICU, intensive care unit; PICC, peripherally inserted central catheter; TLS, tip location system; TPS, tip positioning system.					

5.1.1 Peer-reviewed literature

Johnston et al. (2014) was published after the sponsor's literature searches were carried out and therefore not included in its submission. Following the introduction of the Sherlock 3CG TCS to a UK NHS centre, a retrospective review was undertaken of the first 250 patients to have PICCs using the Sherlock 3CG TCS. The population included patients in the intensive care unit (ICU), where the highest rates of malposition are usually reported. The vascular access team placed PICCs at the bedside, and used a portable chest X-ray to confirm the tip location. Two independent reviewers examined the X-rays. From the first 250 patients, 11 were excluded. The reasons for exclusion were: failed insertion (n=2); no chest X-ray (n=2); unable to determine tip position on X-ray (n=2); unable to interpret ECG criteria (n=4), and catheter being too short (1 case).

Tip location was reported in Johnston (2014) for the 239 PICC placements where ECG was used for tip confirmation. Although there was no direct comparator for the intervention in this study, the same authors published a retrospective service evaluation a year before the Sherlock 3CG TCS was introduced, reviewing records for both ICU and non-ICU patients (Johnston 2013). The EAC used this as a form of comparator to assess the impact of the Sherlock 3CG TCS on malposition rates. Details of Johnston (2013) are outlined in page 25 of the assessment report. Table 2 shows the number of PICCs placed in each position before and after the introduction of the Sherlock 3CG TCS, based on the 2 Johnston studies.

Table 2. Tip positioning rates, as defined by chest X-ray before and after introduction of the Sherlock 3CG TCS [Johnston, 2013, 2014]

Tip position	Appropriate placement [European definition]	Appropriate placement [USA definition]	Using the Sherlock 3CG TCS [Johnston 2014]		Blind bedside insertion [Johnston 2013]			
			ICU		ICU		Non-ICU	
			n=239	%	n=246	%	n=233	%
Malpositions[a] above the superior vena cava	X	X	1 [c]	0.0% [c]	51 [c]	20.7 [c]	33 [c]	14.2 [c]
High superior vena cava	X	X	7	2.9%	27	11	26	11.2
Mid superior vena cava	✓	X	22	9.2%	42	17.1	25	10.7
Low superior vena cava	✓	✓	58	24.3%	36	14.6	70	30
Cavoatrial junction	✓	✓	47	19.7%	23	9.3	23	9.9
Right atrium (upper 2 cm)	✓	X	63	26.4%	20	8.1	18	7.7
Right atrium (lower than 2 cm)	X	X	39	16.3%	35[c]	14.2 [c]	28 [c]	12.0 [c]
Malpositions[b] below the right atrium	X	X	1 [c]	0.0% [c]	5 [c]	2.0 [c]	5 [c]	2.1 [c]
Others	X	X	1	0.4%	7	2.8	5	2.1

[a] Malpositions include ipsilateral and contralateral positioning in the axillary vein, internal jugular vein, subclavian vein and brachiocephalic vein.

[b] Malpositions include the right ventricle and inferior vena cava.

[c] Calculated by EAC from papers due to different presentations of figures between the 2 papers.

The Johnston papers both reported results using 2 different definitions of malposition. The definition of appropriate placement typically used in USA guidelines is the low superior vena cava or cavoatrial junction. European guidelines use a broader definition, stating that appropriate placement is in the mid or lower superior vena cava, cavoatrial junction, or high right atrium (Pittiruti 2009). Table 3 summarises malposition rates before and after the introduction of the Sherlock 3CG TCS.

Table 3. Comparison of malposition rates (Johnston 2013, 2014)

Definition of adequate tip position	Malposition rates					
	The Sherlock 3CG TCS		Blind bedside insertion			
			ICU		Non-ICU	
	n=239	% (95% CI)	n=246	%	n=233	%
Low superior vena cava/cavoatrial junction	134	56.1% (50-62%)	187	76.0%	140	60.1%
Mid and low superior vena cava/cavoatrial junction/high right atrium (upper 2 cm)	49	20.5% (16-26%)	125	50.8%	97	41.6%

The malposition rate using the Sherlock 3CG TCS was significantly lower than blind anthropometric placement for both criteria ($p<0.0001$). However, it was also substantially higher than that reported in other studies. The authors suggest several reasons for this. They noted that it may be difficult to determine the exact point of a maximum or biphasic P-wave for patients in intensive care, who may be likely to have ECG artefacts due to comorbidities. They also noted the possibility that the catheter tip may move due to arm movement, as the PICC is placed with the arm abducted (that is, drawn away from the body), and the chest X-ray taken with the arm adducted (that is, drawn towards the body).

The authors conclude that if the European guideline definition of an adequate tip position is considered to be acceptable, the Sherlock 3CG TCS can be used for tip confirmation without chest X-ray. If a more precise tip position of low superior vena cava/cavoatrial junction is used, such as that defined in the USA guidelines, a chest X-ray may be necessary.

5.1.2 Other evidence

Adams et al. (2013) presented a poster at the Association of Vascular Access Annual Meeting 2013, reporting on the introduction of the Sherlock 3CG TCS to a health care centre in the US. Over a 9-month period, 333 patients had PICC insertion using the Sherlock 3CG TCS, which was subsequently verified using chest X-ray and confirmed by 2 radiologists. Accurate placement was defined as the distal superior vena cava or cavoatrial junction. The Sherlock 3CG TCS was used to confirm tip position in 83.5% of patients (278/333). In the remaining 16.5% (55/333), the ECG system could not be used mainly because of an abnormal P-wave (12.9%), but also because of technical factors (3.6%; loose connections, poor electrode placement and so on). When the Sherlock 3CG TCS was used to confirm tip position, 1 radiologist reported that 96.4% (268/278) of PICCs were placed accurately, and that 3.6% (10/278) were malpositioned; the other radiologist reported that 98.2% (273/278) were placed accurately and 1.8% (5/278) were malpositioned.

For the sake of comparison, in 2011, the malposition rate using the predecessor device the Sherlock Tip Location System (magnetic tracking only) alongside confirmatory chest X-ray was 14%.

Adams et al. also reported that the PICC was ready for infusion 61 minutes earlier using the Sherlock 3CG TCS than using a chest X-ray and a radiologist report for tip position confirmation. No information was reported on how this was measured, but the researchers confirmed that chest X-rays are no longer mandatory for PICCs placed using the Sherlock 3CG TCS at this centre.

The abstract by Barton (2014), from the World Congress of Vascular Access 2014, describes the introduction of the Sherlock 3CG TCS to a nurse-led

PICC service at Frimley Park Hospital. In an initial trial, clinicians used the Sherlock 3CG TCS for PICC placement in 65 adults with no atrial fibrillation. They then used chest X-rays, reviewed by an independent physician, to confirm tip location. Following the initial trial, an application to amend local protocol and remove the need for a mandatory chest X-ray following PICC placement was made. During the application process, clinicians placed another 160 PICCs using the Sherlock 3CG TCS, with position confirmed using a chest X-ray. In total, data were reported on 225 patients. The definition of acceptable tip position was the lower third of the superior vena cava or the cavoatrial junction. In correspondence with the EAC, the author stated that positioning in the right atrium would have been clinically unproblematic, and may not be clearly distinguished using chest X-ray.

Chest X-rays confirmed that tip position was acceptable in 100% of cases reported. Only success rates of tip positioning in patients for whom magnetic tip position and ECG tip confirmation could be used were reported. Cases where the Sherlock 3CG TCS was not suitable or where there was a failure of the ECG system were not accounted for. The author reported to the EAC that throughout the trial period, 2 patients were not suitable for Sherlock 3CG TCS and had PICCs placed with fluoroscopy. Since the introduction of the Sherlock 3CG TCS to Frimley Park Hospital, 11 patients have needed chest X-rays due to the failure of the ECG system to provide tip confirmation. Five of these cases were because of atrial fibrillation, and 6 because of a failure of the electrode connections. Frimley Park Hospital has since removed the need for chest X-ray.

Parikh (2012) is a poster presented to the Radiological Society of North America Meeting 2012. It reports a prospective case series from October 2011 to April 2012 of 247 PICCs placed in 221 patients (mean age=62, range 15–100). The Sherlock 3CG TCS was used for tip placement and confirmation, except in patients with atrial fibrillation, atrial flutter or no discernible P-wave (15.4%, 38/247). Tip position was confirmed by chest X-

ray and evaluated by 2 independent observers. Successful tip placement was defined as the superior vena cava or cavoatrial junction.

The study was divided into 2 phases. Phase 1 involved voluntary training (completed by 4 of 7 nurses), which consisted of a PICC refresher course, an online course, a 1-hour taught course and 1-to-1 training with a nurse trainer provided by the sponsor. The nurses then placed 62 PICCs using the Sherlock 3CG TCS. As per the exclusion criteria, 3 patients were excluded. Successful tip placement was 83% (n=62) for those using the Sherlock 3CG TCS.

To take part in phase 2 of the study, all nurses underwent all aspects of the phase 1 training and inserted 5 PICCs while being observed by a nurse trainer. All staff completed Phase 2 training. Staff placed 147 PICCs using the Sherlock 3CG TCS, excluding 35 patients as per the criteria. Successful tip placement was 96% (n=147) for those using the Sherlock 3CG TCS.

From November 2012 to May 2013, staff placed a further 567 PICCs, 437 using the Sherlock 3CG TCS. Of these, 24.9% (109/437) still needed a chest X-ray for confirmation. It is unknown if the PICCs which did not use Sherlock 3CG TCS then needed a chest X-ray to confirm, although this is probable.

An abstract and poster by Stewart (2013) presented at the Association of Vascular Access Annual Meeting 2013 describe a study in which more than 65 patients were recruited between November 2012 and March 2013. The exact number of patients and methodology were not reported. Clinicians placed PICCs using the Sherlock 3CG TCS and confirmed the tip position using a chest X-ray. No information was given on what tip positions were considered to be acceptable or who reported on the chest X-ray. The abstract reported that 100% of malpositions were corrected at time of placement. 96% of PICC placements using the Sherlock 3CG TCS were within the cavoatrial junction. The other 4% were reported in the right atrium. Discrepancies were noted between locations reported by ECG and X-ray, which were resolved with clinical experience and collaboration. A time saving of 1 hour and

51 minutes was reported, being the average wait time between PICC insertion and X-ray results.

Symington et al. (2011) was a presentation on a US centre using the Sapiens TCS in conjunction with the Sherlock TLS II (the predecessor device, which has the same system components as the Sherlock 3CG TCS). The author reported on a consecutive case series which took place in April 2011 (n=63). No information was given on patient population. Tip placement was verified with a chest X-ray, reviewed by the author. The sponsor provided training.

The author reported a 5% technical failure rate, for example because of difficulties with cannulation of the vein, advancement of the catheter, and occluded veins. It was reported that technical failures were ‘thrown out’, although this is not explained in greater detail. The author reported that 62 of 63 tip placements were appropriately positioned, although no specific criteria of appropriate placement are reported. The author reported that, as of July 2011, there had been 604 PICC placements using the Sapiens TCS in conjunction with the Sherlock TLS II in the US centre in question. The author reported that he was to formally request that the medical executive committee at his hospital remove the requirement for mandatory chest X-ray from procedural guidelines. The author was a paid presenter for Bard Access Systems, which was clearly stated.

The sponsor collected data from 7 UK NHS centres currently using the Sherlock 3CG TCS. The initial clinical submission did not include these data, but they were provided to the EAC subsequently. The data received are summarised on page 32 of the assessment report. The EAC judged that the structuring of the questions and format of the answers made any meaningful synthesis impossible. The EAC noted the variation in reported clinical practice for issues such as hospital policy for confirmation, typical levels of malposition, dealing with malpositions and PICC replacements. In general, all respondents reported fewer malpositions using the Sherlock 3CG TCS than prior to its introduction. The EAC noted that there was a risk of bias because not all centres using the Sherlock 3CG TCS were asked to provide data to the

sponsor. To explore this, the EAC contacted 7 of the other 8 centres currently using the device, and 1 centre that had not responded to the sponsor's initial questionnaire. Data from the 6 centres which responded to the EAC are reported on page 37 of the assessment report.

Overall, the sponsor reported that the Sherlock 3CG TCS is currently in use at 14 NHS sites in England and 2 in Northern Ireland. Nine of the English sites have discontinued routine chest X-ray confirmation following PICC placement. The EAC was able to confirm this position for 6 of the 9 centres.

5.1.3 Adverse events

Neither the sponsor nor the EAC found any adverse events reported in any studies, or in a search of the Medicines and Healthcare Products Regulatory Agency's website. The sponsor retrieved 51 records from the Food and Drug Administration's MAUDE database, commenting that they were not necessarily device-related adverse events. The EAC retrieved 100 records from the same database, using a wider search strategy. No searches were carried out for PICC insertion using other technologies so the adverse event rates for comparators (blind PICC insertion with chest X-ray, or fluoroscopy) were not reported. The EAC could not rule out the possibility that the adverse events reported were common to all PICC insertions. Adverse events submitted to MAUDE are not verified.

Recorded events include: broken or damaged wire tip or stylet (n=29); adverse patient reactions (such as shortness of breath; n=23); catheter malfunction (such as leaks or splits; n=18) and tip malposition (n=14). The EAC judged that there was insufficient information to draw any conclusions.

5.1.4 Advice from experts and patient organisations

Expert adviser questionnaires were completed by 8 experts at the selection and routing stage and presented to the Medical Technologies Advisory Committee in April 2014. One additional questionnaire was received too late for presentation but the answers have been incorporated into the collated expert adviser table. All 9 questionnaires are summarised in appendix B.

5.2 Summary of economic evidence

The sponsor's search for economic evidence identified 13 texts for full evaluation but 11 were excluded, with reasons given. The sponsor presented 2 health economics studies in its submission (Adams 2013; Stewart 2013). Both studies were cost-comparison studies from outside the UK healthcare system (USA and Australia respectively). The sponsor noted that the studies were low quality and of limited relevance to the decision problem. The EAC did not identify any additional relevant studies and agreed with the sponsor's assessment of the limited value of those that were identified (assessment report page 49).

5.2.1 De novo analysis

The sponsor's cost analysis was designed to estimate the cost consequences of using the Sherlock 3CG TCS in the NHS.

The patient group used in the model was defined as adults having PICC insertion. It was specified that none had medical conditions contraindicated for the Sherlock 3CG TCS. The intervention was defined as bedside placement of a PICC using the Sherlock 3CG TCS, both with and without confirmatory X-ray. The comparators used in the cost analysis were consistent with those specified in the scope: blind bedside placement with confirmatory X-ray and fluoroscopy to guide PICC insertion and confirm tip placement. The model was cost-based, and did not incorporate any health states.

The model used a decision-tree structure, reflecting all potential clinical pathways of patients having PICC insertion. PICC line insertion and tip placement may be achieved through:

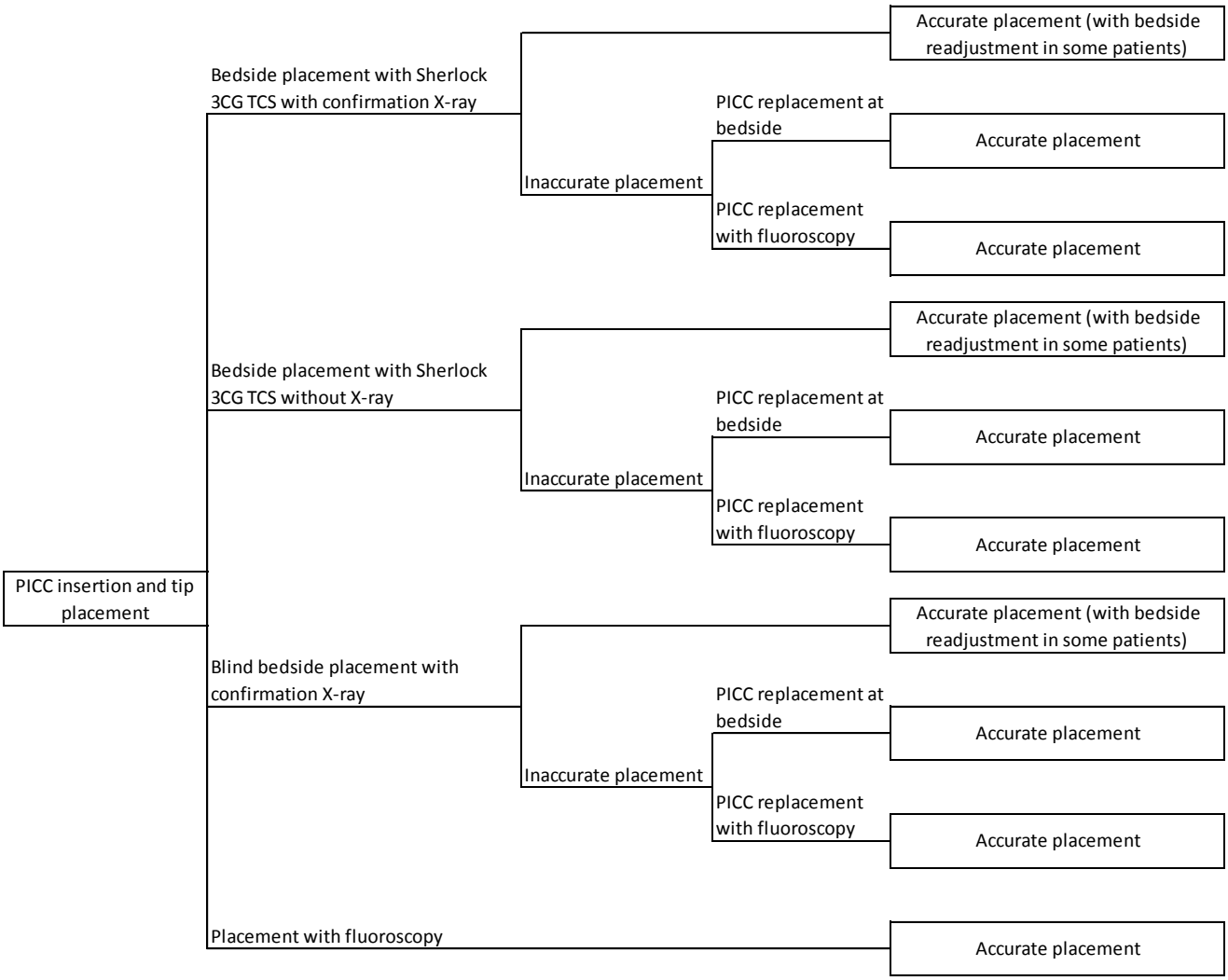
- bedside placement with the Sherlock 3CG TCS with confirmation X-ray
- bedside placement with the Sherlock 3CG TCS without confirmation X-ray
- blind bedside placement with confirmation X-ray
- fluoroscopy to guide PICC insertion and confirm tip placement.

PICC lines inserted at the bedside may have tips placed accurately or inaccurately. An inaccurately placed PICC may have been readjusted at the bedside following X-ray or may have been replaced, either using the original insertion method or under fluoroscopy (although the sponsor's base case assumed that all PICC tip replacements were done under fluoroscopy; Barton 2013; Walker et al. 2013). Clinical advice given to the sponsor suggested that patients who have failed PICC line insertion with the Sherlock 3CG TCS subsequently have blind PICC line reinsertion at the bedside with an X-ray. To account for this, a sensitivity analysis explored the effect of some patients having a second placement attempt at the bedside, rather than immediate fluoroscopy. The model assumed that there was no malposition in patients who had initial insertion under fluoroscopy; accurate insertion was achieved at the first attempt (Walker et al. 2013). All patients ended the model with accurate insertion.

Bedside placements with the Sherlock 3CG TCS, both with and without an X-ray, were considered in the model. This reflects current practice in the NHS. Potentially, as practitioners become more skilled and confident when using the Sherlock 3CG TCS, the need for a confirmatory X-ray would decrease.

A figure of the model structure provided by the sponsor is shown in figure 1.

Figure 1. Decision tree used in sponsor's economic model



The assumptions made by the sponsor in the cost model are described on page 69 of the sponsor's submission. These assumptions and associated EAC comments are presented on page 53 of the assessment report. Some key assumptions and critique are presented in table 4.

Table 4. Key model assumptions and EAC comments

Assumption listed by sponsor in submission	EAC comments
Time taken to achieve successful placement with the Sherlock 3CG TCS is equal to the time for successful placement at bedside without the technology.	The EAC agrees with this assumption, but noted that it does not match the inputs in the model. The same nurse times were used for the Sherlock 3CG TCS with X-ray and blind placement, but a shorter time was used for the technology without X-ray, even after X-ray time is separately accounted for. Staff time needed for the X-ray is accounted for separately.
The sponsor clarified that this should read "time taken to achieve successful placement with Sherlock 3CG TCS *with X-ray* is equal to the time for successful placement at the bedside without the technology."	The EAC states that this now matches the input in the model, and is a reasonable assumption, but there is no valid reason to assign a shorter nurse time to the Sherlock 3CG TCS *without X-ray*. It is plausible that the patient pathway may be shorter, but PICC insertion time will remain similar. The cost of X-ray (including radiologist time) is costed separately.
Infrastructure costs other than those modelled are assumed to be the same for the Sherlock 3CG TCS and the comparators.	There is an underlying assumption that centres have a bedside PICC service in place, as the costs of setting up a new service are not included. If the current practice is fluoroscopy-guided PICC insertion, this assumption may not be valid.
Within the model it is assumed that nurses and radiologists are trained in PICC line insertion and additional training required relates to learning how to use the Sherlock 3CG TCS only.	The model includes a branch for fluoroscopy-guided PICC insertion as a comparator. If a service changed from fluoroscopy-guided PICC to the Sherlock 3CG TCS at the bedside, there would be additional setup costs to train the PICC teams. These are not included in the model.

5.2.2 Model parameters

The model parameters used in the sponsor's cost model were based on the results reported by Parikh et al. (2012), because it had the largest patient population. The results from phase 2 of the study were used, including training costs. Success rates from the remaining 3 case series were applied in sensitivity analyses.

A summary of all the model parameters used in the sponsor's economic model is presented in table 5.

Table 5. Summary of model parameters and values used in sponsor's cost model

Variable	Value	Source
Proportion of successful placements (the Sherlock 3CG TCS, with or without confirmation X-ray)	96%	Parikh et al. 2012
Proportion of successful adjustments at bedside (the Sherlock 3CG TCS)	0%	Assumption. After failure with the Sherlock 3CG TCS patients have reinsertion under fluoroscopy (in base case)
Proportion of successful placements (blind placement at bedside with X-ray)	93%	Walker et al. 2013. This will include patients needing some readjustment following X-ray.
Proportion of successful adjustments at bedside (bedside)	0%	Walker et al. 2013. All patients undergo reinsertion with fluoroscopy after bedside failure (in base case).
Proportion of successful insertions (fluoroscopy)	100%	Walker et al. 2013

5.2.3 Costs and resource use

The sponsor decided that a case series study by Walker et al. (2013) was the most appropriate source for information on cost and resource use, because it was a recent study conducted in a UK NHS setting. The assessment report described the paper as a good source for resource identification and quantification, and for costing equipment, although less useful for other cost data. A poster by Adams (2013) was used to identify the proportion of the patient population for whom the Sherlock 3CG TCS was suitable (83.5%) and to provide data on the time taken to insert a PICC using the Sherlock 3CG without X-ray (39.5 minutes).

The list price excluding VAT of the Sherlock 3CG TCS with stand and printer was stated to be £9990. A breakdown of the costs associated with a PICC insertion using the Sherlock 3CG TCS (both with and without confirmatory X-

ray) is given in table 6. The cost of the technology was spread over a 4-year lifespan. The sponsor assumed 468 potential uses of the technology per year, then took into account the proportion of the patient population for whom the technology was suitable (83.5%, as per Adams 2013). The cost of the Sherlock 3CG TCS equipment per PICC line insertion was calculated to be £6.39. Annual maintenance costs of £595 were calculated to be £1.52 per insertion, using the same patient criteria.

The resource use data associated with the comparator interventions – bedside PICC insertion and insertion using fluoroscopy – were also sourced from Walker et al. (2013). Costs were identified using the Unit Costs of Health and Social Care (Curtis 2012). The key resource identified by the sponsor was the time needed to position and reposition PICCs, and is discussed on page 84 of the sponsor's submission.

Table 6. Costs per PICC line inserted associated with the Sherlock 3CG TCS and comparator technologies (adapted from tables 13–16 of assessment report)

Type of cost	Value (£)			
	The Sherlock 3CG TCS (without confirmatory X-ray)	The Sherlock 3CG TCS (with confirmatory X-ray)	Bedside insertion	Fluoroscopy
Price of the Sherlock 3CG TCS per PICC line insertion	£6.39	£6.39	N/A	N/A
Consumables	£189.91	£189.91	£163.18	£217.88
Maintenance cost	£1.52	£1.52	N/A	N/A
Training cost	£1.42	£1.42	N/A	N/A
Other costs	£83.83	£111.15	£111.15	£579.05
Total cost per insertion	£272.30	£310.15	£274.33	£814.93

The sponsor's submitted clinical evidence reported no adverse events (for example infection due to PICC line insertion). As such, the base case of the

sponsor's economic model does not incorporate any costs for adverse events. It was assumed that they were constant across all treatment arms.

5.2.4 Results of sponsor's base case model and sensitivity analyses

The base case presented by the sponsor found the Sherlock 3CG TCS without X-ray to be the most cost-efficient option (£272.30 per insertion). A summary of cost differences compared with the Sherlock 3CG TCS is shown in table 7.

Table 7: Cost differences per patient as per sponsor's base case model

	Total cost	Cost difference compared with the Sherlock 3CG TCS (no X-ray)
PICC insertion with the Sherlock 3CG TCS (without X-ray confirmation)	£304.90	–
Blind PICC insertion with X-ray confirmation	£330.56	+ £25.66
PICC insertion with the Sherlock 3CG TCS (with X-ray confirmation)	£342.75	+ £37.85
PICC insertion with fluoroscopy	£814.93	+ £510.03

The sponsor carried out sensitivity analysis to test the structural assumptions and key drivers of its base-case model. The sponsor's sensitivity analyses are outlined on pages 92–125 of its submission. The cost of PICC line insertion and the success of placement at initial insertion were identified by the sponsor as the key drivers of the cost model. The sponsor's threshold analysis reported that the Sherlock 3CG TCS becomes cost-incurring with less than 93% successful placement, but can also become cost-incurring if blind placement has a success rate greater than 96%. When considering the Sherlock 3CG TCS compared with insertion using fluoroscopy, the sponsor found the Sherlock 3CG to be always cost-saving across the parameters considered. The Sherlock 3CG TCS without confirmatory X-ray remained cost-saving in all scenarios identified by the sponsor, except when the associated costs are increased by 25% (incurring an additional cost of £50.20).

5.2.5 EAC revisions to the sponsor's cost model

The assessment report noted that the majority of cost savings in the model came from moving PICC insertion from the fluoroscopy suite to the bedside. The EAC felt that this could equally be true of blind bedside insertion, and that cost savings were not directly attributable to the Sherlock 3CG TCS. The EAC also noted that the model does not include the setup costs of a bedside insertion service for centres currently using a fluoroscopy service. The assessment report did not identify any major issues with either the structure of the model, or the model parameters used by the sponsor.

The EAC considered that the most valid comparison in the model was the Sherlock 3CG TCS compared with blind PICC insertion and confirmatory X-ray, which is associated with a cost saving of £25.66 for the Sherlock 3CG TCS. The sponsor provides a detailed breakdown of this cost comparison on pages 99–101 of its submission, and the EAC provides commentary on these costs on page 665 of the assessment report.

The EAC noted that the scope of the sponsor's economic submission contained a deviation from that specified by NICE and from the clinical evidence submitted. It specified that the patient population was only those for whom the Sherlock 3CG TCS is suitable. This ignored the proportion of the population needing PICC insertion for whom the Sherlock 3CG TCS is not suitable. The EAC adapted the sponsor's base-case model to correct this inconsistency and ensure that all patients were incorporated into the model, thereby reflecting the scope.

A significant factor in the sponsor's cost analysis was the time taken by a nurse to perform a bedside PICC line insertion. The sponsor's base-case model assumed that a blind bedside insertion took the same time as a bedside insertion using the Sherlock 3CG TCS plus confirmatory X-ray: 62.49 minutes, based on Walker et al. (2013). Bedside insertion using the Sherlock 3CG TCS without a confirmatory X-ray was assumed to take

39.5 minutes (Adams et al. 2013). The EAC considered the use of two different data sources to inform the same procedure to be irrational. In its own analysis, nurse time was adjusted to ensure parity across both treatment groups (62.49 minutes; Walker et al., 2013).

5.2.6 Results of the EAC's revisions to sponsor's base-case model analysis

The EAC reran the sponsor's base-case model, changing some inputs and parameters in the original model. The EAC recognised that there is widespread variation in practice and considered that its revised analysis was based on an alternative set of assumptions. Specifically, it set the amount of nurse time needed for PICC insertion to be equal for both insertion with the Sherlock 3CG TCS and blind bedside insertion. It set the standard re-insertion option for unsuccessful insertions with the Sherlock 3CG TCS to be blind placements followed by confirmatory X-ray, instead of fluoroscopy, to reflect clinical experts' advice. The EAC noted that results of the model for bedside procedures were strongly driven by the difference in nurse time.

The EAC incorporated the additional costs of patients needing PICC insertion who are not suitable for the Sherlock 3CG TCS (16.5% of patients). These patients had not been accounted for in the original economic model, despite being specified in the scope. The EAC also reset the malposition rate for the Sherlock 3CG TCS with no X-ray to 0% instead of 4%, pointing out that there was no way to confirm a malpositioned PICC in the time horizon of the model. Theatre costs for fluoroscopy were reset from £507.18 to £101.00. The overall results of these analyses are shown in table 8, based on pages 70–72 of the assessment report. The EAC reported that there were no reliable data on adverse events to inform the model, and so did not include them in its revised model.

Table 8. Cost differences from EAC revisions to sponsor's base-case model

	Total cost	Cost difference compared with Sherlock 3CG TCS and no X-ray
PICC insertion with the Sherlock 3CG TCS (without X-ray confirmation)	£302.63	−
Blind PICC insertion with X-ray confirmation	£293.26	−£9.37
PICC insertion with the Sherlock 3CG TCS (with X-ray confirmation)	£317.73	+£15.10
PICC insertion with fluoroscopy	£408.75	+£106.12

Results from the revised model show that the Sherlock 3CG TCS without X-ray becomes cost-incurring (£9.37) compared with blind PICC placement and X-ray confirmation and the Sherlock 3CG TCS with X-ray is cost-incurring by £24.47 per patient.

5.2.7 Additional sensitivity analysis carried out by the EAC – critical care patients

The EAC used data from 2 separate papers reporting on the same critical care unit by the same author (Johnston 2013, 2014) to run a scenario analysis (page 72 of assessment report). The EAC assumed that the technology was the Sherlock 3CG TCS with X-ray confirmation and that the comparator was blind PICC placement with X-ray confirmation. PICC replacement was by the original insertion method in all cases. The results are shown in table 9, replicated from page 73 of the assessment report.

Table 9. Results of the EAC scenario for intensive care patients

	Blind PICC insertion (with X-ray)	The Sherlock 3CG TCS (with X-ray)	Cost difference	EAC comment
Total cost	£413.69	£372.35	−£41.35	Based on sponsor base-case model with intensive care unit accuracy rates.

In this population of critical care patients, the Sherlock 3CG TCS with X-ray confirmation is significantly cost-saving because of fewer PICCs needing to be repositioned, and the cost savings associated with this reduction (such as a reduction in staff time and fewer X-rays). The EAC noted some limitations of this scenario: the data were taken from a single centre and may not be generalisable, comparison data were historical data from the same centre, only intermediate outcomes were included, and the actual number of replacements was not reported.

5.2.8 Subgroup analysis

No subgroup analysis was undertaken. The EAC considered that critical care patients could have been an appropriate subgroup for analysis, although this group was not specified in the scope.

6 Ongoing research

The sponsor's submission identified 1 ongoing French study: NCT01969981. This is a prospective, single-centre, observational study of adults needing a PICC. The study started in October 2013, with an estimated completion date of April 2014. ClinicalTrials.gov states that it was completed in September 2014 [n=571]. The EAC contacted the principal investigator, but did not receive any additional information.

The EAC also identified study NCT01275430, which is reported on ClinicalTrials.gov as terminated. The sponsor informed the EAC that part 1 has been completed but not yet reported, and that part 2 is awaiting approval. The study is taking place in the USA, sponsored by Bard. No additional information was submitted.

7 Issues for consideration by the Committee

Clinical evidence

Quality and quantity of the clinical evidence

The EAC considered the existing evidence base to be of insufficient size, relevance and methodological quality to allow any definitive conclusions to be drawn on the clinical benefits of the Sherlock 3CG TCS. The sponsor also recognised the limitations of the existing evidence base in its submission. Of the clinical evidence considered, Johnston et al. (2014) was the only published paper, and the only study for which the EAC was able to conduct appropriate critical appraisal. The poster by Parikh et al. (2012) was considered to be sufficiently detailed for some analysis, but the other evidence – the abstract by Barton (2014), the posters by Adams (2013) and Stewart (2013), the presentation by Symington (2011) and the NHS questionnaire data – were considered to be of too poor quality for any kind of critical appraisal. This made it impossible for the EAC to draw a strong evidence-based conclusion. Nevertheless, all of the evidence assessed was broadly in favour of the Sherlock 3CG TCS, as were the current NHS users contacted by both the sponsor and the EAC. The lack of comparative evidence and poor reporting of existing studies precluded the EAC from quantifying the extent of the improvement in PICC positioning attributable to Sherlock 3CG TCS.

Definition of correct PICC placement

The EAC noted a lack of consensus about the definition of a clinical malposition, and about the likely clinical consequences of a malpositioned PICC line. Increased accuracy of placement and fewer malpositions are specified as outcomes in the decision problem, but it may be difficult to assess the robustness of these claims with so much variation surrounding what actually constitutes a malposition.

The EAC also noted that no evidence was identified which considers the consequences of malpositioning, such as adverse events, for either the

Sherlock 3CG TCS or blind insertion with X-ray confirmation. The time horizon used only considers the insertion of the PICC, and none of the potential longer-term consequences associated with either the technology or comparators. There was no patient follow-up in any of the studies reviewed.

Cost evidence

The EAC noted that there was some uncertainty around some of the outputs of the cost model, largely due to the low-level evidence base used to inform it. Based on the sponsor's sensitivity analysis, the key drivers of the cost model in the most relevant case – the Sherlock 3CG TCS with no confirmatory X-ray compared with bedside insertion with X-ray – were the accuracy of placement using the Sherlock 3CG TCS and comparator technologies, and the time taken to carry out insertion.

The model does not include the costs of complications or adverse events for the Sherlock 3CG TCS or either of the comparator technologies. The effect of this is unknown.

8 Authors

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NICE Medical Technologies Evaluation Programme

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

A Details of assessment report:

- Dale M. et al. (2014) Sherlock 3CG Tip Confirmation System for placement of peripherally inserted central catheters, September 2014.

B Submissions from the following sponsors:

- C.R. Bard

C Related NICE guidance

- Infection: Prevention and control of healthcare-associated infections in primary and community care. NICE clinical guideline 139 (2012). Available from www.nice.org.uk/guidance/cg139
- Nutrition support in adults: Oral nutrition support, enteral tube feeding and parenteral nutrition. NICE clinical guideline 32 (2006). Available from www.nice.org.uk/guidance/cg32
- Guidance on the use of ultrasound locating devices for placing central venous catheters. NICE technology appraisal 49 (2002). Available from www.nice.org.uk/guidance/ta49

D References

Adams T (2013) The Clinical Efficacy of PICC Tip Confirmation using ECG Tip Locator Technology. Poster Presentation at the Association of Vascular Access Annual Scientific Meeting..

Barton A (2014) Evaluation of ECG and PICC Tip Location Technology; is it Safe to Stop Using X-Ray. *Journal of Vascular Access*. 15(3): 202

Curtis L (2012) *Unit Costs of Health and Social Care 2012*, PSSRU.

Department of Health (2013) NHS reference costs: financial year 2012 to 2013.

Funaki B (2002) Central Venous Access: A Primer for the Diagnostic Radiologist. *American Journal of Roentgenology.* 179: 309–18.

iData Research Inc. (2014). European Markets for Vascular Access Devices. iData European Union Vascular Access 2014 Report: Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, UK. British Colombia, iData Research Inc.

ISD Scotland (2013) NHS Scotland radiology services costs 2013. Available from http://www.isdscotland.org/Health-Topics/Finance/Costs/Detailed-Tables/Radiology.asp

Johnston AJ et al. (2014) Evaluation of the Sherlock 3CG Tip Confirmation System on peripherally inserted central catheter malposition rates. *Anaesthesia.* [epub ahead of print].

Johnston AJ et al. (2013) Defining peripherally inserted central catheter tip position and an evaluation of insertions in one unit. *Anaesthesia.* 68: 484–91.

Parikh A et al. (2012) Successful Implementation of Electrocardiocardiographic-Guided PICC placement with a Nurse-Comprised PICC Team. Poster Presentation at Radiological Society of North America.

Pittiruti M, Hamilton H, Biffi R, MacFie J et al. (2009) ESPEN Guidelines on Parenteral Nutrition: central venous catheters (access, care, diagnosis and therapy of complications). *Clinical Nutrition.* 28(4): 365–77.

Stewart F (2013) New Australian Experience: Improvement in Peripherally Inserted Central Catheter (PICC) Insertion technique using real time tracking and ECG for optimal PICC tip position (without need for CXR). Poster Presentation at the Association of Vascular Access Annual Scientific Meeting 2013.

Symington K (2011) The Spokane Sapiens TCS Experience…Are You Next. Sponsored presentation at the Association of Vascualar Access, 2011.

Walker G, Todd A (2013) Nurse-led PICC insertion: is it cost effective? *British Journal of Nursing*. 13; 22(19):S9–15.

Appendix B: Comments from professional bodies

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

Mr. 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

Ms. Elizabeth Elfleet

Advanced Radiographer Practitioner, Society of Radiographers

Dr. Tim Jackson

Consultant Anaesthetist, National Infusion and Vascular Access Society

Dr. Andrew Johnston

Consultant in Intensive Care, Royal College of Anaesthetists

Dr. Richard Leech

Consultant Anaesthetist, Royal College of Anaesthetists

Ms. Dympna McParlan

Infusion Services Coordinator, Nursing and Midwifery Council

Professor Richard McWilliams

Consultant Vascular Radiologist, Royal College of Radiologists

- Eight of 9 experts reported direct experience with the Sherlock 3CG TCS. One had referred a patient for its use, and 3 claimed that they would like to use the technology but currently do not have access.
- Three experts reported being involved in research on the technology: a service evaluation, a literature review, and research aimed at assessing the value of chest X-rays.
- Four of the 9 experts described the technology as thoroughly novel, and 4 described it as a significant modification of an existing technology. One expert described it as both.
- There was no clear agreement on the most appropriate use of the technology. Some of the clinical areas specified included haematology, oncology, and any indication needing long-term vascular access. One expert stated it was suitable for any PICC line insertion except those where a P-wave is intermittent or unobservable.
- The comparator technologies identified by expert advisers were the same as those identified in the evaluation, namely insertion under fluoroscopy or insertion using confirmatory chest X-ray. Three experts referenced the Vygon Nautilus ECG tip location system.
- Patient benefits identified included fewer malpositions due to increased tip accuracy, a reduced waiting time before use of the PICC line due to instant confirmation, less need for repeated positioning procedures and less exposure to radiation. The majority of experts felt these benefits would be realisable in practice. One expert felt that confirmatory X-ray would still be needed. Opinions on the quality of the evidence varied from ‘good quality’ to ‘very poor’. There was no consensus.
- Benefits for the healthcare system focused mainly on resource savings associated with lower radiology costs, fewer repeat procedures and greater patient throughput. In general, it was felt these could be realised in practice. One adviser noted that there was a learning curve associated with correct interpretation of the ECG trace. Again, opinion on the quality of the evidence varied from ‘uncertain’ to ‘robust’.

- Expert advisers seemed uncertain about the cost-saving potential of the technology, noting the initial outlay needed. It was acknowledged that these costs could be recouped if patient throughput was sufficiently high, and enough fluoroscopies and confirmatory X-rays could be avoided. There was insufficient evidence at this stage to judge if this would be the case.

Appendix C: Comments from patient organisations

The following patient organisations were contacted. No response was received.

- Cancer Black Care
- Cancer Equality
- Cancer Voices
- Cancer52
- Crohn's and Colitis UK
- Helen Rollason Cancer Charity
- Macmillan Cancer Support
- Maggie's Centres
- Marie Curie Cancer Care
- MRSA Action UK
- Neurological Alliance
- Neurosupport
- PINNT (Patients on Intravenous and Nasogastric Nutrition Therapy)
- Rarer Cancers Foundation
- Spinal Injuries Association
- Sue Ryder
- Tenovus
- Ulcerative Colitis UK