NICE National Institute for Health and Care Excellence

NICE guidance

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

Medical technologies guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by companies. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

1.1 The case for adopting the Sherlock 3CG Tip Confirmation System for placement of peripherally inserted central catheters is supported by the evidence. The technology usually avoids the need for a confirmatory chest X-ray in patients who would otherwise have blind insertion, minimising the delay before the catheter can be used for infusion. Using the technology increases staff confidence during catheter insertion.

1.2 The Sherlock 3CG Tip Confirmation System should be considered as an option for placement of peripherally inserted central catheters in adults. For patients whose electrocardiogram does not show a P wave (for example, patients with atrial fibrillation), a chest X-ray will still be needed to confirm tip location of the peripherally inserted central catheter.

1.3 The cost of using the Sherlock 3CG Tip Confirmation System (TCS) is similar to that of blind insertion and subsequent chest X-ray in adults who need a peripherally inserted central catheter in a non-intensive care setting. When the Sherlock 3CG TCS is used instead of fluoroscopy, the estimated cost saving is £106 per patient. In an intensive care setting, where the rate of misplacement with blind insertion is generally higher, there is an estimated cost saving of £41 per patient per use of the Sherlock 3CG TCS and a confirmatory chest X-ray compared with using blind insertion and chest X-ray. All these cost savings are subject to some uncertainty and need to be considered in the context of the clinical benefits.

2 The technology

Description of the technology

2.1 The Sherlock 3CG Tip Confirmation System (TCS; CR 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 (ECG) real-time tracking of the PICC tip, the device is intended to allow the person placing the PICC to detect and correct any error in tip positioning. The tip location sensor is only compatible with a Bard PowerPICC SOLO catheter. The Sherlock 3CG TCS is designed to remove the need for a chest X-ray which is used to confirm tip location after insertion of a PICC in most patients.

2.2 The Sherlock 3CG TCS comprises: a system console, including a control processor with display interface; a tip location sensor; a PowerPICC SOLO catheter with the Sherlock 3CG tip positioning stylet; a remote control; and an optional miniature wireless printer to create a paper record of the ECG. The sensor is positioned on the patient's sternum with 2 leads placed to pick up external ECG waveforms. The catheter is then inserted into a suitable vein in the upper arm with the stylet. During insertion, magnets in the stylet 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 taking the correct path towards the cavoatrial junction. The stylet is removed once the catheter has been appropriately positioned. The display interface also shows real-time ECG waveforms received from the patient's skin (baseline) and from the tip of the catheter (intravascular, measured by a column of saline which the placer injects into the PICC). 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 relative to the chambers of the heart and the superior vena cava.

2.3 The Sherlock 3CG TCS is intended for use in any indication in adults where therapy means accessing a vein through a PICC. PICCs have a wide range of applications and are commonly used for 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

when there is poor peripheral access). The instructions for use state that the device should be used with caution in patients with altered cardiac rhythms, specifically those in whom a P wave is not easily detectable, for example patients with atrial fibrillation, rapid tachycardia, or pacemaker-driven rhythm. Although the Sherlock 3CG TCS can be used in these patients, the company recommends a chest X-ray to confirm PICC tip location.

2.4 The cost of the Sherlock 3CG TCS – comprising the system console, tip location sensor, remote control, stand and printer – is stated in the company's submission as £9990 (excluding VAT). The cost of consumables associated with each insertion is £189.91, comprising primarily the cost of the PICC (including the stylet), sterile barrier and ECG leads. Maintenance costs associated with the technology are £595 per year per system console.

2.5 The claimed benefits of the Sherlock 3CG TCS in the case for adoption presented by the company were as follows:

- Better accuracy of PICC placement (reducing the need for repositioning after insertion).
- Removed 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.
- 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.
- Increased patient confidence in whoever is placing the PICC, because the rate of malpositioning and repositioning is reduced.
- 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.

Current management

2.6 In current NHS clinical practice, there is substantial variation between sites in the ways in which PICCs are inserted. Catheters are typically inserted by nurse-led or consultant-led vascular access teams, although PICCs may be inserted by a range of healthcare professionals, including nurse specialists, intensive care consultants, anaesthetists, general physicians, radiologists and radiographers. Clinical settings where PICCs are inserted include operating theatres, emergency rooms, oncology, orthopaedic and other wards, radiology departments, intensive care units, high dependency units and outpatient clinics. Sterility is a major concern, and can best be achieved using a maximum barrier sterile field at the bedside.

2.7 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 indicating the target site for the tip of the PICC (for example, the third right intercostal space below the right clavicular head). This technique is referred to as blind bedside insertion or blind insertion. The position of the PICC is confirmed by chest X-ray, which typically requires the patient to go to the X-ray department; the X-ray then needs to be checked by whoever inserted the PICC, or by a radiologist. Alternatively, fluoroscopy can be used to position the PICC, especially when this is difficult, such as in patients with narrow vessels.

3 Clinical evidence

Summary of clinical evidence

3.1 Full details of all clinical outcomes considered by the Committee are available in the assessment report overview.

3.2 The key clinical outcomes for the Sherlock 3CG Tip Confirmation System (TCS) presented in the decision problem were:

- accuracy of catheter tip placement
- incidence of catheter malposition
- need for catheter repositioning
- impact of malposition-related complications such as infection or thrombosis
- treatment delay following catheter placement
- reduced staff time
- reduced hospital stay
- need for confirmatory chest X-ray
- need for fluoroscopy to place the peripherally inserted central catheter (PICC) tip correctly
- time taken to insert PICC
- PICC failure and reinsertion rates
- patient experience measures
- quality of life
- device-related adverse events.

3.3 The External Assessment Centre considered that 5 of the 14 outcomes in the decision problem were reported in the published evidence. These were: accuracy of catheter tip placement; incidence of catheter malposition; treatment delay following catheter placement; change in staff time, and need

for confirmatory chest X-ray. The External Assessment Centre considered that some additional outcomes had also been partially addressed. Outcomes for which no evidence was presented included reduced hospital stay and treatment delay following catheter placement. The company stated that it was unable to report on device-related adverse events because of a lack of reported evidence.

3.4 The company identified 13 studies from its literature search but it excluded 9 and presented 4 published abstracts (Adams et al. 2013; Barton, 2014; Parikh, 2012; Stewart, 2013). It also presented responses from a questionnaire sent to 6 NHS hospitals, as supporting clinical evidence. The External Assessment Centre considered that the studies presented by the company were in keeping with the scope and were appropriate for inclusion. It also identified 1 study published after the company submission and that it considered suitable for assessment (Johnston et al. 2014). To ensure that all relevant evidence was identified, the External Assessment Centre carried out a further literature search with a wider scope which included any previous model of the device that had both magnetic tracking and electrocardiogram (ECG) tip confirmation components. One additional presentation was identified (Symington et al. 2013).

3.5 Johnston et al. (2014) reported a retrospective case-series review of the first 250 patients to have PICCs inserted using the Sherlock 3CG TCS following its introduction to a UK NHS hospital. The population comprised patients in the intensive care unit (ICU). 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 because of: failed insertion (n=2); no chest X-ray being taken after the procedure (n=2); a failure to identify the tip position on the chest X-ray (n=2); a failure to interpret the ECG criteria (n=4); and the catheter being too short (n=1). Tip location was reported 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 patients (n=246) and non-ICU patients (n=233, Johnston 2013). The External Assessment Centre used this as a form of comparator to assess the impact of the Sherlock 3CG TCS on malposition rates. Both Johnston studies reported results using 2 different definitions of malposition, 1 from the USA and the other from Europe. The definition of appropriate placement

typically used in US guidelines is the low superior vena cava or cavoatrial junction (National Association of Vascular Access Networks 1998, Infusion Nurses Society 2006, Funaki 2002). A European guideline uses a broader definition, stating that appropriate placement is in the mid or lower superior vena cava, cavoatrial junction, or high right atrium (Pittiruti 2009). Using the definition as per US guidelines, 56.1% (95% confidence interval [CI] 50% to 62%, n=134) of ICU patients had a malpositioned PICC using the Sherlock 3CG TCS compared with 76% (n=187) who had blind bedside insertion. Using the definition as per European guidelines, 20.5% (95% CI 16% to 26%, n=49) of ICU patients had a malpositioned PICC using the Sherlock 3CG TCS compared with 50.8% (n=125) who had blind bedside insertion. The malposition rate using the Sherlock 3CG TCS was significantly lower than blind placement using both sets of 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 have ECG artefacts due to comorbidities. The authors also noted that tip position is not static, and that the catheter tip may move (due to, for example, arm movement, because the PICC is placed with the arm drawn away from the body and the chest X-ray is taken with the arm drawn towards the body). The authors concluded 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 or cavoatrial junction is used, as in the US guidelines, a chest X-ray may be necessary.

3.6 Adams et al. (2013) presented a poster reporting on the introduction of the Sherlock 3CG TCS to a healthcare 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 catheter tip being in the distal superior vena cava or at the 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 either because of an abnormal P wave (12.9%) or because of technical factors such as loose connections and poor electrode placement (3.6%). 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) of PICCs were placed accurately and 1.8% (5/

278) were malpositioned. In 2011, the malposition rate using the predecessor device, the Sherlock Tip Location System (magnetic tracking only) was reported to be 14% based on a subsequent chest X-ray. Adams et al. also reported that the PICC was ready for infusion 61.0 minutes earlier using the Sherlock 3CG TCS (39.5 minutes) than using a chest X-ray and a radiologist report for tip position confirmation (101.0 minutes), although no information was reported on how this was measured. The researchers confirmed that chest X-rays are no longer mandatory for PICCs placed using the Sherlock 3CG TCS at this centre.

3.7 The abstract by Barton (2014) described the introduction of the Sherlock 3CG TCS to a nurse-led PICC service at a UK NHS hospital. In an initial trial, clinicians used the Sherlock 3CG TCS for PICC placement in 65 adults with no atrial fibrillation. They used chest X-rays, reviewed by an independent physician, to confirm tip location. Following the initial trial, an application was made to amend local protocol and remove the need for a mandatory chest X-ray following PICC placement. 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, as used in US guidelines. 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 included. The authors reported to the External Assessment Centre that, during the trial period, 2 patients were not suitable for the Sherlock 3CG TCS and had PICCs placed with fluoroscopy. Since the introduction of the Sherlock 3CG TCS, 11 patients 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. The hospital has since removed the need for chest X-ray after PICC placement using the Sherlock 3CG TCS.

3.8 Parikh (2012) presented a poster reporting a prospective case series from October 2011 to April 2012 of 247 PICCs placed in 221 patients (mean age 62 years, range 15–100) in a US hospital. 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, as in the US guidelines. The study was divided into 2 phases. Phase 1 was a voluntary training phase. Nurses who wished to be trained in the use of the Sherlock 3CG TCS (4 of 7 nurses) had training, 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 company. 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. For phase 2, the 3 other nurses who had not had training in the Sherlock 3CG TCS had phase 1 training. All 7 nurses then 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, for reasons that included unclear baseline rhythm, and complicated or uncertain PICC placement. It is unknown if the PICCs which did not use the Sherlock 3CG TCS needed a chest X-ray to confirm, but this is probable.

3.9 An abstract and poster by Stewart (2013) presented a study in an Australian hospital which recruited over 65 patients 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. Of PICC placements using the Sherlock 3CG TCS, 96% 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. No information was given on how time savings were measured or if there was any resulting change in treatment time or outcomes.

3.10 Symington et al. (2011) was a conference presentation on a US centre using the Sapiens TCS in conjunction with the Sherlock TLS II. These devices are the predecessor devices to, and when used together have the same mode of action as, the Sherlock 3CG TCS. The author reported on a consecutive case series during April 2011 (n=63). No information was given on the patient population. The company provided training. Tip placement was verified with a chest X-ray, reviewed by the author. The author reported a 5% technical failure rate, including difficulties with cannulation of the vein, advancement of the catheter and occluded veins. It was reported that technical failures were 'thrown out', although this was not explained in greater detail. The authors reported that 62 of 63 tip placements were appropriately positioned, although no specific criteria for appropriate placement were reported. They reported that, by July 2011, there had been 604 PICC placements using the Sapiens TCS in conjunction with the Sherlock TLS II. The lead author reported that he was formally requesting that his hospital remove the need for mandatory chest X-ray from its procedural guidelines. He was also a paid presenter for Bard Access Systems (a division of CR Bard), which was clearly stated.

3.11 The company contacted 7 UK NHS hospitals currently using the Sherlock 3CG TCS and collected questionnaire responses from them. The initial clinical evidence submission did not include these data, but they were later provided to the External Assessment Centre. The External Assessment Centre judged that the structuring of the questions and format of the answers did not allow for the assessment of relevant evidence on outcomes as defined in the decision problem. The External Assessment Centre noted the variation in reported clinical practice for issues such as hospital policy for confirmation, typical levels of malposition, dealing with malpositions and PICC reinsertions. In general, all respondents reported fewer malpositions using the Sherlock 3CG TCS than before its introduction. The External Assessment Centre noted that there was a risk of bias because not all hospitals using the Sherlock 3CG TCS were asked to provide data to the company. To explore this, the External Assessment Centre contacted 7 of the other 8 hospitals (not included in the company's survey) currently using the device, and 1 hospital that had not responded to the company's initial questionnaire. The External Assessment Centre concluded that the hospital questionnaires provided no assessable data relevant to the scope.

3.12 The company did not identify any adverse events from the published literature, or from a search of the Medicines and Healthcare Products Regulatory Agency's website. The company retrieved 51 records from the US Food and Drug Administration's MAUDE database, but stated that they were not necessarily device-related adverse events. The External Assessment Centre retrieved 100 records from the same database, using a wider search strategy. Adverse events submitted to MAUDE are not verified. No searches were carried out for adverse event reports from PICC insertion using comparator technologies (blind PICC insertion with chest X-ray, or fluoroscopy). Reported adverse events included: 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 External Assessment Centre sought clinical expert opinion, but could not rule out the possibility that the adverse events reported with the Sherlock 3CG TCS were common to all PICC insertion techniques.

Committee considerations

3.13 The Committee noted that the overall quality and quantity of the clinical evidence was low, consisting largely of abstracts and posters reporting on case series. The only comparative data available were from a historical comparison by the External Assessment Centre, based on the outcomes reported by Johnston et al. (2013, 2014) before and after the introduction of the Sherlock 3CG TCS. Nevertheless, the Committee judged that the available evidence all pointed towards the use of the Sherlock 3CG TCS providing more reliable tip placement than blind insertion.

3.14 The Committee noted in particular that a number of hospitals had stopped using chest X-rays for confirmation of PICC tip position after their clinicians had become experienced at using the Sherlock 3CG TCS and they had audited success rates. It was mindful of the benefits to patients of avoiding confirmatory chest X-rays, including avoidance of radiation exposure and travel to the X-ray department, and the possibility of having treatments through their PICCs without delay.

3.15 The Committee considered that the variation between definitions of correct PICC placement was less important than whether a PICC is so misplaced that a further procedure is needed to correct its position. Although the definitions

provide a means of assessing the accuracy of different methods of PICC placement, experts told the Committee that minor discrepancies in catheter tip position identified by a chest X-ray after blind insertion would be unlikely to have serious clinical consequences. They also stated that the need for catheter repositioning as a result of malpositioning is uncommon. The External Assessment Centre told the Committee that no published evidence was available about further procedures to reposition misplaced PICCs following placement with the Sherlock 3CG TCS. The Committee was also advised that the PICCs may change position after insertion.

4 NHS considerations

System impact

4.1 The company claimed that the Sherlock 3CG Tip Confirmation System (TCS) increases efficiency in the care pathway by eliminating the need for a confirmatory chest X-ray following the insertion of a peripherally inserted central catheter (PICC). The costs and time involved in transporting patients to an X-ray department for a confirmatory X-ray would be eliminated in most cases. This would reduce staff requirements, particularly in nursing and radiology, and allow these staff to be directed to other areas of need.

4.2 Experts also advised the Committee about potential system benefits associated with the reduced need for fluoroscopy and reduced number of X-rays, including cost savings and an increased throughput of patients, meaning that patient access to radiology departments would be quicker and more efficient. One expert also advised that earlier access to infusion treatment may result in earlier discharge of patients from hospital.

4.3 The Sherlock 3CG TCS was launched in the UK in April 2013. The company reported that it was being used in 14 NHS hospitals in England and 2 in Northern Ireland. The company also stated that 9 of the English hospitals have discontinued routine chest X-ray confirmation following PICC placement. The External Assessment Centre was able to confirm this for 6 of the 9 hospitals.

Committee considerations

4.4 The Committee recognised that avoiding the need for routine confirmatory chest X-rays by using the Sherlock 3CG TCS for PICC placement would release resources in X-ray departments. It would also mean that nurses and porters would not be needed to help transfer patients between X-ray departments and other parts of the hospital.

4.5 The Committee noted that using the Sherlock 3CG TCS could increase staff and patient confidence compared with using blind insertion. An expert adviser from a hospital which has discontinued X-ray confirmation advised the Committee that procedures performed without the Sherlock 3CG TCS now feel more uncertain and less secure.

4.6 The Committee considered the need for training in the use of the Sherlock 3CG TCS. It recognised that there is a learning curve associated with the technology and that confirmatory chest X-rays may be useful during this phase. It was also advised that clinical experience and judgement are needed to use the system reliably. An expert adviser described to the Committee some incidents of the ECG component of the Sherlock 3CG TCS showing that the PICC had reached the cavoatrial junction before this was actually the case. This could have led to a malpositioned PICC without sufficient understanding of the procedure and the application of appropriate clinical judgement.

4.7 The Committee was advised that the Sherlock 3CG TCS may also be useful for patients for whom it is difficult to identify a P wave (patients with atrial fibrillation, tachycardia, or paced rhythm). In such cases, the magnetic tracking component functions normally and can help to guide insertion, although a confirmatory chest X-ray is still needed in these patients.

5 Cost considerations

Cost evidence

5.1 The company identified 2 health economic studies in its submission (Adams 2013; Stewart 2013). Both studies were cost-comparison studies from outside the UK healthcare system. The company noted that these studies were of low quality and limited relevance. The External Assessment Centre agreed with the company's assessment of the studies, and did not identify any additional relevant studies.

5.2 The company submitted a de novo cost analysis comparing the cost consequences of using the Sherlock 3CG Tip Confirmation System (TCS), both with and without confirmatory chest X-ray, for both blind bedside insertion with confirmatory chest X-ray of a peripherally inserted central catheter (PICC) and insertion using fluoroscopy. Costs were modelled from an NHS and Personal Social Services perspective. The population included in the model was adult patients needing a PICC, for whom the Sherlock 3CG TCS was suitable (that is, adult patients needing PICC insertion who had an identifiable P wave). Patients for whom it was difficult to identify a P wave (see section 2.3) were not included in the model. The model used a decision tree structure, presenting all clinical pathways of patients having PICC insertion. All patients exited the model with an accurate insertion. The model was cost-based and did not include any health states. The time horizon was limited to the time taken to successful insertion.

5.3 The company used parameters derived from Parikh et al. (2012) and Adams (2013) and resource-use figures presented in Walker et al. (2013) to inform its model. The model used different accuracy rates for the Sherlock 3CG TCS (96%), blind bedside insertion (93%) and fluoroscopy (100%). In cases where initial insertion was unsuccessful, all reinsertions were performed under fluoroscopy. The Sherlock 3CG TCS was considered to be suitable for 83.5% of the patient population. The company's model only considered patients for whom the technology was suitable, and not the estimated 16.5% of patients with an altered cardiac rhythm for whom the ECG component may be unreliable.

5.4 The price of the technology (£9990 excluding VAT) was calculated to be £6.39 per PICC inserted, based on the assumed patient population of 468 potential

uses per year, spread over a 4-year lifespan. The company also reported the cost of consumables (£189.91), maintenance (£1.52) and training (£1.42), and other costs for each insertion using the Sherlock 3CG TCS. The overall cost of each insertion using the Sherlock 3CG TCS with X-ray was estimated to be £310.15, and without X-ray to be £272.30. The company calculated the cost of blind bedside insertion to be £274.33, and insertion under fluoroscopy to be £814.93.

5.5 The results of the company's base case suggested that the Sherlock 3CG TCS without X-ray confirmation was associated with a cost of £304.90 per patient, assuming that 96% of all placements were successful and that reinsertions were done under fluoroscopy. Based on this result, the technology was associated with a cost saving of £25.66 compared with blind PICC insertion with X-ray confirmation and a cost saving of £510.03 compared with PICC insertion with fluoroscopy.

5.6 The company carried out extensive sensitivity analyses to test the structural assumptions underlying its base-case model, and to identify the key drivers. The company acknowledged the limitations of the available evidence base, but considered that the extensive sensitivity analyses mitigated this somewhat. The cost of a PICC insertion and the success of placement at initial insertion were identified by the company as the key drivers of the cost model. The company's threshold analysis reported that the Sherlock 3CG TCS became cost-incurring with less than 93% successful placement, but also became cost-incurring if blind placement had a success rate greater than 96%. When considering the Sherlock 3CG TCS compared with insertion using fluoroscopy, the company found the Sherlock 3CG TCS to be always cost saving across the parameters considered. The company carried out scenario analyses, testing parameters such as the proportion of failed insertions, the proportion of successful reinsertions after an initial misplacement, and a variety of changes to the costs presented in the base case. The Sherlock 3CG TCS without confirmatory X-ray remained cost saving in all scenarios identified by the company, except when the costs associated with the Sherlock 3CG TCS itself were increased by 25% (incurring an additional cost of £50.20).

5.7 The External Assessment Centre did not report any major concerns with either the structure of the company's model or its parameters, although it reported that the lack of evidence made it difficult to be confident about the cost-model results, both from the company's analysis and its own revised analysis.

5.8 The External Assessment Centre considered that some of the clinical parameters and inputs into the company's model needed revisions to ensure their accuracy and completeness. The model did not include the setup costs of a bedside insertion service for hospitals currently using a fluoroscopy service. The External Assessment Centre noted that the scope of the company'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, which overlooked the proportion of the population needing PICC insertion for whom the Sherlock 3CG TCS is not suitable. The External Assessment Centre also reported that a significant factor in the company's cost analysis was the time taken by a nurse to perform a bedside PICC insertion. The company'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 External Assessment Centre considered the use of 2 different data sources to inform the same procedure in different arms of the model 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).

5.9 The External Assessment Centre updated the parameters in the company's model to reflect alternative assumptions made:

- It 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 amount of nurse time need for PICC insertion was set to be equal for both insertion using the Sherlock 3CG TCS and blind bedside insertion. The External Assessment Centre noted that results of the model for bedside procedures were strongly driven by nurse time.
- It set the standard reinsertion option for unsuccessful insertions to be reinsertion using the original method, instead of fluoroscopy, to reflect the clinical experts' advice. For example, a PICC that was misplaced using the Sherlock 3CG TCS would be reinserted using the Sherlock 3CG TCS.

- The malposition rate for the Sherlock 3CG TCS with no X-ray confirmation was set to 0% instead of 4%, on the basis 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.

5.10 Results of the base case in the company's model when run with the External Assessment Centre's revised parameters suggested that the Sherlock 3CG TCS without X-ray confirmation was associated with a cost of £302.63 per patient. At this cost, it became cost incurring by £9.37 compared with blind bedside insertion. It was still associated with a cost saving compared with PICC insertion under fluoroscopy (£106.12), although this was lower than in the company's base case.

5.11 The External Assessment Centre carried out sensitivity analyses to test the impact on the costs of the technology of the accuracy of placement using both the Sherlock 3CG TCS and blind PICC placement, because there had been considerable uncertainty surrounding the clinically realistic accuracy rates of both. The External Assessment Centre also carried out a 1-way sensitivity analysis to test the impact of varying the nurse time associated with insertion, because this had been noted to be a key driver in the model.

5.12 The results of the sensitivity analysis surrounding accuracy rates showed that, if use of the Sherlock 3CG TCS was accurate in 100% of patients (confirmed using chest X-ray), then it would become cost incurring if blind PICC placement was accurate in just over 87% of patients. If the Sherlock 3CG without X-ray confirmation had a 100% accuracy rate, it was cost saving if blind bedside insertion was less than 89% accurate.

5.13 The sensitivity analysis surrounding nurse times explored the impact of varying the nurse time needed for insertion of the Sherlock 3CG TCS by ±20 minutes when the nurse time needed for blind PICC insertion was 30 minutes and 80 minutes. The results showed that the factor which made the most impact was the difference in nurse times between the 2 technologies, rather than the actual length of time allocated to the procedure, and that a 10 minute difference between nurse times could make the Sherlock 3CG TCS cost saving or incurring. The External Assessment Centre reported that there was no evidence available to state with certainty that the nurse times used as inputs in the model were

definitive. Expert advice reported a wide variation in nurse time depending on clinical setting and patient population.

5.14 The External Assessment Centre also carried out a separate analysis based on the results for intensive care patients presented in the studies by Johnston et al. (2013, 2014). In this analysis, the Sherlock 3CG TCS with X-ray confirmation was compared with blind PICC placement with X-ray confirmation to reflect the available data. PICC reinsertion was done with the original method in all cases. The External Assessment Centre used effectiveness rates based on results that met European guideline requirements as reported in Johnston et al. (2013, 2014): specifically, 79.5% for the Sherlock 3CG TCS with X-ray, and 49.2% for blind PICC placement with X-ray. This analysis showed that use of the Sherlock 3CG TCS with confirmatory X-ray compared with blind insertion with X-ray was associated with a cost saving of £41.35 per patient. The External Assessment Centre considered that intensive care patients may be a subgroup for whom the Sherlock 3CG TCS holds particular benefit, given the higher rates of malposition associated with this patient population. However, it noted that the evidence may not be generalisable, because the data were historical and from a single centre, and the actual number of repositionings was not reported.

5.15 The External Assessment Centre reported that there were numerous uncertainties in the model structure and inputs due to the lack of data available. The model was limited by the lack of available evidence, which was exacerbated by large variations in clinical practice, and different patient groups and settings. No evidence was available to the company on the impact of identified malpositions, and it was therefore unknown if PICCs were repositioned or reinserted as a result. No comparative evidence was available on the rate of complications or adverse events. The External Assessment Centre presented an alternative set of assumptions in its analysis, but stated that the lack of information did not allow for absolute certainty over which were correct. The External Assessment Centre reported that, given currently available information, use of the Sherlock 3CG TCS compared with blind PICC insertion using a chest X-ray appeared overall to be close to cost neutral.

5.16 Following discussions at the Committee meeting, the External Assessment Centre carried out additional analysis to assess more fully the impact of an increasingly streamlined care pathway, in particular as a result of the reduced need for X-ray confirmation. It considered potential cost savings in areas

associated with this, such as portering and X-ray interpretation. The External Assessment Centre considered a scenario in which nurse time was slightly reduced, because there was no need for interpretation of an X-ray, and where the radiologist and portering time associated with a typical X-ray did not need to be included. Using these parameters, use of the Sherlock 3CG TCS without X-ray compared with blind bedside insertion was associated with a cost saving of £1.16 per patient.

Committee considerations

5.17 The Committee recognised that the uncertainties in the economic evidence and cost modelling assumptions were substantial. It was told by the External Assessment Centre that the company had carried out substantive and appropriate sensitivity analyses to address the problem of the poor evidence base.

5.18 The Committee considered that use of the Sherlock 3CG TCS was likely to be cost saving compared with fluoroscopy-guided PICC insertion, based on the results in both the company's base case and the results of the External Assessment Centre's revised model parameters. The Committee considered the costs presented by the External Assessment Centre to be more realistic, and accepted its estimated cost savings of £106.12 per patient to be reasonable within certain clinical settings. The External Assessment Centre noted at consultation stage that the cost savings presented may be an overestimate in a clinical setting that only uses fluoroscopy-guided PICC insertion, because of the additional service redesign costs and the need to train staff in bedside insertion. As a result of the substantial variation in clinical settings, and the different training costs which may apply depending on the setting, the exact effect of these changes on the estimated cost saving is unknown.

5.19 The Committee considered the estimated proportion of the patient population for whom ECG tip confirmation was not used, namely those patients in whom it is difficult to identify a P wave. The External Assessment Centre presented the Committee with the full range of unsuccessful tip confirmation rates reported in the clinical evidence, ranging from 4.4% to 29.9%, and noted that varying the figure of 16.5% did not have a substantial impact on the cost modelling. The Committee noted this summary of tip confirmation failure rates, and accepted

the value used by the External Assessment Centre (16.5%, Adams et al. 2013) in the cost modelling as reasonable (see section 3.6).

5.20 The Committee considered the evidence presented on the use of the Sherlock 3CG TCS in an intensive care population. It noted input from clinical experts, who confirmed that accurate PICC insertion is more difficult in intensive care patients due to problems with positioning and comorbidities. The External Assessment Centre advised the Committee that the primary driver of cost savings is the relative difference in the accuracy rates between the Sherlock 3CG TCS and bedside insertion. The Committee accepted the estimated cost saving of £41.35 obtained in a scenario analysis using the revised model with parameters from the Johnston et al. (2013, 2014) studies.

5.21 With regard to the use of the Sherlock 3CG TCS compared with blind insertion with confirmatory X-rays, the Committee considered that the outputs of the company's model using the External Assessment Centre's updated parameters were appropriate. It was advised that the removal of X-rays from the care pathway led to increased efficiency of service and an improved patient experience. Depending on the exact clinical context and whether or not it is used with X-ray, the use of the Sherlock 3CG TCS in adults who need a PICC in a non-intensive care setting ranged from slightly cost incurring (£24) to slightly cost saving (£26) compared with blind insertion with confirmatory chest X-ray. These results led the Committee to conclude that the technology was likely to be more or less cost neutral.

6 Conclusions

6.1 The Committee concluded that the available clinical evidence, together with expert clinical advice, showed that the Sherlock 3CG Tip Confirmation System (TCS) is an effective method of placement for peripherally inserted central catheters (PICCs). The Committee concluded that the main benefit of the technology for patients who would otherwise have blind insertion is avoidance of a confirmatory chest X-ray. Patients for whom the Sherlock 3CG TCS was used would not need to make journeys to an X-ray department, would not be exposed to radiation and their PICC could be used without the associated delay. The Committee was advised by a clinical expert that avoidance of chest X-rays also saves staff time (porters, nurses and sometimes radiologists). The Committee further concluded that use of the technology increases the confidence of both staff and patients during PICC insertion.

6.2 The Committee accepted modelling using revised parameters and sensitivity analyses and concluded that use of the Sherlock 3CG TCS could generate cost savings of about £106 per patient compared with using fluoroscopy as a guide to PICC insertion. The Committee also accepted the estimate of a cost saving of £41 per patient in an intensive care setting when the Sherlock 3CG TCS and confirmatory chest X-ray are used in place of blind insertion and confirmatory chest X-ray. The Committee concluded that in other settings, the cost of using the Sherlock 3CG TCS is similar to that of blind PICC insertion with a subsequent chest X-ray.

Andrew Dillon
Chief Executive
December 2014

7 Committee members and NICE lead team

Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)
Consultant Vascular Surgeon, Royal Devon and Exeter Hospital

Dr Peter Groves (Vice Chair)
Consultant Cardiologist, Cardiff and Vale UHB

Ms Susan Bennett
Lay member

Professor Nigel Brunskill
Professor of Renal Medicine, University of Leicester

Mr Matthew Campbell-Hill
Lay member

Mr Andrew Chukwuemeka
Consultant Cardiothoracic Surgeon, Imperial College Healthcare NHS Trust

Professor Daniel Clark
Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Dr Fiona Denison
Reader/Honorary Consultant in Maternal and Fetal Health, University of Edinburgh

Professor Tony Freemont
Professor of Osteoarticular Pathology, University of Manchester

Professor Shaheen Hamdy
Professor of Neurogastroenterology, University of Manchester

Dr Jerry Hutchinson
Independent Medical Technology Advisor

Dr Cynthia Iglesias
Health Economist, University of York

Professor Mohammad Ilyas
Professor of Pathology, University of Nottingham

Dr Greg Irving
General Practitioner and Clinical Lecturer, University of Cambridge

Dr Eva Kaltenthaler
Reader in Health Technology Assessment, School of Health and Related Research (ScHARR), University of Sheffield

Dr Paul Knox
Reader in Vision Science, University of Liverpool

Dr Rory O'Connor
Senior Lecturer and Honorary Consultant Physician in Rehabilitation Medicine, University of Leeds

Mrs Karen Partington
Chief Executive, Lancashire Teaching Hospitals NHS Foundation Trust

Mr Brian Selman
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Professor Wendy Tindale
Scientific Director, Sheffield Teaching Hospitals NHS Foundation Trust

Professor Allan Wailoo
Professor of Health Economics, School of Health and Related Research (ScHARR), University of Sheffield

Mr John Wilkinson
Director of Devices, Medicines and Healthcare products Regulatory Agency (MHRA)

Dr Janelle Yorke
Lecturer and Researcher in Nursing, University of Manchester

Dr Amber Young
Consultant Paediatric Anaesthetist, Bristol Royal Hospital for Children

NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

Ailish Higgins
Technical Analyst

Bernice Dillon
Technical Adviser

Dympna McParlan
Lead Expert Adviser

Andrew Bodenham
Lead Expert Adviser

Eva Kaltenthaler
Non-Expert MTAC Member

Megan Dale and Helen Morgan
External Assessment Centre Representatives

8 Sources of evidence considered by the Committee

The External Assessment Centre report for this assessment was prepared by Cedar:

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

Submissions from the following company:

- CR Bard

The following individuals gave their expert personal view on the Sherlock 3CG TCS by providing their expert comments on the draft scope and assessment report.

- Mr Andrew Barton, nominated by company – clinical expert
- Dr Andrew Bodenham, nominated by National Infusion and Vascular Access Society – clinical expert
- Dr Lisa Dougherty, nominated by company – clinical expert
- Ms Elizabeth Elfleet, nominated by NICE– clinical expert
- Dr Tim Jackson, nominated by National Infusion and Vascular Access Society – clinical expert
- Dr Andrew Johnston, nominated by company – clinical expert
- Dr Richard Leech, nominated by company – clinical expert
- Ms Dympna McParlan, nominated by company – clinical expert
- Professor Richard McWilliams, nominated by company – clinical expert

About this guidance

This guidance was developed using the NICE medical technologies guidance process.

We have produced a summary of this guidance for the public. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Related NICE guidance

For related NICE guidance, please see the NICE website.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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