Healthcare Technology Research Centre

Review report of MTG24:

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

Cost update: February 2019

Produced by: Cedar

Authors: Megan Dale, Cedar Researcher
Susan O'Connell, Cedar Researcher
Grace Carolan-Rees, Cedar Director

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1. Background

Medical technology guidance for Sherlock 3CG was published in March 2015. All medical technology guidance is reviewed 3 years after publication.

As part of their review process, NICE have requested an update on the cost analysis of the original assessment.

As changes have been made to the technology, NICE have also requested that the EAC assess any impact the new version (SiteRite8 incorporating Sherlock 3CG Diamond Tip) may have on the relevance and accuracy of the current model.

2. The technology

The Sherlock 3CG Tip Confirmation System is designed to confirm the correct tip placement of a peripherally inserted central catheter (PICC). It integrates tip location and confirmation by enabling the magnetic and electrocardiographic real-time tracking of the PICC tip during insertion.

Ultrasound is used to visualise and identify a suitable vein in the upper arm before the Sherlock 3CG Tip Confirmation System (TCS) is deployed.

The Sherlock 3CG TCS comprises:

- a system console which includes a control processor with display interface
- a tip location Sherlock sensor
- a single use PowerPICC SOLO catheter with Sherlock 3CG Tip Positioning System (TPS) stylet. The position of the stylet shows on the display interface when the tip location mode is active.
- a remote control which allows the user to change settings through the procedure and maintain the sterile field
- an optional miniature, wireless printer to create a paper record of the ECG readings which are used to confirm PICC tip placement.

The Sherlock 3CG Tip Confirmation System is intended to be used in any indication where therapy requires venous access through a PICC in adult patients. The mode of action is such that it is advisable to use this technique with caution in patients with altered cardiac rhythms, specifically those in whom an electrocardiography (ECG) P-wave is not easily detectable such as in atrial fibrillation, rapid tachycardia and paced rhythm. Sherlock 3CG TCS can be used in these patients but a chest X-ray will still be required to confirm PICC tip location.

3. Original objective of guidance

To assess the clinical and cost effectiveness of the Sherlock 3CG Tip Confirmation System for placement of peripherally inserted central catheters.

4. Current guidance recommendations

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.

5. New evidence

5.1. Changes in technology

The company has indicated that there is a new version (Site Rite v8 incorporating Sherlock 3CG Diamond tip) which has a CE mark and is available for sale to the NHS. This version has updated software (for ECG P wave identification and identification of the correct P wave shape). It is integrated within ultrasound hardware (Site Rite) for initial introduction of the peripherally inserted central catheter (PICC). This ultrasound-assisted identification of a vein would otherwise be a stand-alone device, and was out of scope for the original guidance. TA49 is on ultrasound assisted introduction of central venous catheters, and is cited by the company as relevant. However, TA49 was on the placement of central venous catheters via a central vein e.g. jugular vein, and did not include any clinical or economic evidence on the

placement of PICCs. The cost of the Site Rite v8 incorporating Sherlock 3CG Diamond tip is £[redacted]

There is also a new version (Sherlock 3CG+ TCS) that can be used for PICC placement, and other central lines (out of scope), in all ages. This is approved for use in the USA, but is pending a CE mark and is not available for sale in the EU.

5.2. New studies

The EAC has not carried out a review of the literature for this update, however, the manufacturer has submitted information on a number of studies which have been published since the publication of the original guidance. This information has been submitted to NICE by the company. We have briefly reviewed 3 of the papers identified as reporting economic models.

Information that would potentially affect the economic model includes the rate of mal positions for blind PICC placement, and how many of these result in a second repositioning procedure and additional x-ray. Studies showing any requirements for repositioning after initial tip confirmation and start of use for either method may have an impact on economic considerations.

Two economic abstracts and one full paper were identified. The abstracts contain very little information and cannot be critically appraised. It seems unlikely that they would have a significant impact on the model. The full paper (Tomaszewski et al. 2017) is based on a comparative time and motion study and reports an economic model showing a cost saving for use of Sherlock 3CG. Tomaszewski et al. (2017) report that nurse time for initial PICC insertion is similar for blind PICC and Sherlock 3CG (42.5 min vs 42 min). There is a malposition rate of 0 for Sherlock 3CG and 20% for the comparator. Since only the blind PICC placement is checked by x-ray and the data is only collected until ready for IV use, there is very little opportunity to identify mis-placement in the Sherlock arm.

The paper finds Sherlock to be cost saving, while we do not have access to the full model, this would appear to be based on the lower success rate of blind PICC placement (the submission to NICE used 93.1% successful) and higher costs for some components. The cost of x-ray and repositioning procedure used by Tomazewski et al. (2017) are from US hospitals and are much higher than in the submission to NICE.

Towazewski et al. (2017) also find that there is a much longer time from start of PICC placement until being ready for IV access when using blind PICC and x-ray confirmation than with Sherlock 3CG. This is due to time for x-ray confirmation and any repositioning. The paper implies that this time is not assigned costs in the economic model, which is in line with the manufacturer's model originally submitted to NICE.

5.3. Ongoing trials

Seven trials that investigated Sherlock 3CG were identified. 3 were completed, 3 were recruiting and 1 had been terminated before commencing the phase 2 randomised part of the trial.

Two of these were identified in the original guidance. One has a poster available (Boiza 2015), and the other was the trial that was terminated.

Two RCTs are currently recruiting to compare PICC placement with fluoroscopy vs Sherlock 3CG. The model finds Sherlock 3CG to be cost saving compared to fluoroscopy, and the results of the RCTs would be unlikely to change that finding.

The table below summarises any publications that were noted, however the EAC has not done any form of critical review or additional searching. Fuller information from the trial database is included in appendix A

Table 1 Clinical trials

Trial Number	Summary	Status	completion
NCT01275430	Phase I: PICC placement with Sherlock	Phase 1 completed, Phase 2 terminated	Results for Phase 1 posted July 2016
NCT03288766	A single-arm, prospective, multi-centre study to assess clinical performance of SHERLOCK 3CG with MODUS II software	Recruiting	December 2020
NCT01969981	Prospective, single centre, observational study. No follow up. 571 patients enrolled. Results online	Completed	April 2014
NCT03028090	Observational, prospective, non-comparative study to assess development of software package.	Completed	Study completion was March 2014 No results posted
NCT02929368	RCT, fluoroscopy vs Sherlock for PICC placement. 210 participants, single centre, Germany. No follow-up past discharge from hospital.	Recruiting	March 2018
NCT02498821	Observational study, non-randomised, comparative. Blind PICC with x-ray vs Sherlock 3CG without x-ray. No follow up past final tip confirmation. To evaluate differences in the time and costs between Sherlock 3CG® TCS and Chest X-ray to	Completed (has results)	May 2016

	confirm the location of a Peripherally Inserted Central Catheter (PICC). Results published by Tomaszewski and include an economic model.		
NCT03652727	RCT study of fluoroscopy vs Sherlock for PICC placement to determine accuracy of placement. Both confirmed by chest x-ray. 120 participants, Switzerland	Recruiting	March 2019

6. Changes in costs in the model

Information highlighted in yellow should be treated as commercial in confidence

Table 2: Updated Costs

Items	Original Value 2014	Source	Updated value 2019	Updated source, and comment
Ultrasound to locate PICC placement area	£18	NHS reference costs (2012-13). Diagnostic imaging, anaesthetics. RA23Z – ultrasound scan, less than 20 mins. £18	£49	NHS Reference Costs 2018/2019 IMAG, RD40Z (Direct Access, less than 20 mins without contrast)
Nurse time, hour face-to-face contact	£84	PSSRU 2013, day ward. Based on band 5, per hour patient contact	£90	Band 5 PSSRU 2018, hospital based nurse per hour of patient contact
Radiographer cost per hour	£34	PSSRU 2013, based on band 5.	£37	Band 5 PSSRU 2018, hospital based scientific and professional staff (radiographer)
Unit cost of Sherlock 3CG TCS	£9,990	Bard 2013	[redacted]	BD 2019
SiteRite5 Ultrasound Device	N/A	N/A	[redacted]	Provided by BD (was not listed for original AR). For information only, this is not included in model
SiteRite8 including Sherlock 3CG	N/A	N/A	[redacted]	provided by BD (was not available for original AR) For information only, this is not included in model
Annual Maintenance	£595	Bard 2013	[redacted]	BD 2019
Consumables:				
Pack including PICC, sterile maximum barrier, procedure tray, EGC leads	£187.74	Bard 2013: £175-£200 – midpoint = £187.74	£212.59	Inflated to 2018 prices using indices from PSSRU 2018

Consumables including: Chloraprep 3ml applicator, gloves, Lidocaine for surface anaesthesia, 15g, Saline 10ml, ECG electrodes (each, 2 required)	£2.17	Including: Chloraprep 3ml applicator, gloves, Lidocaine for surface anaesthesia, 15g, Saline 10ml, ECG electrodes (each, 2 required)	£2.46	Inflated using indices from PSSRU 2018
		Insertion at bedside with X-ray		
Equipment cost	£163.18	Walker, 2013: Equipment cost for nurses £195.81 with VAT (at 20%) removed	£184.78	Inflated using indices from PSSRU 2018
		Cost of insertion with fluoroscopy		
Equipment cost	£217.88	Walker, 2013: Equipment cost for nurses £261.46 with VAT (at 20%) removed	£246.72	Inflated using indices from PSSRU 2018
Radiologist cost per hour		PSSRU, 2013. Hospital consultant(medical): £99 per contract hour	£108	Medical Consultant PSSRU 2018
Nurse, day ward, per hour	£34	PSSRU 2013, day ward. Per working hour. Based on band 5.	£37	Band 5 PSSRU 2018, hospital based nurse per working hour
Theatre cost	£101.00	The National Schedule of Reference Costs 2012-3 contrast fluoroscopy procedures >40 minutes of £101 (code RA18Z), Total HRGs	£209	NHS Reference Costs 2017-18 Total HRG, RD32Z Contrast Fluoroscopy Procedures with duration of more than 40 minutes

Staff costs were updated using the 2018 PSSRU Unit Costs of Health and Social Care, for staff at the same band.

Procedure costs were updated to values in the 2017-18 NHS National Schedule of Reference Costs. It was not possible to use the same HRG codes, as they no longer exist. Codes were identified to match as closely as possible the same description and setting. These are specified in table 2.

Equipment costs for Sherlock 3CG TCS were provided by the manufacturer, BD, for 2019. The costs for SiteRite5 and SiteRite8 are included for information but have not been included in the model. The submitted economic model used the HRG cost for an ultrasound, which includes costs for equipment, staff and other resources, therefore the updated costs cannot be substituted into the model.

On request the manufacturer also provided costs for an optional annual service contract which are:

[redacted]

[redacted]

The cost for Sherlock 3CG standalone contract are included in the model. The SiteRite8 information cannot be readily added to the existing model.

Other equipment costs were inflated using the Pay and Prices Series with additional indices for 2017-18 as listed in PSSRU 2018.

All costs are updated in the cost spreadsheet page of the model. No cost updates were required in other locations. The model has been annotated to give the new updated sources in addition to the original ones.

The updated costs were added to both the base case scenario (with all EAC alterations) and the ICU scenario (both including all EAC alterations from

The model was also modified to add an additional table to the summary page for the base scenario. The original EAC assessment report calculated a total cost where 16.5% of patients were unsuitable for Sherlock and were treated with blind PICC insertion and x-ray. This total was calculated from the model results and was used to give the results reported in the guidance. The new table in the summary worksheet presents these results within the model.

7. Results from updated changes

The updated results of the base case (table 3) from the submitted manufacturer model, incorporating the EAC revised parameters, as described in the MTG24 guidance are that the Sherlock 3CG TCS without X-ray confirmation was associated with a cost of £366.16 per patient. At this cost, it became cost incurring by £9.45 compared with blind bedside insertion. It was associated with a cost saving compared with PICC insertion under fluoroscopy of £108.95.

For the original assessment report, the EAC created an additional scenario based in an ICU setting with data from studies by Johnston et al. (2013, 2014). An update of this scenario (table 4) showed that use of Sherlock 3CG with confirmatory X-ray compared with blind insertion with X-ray was associated with a cost saving of £53.85 per patient.

For the original guidance, following committee discussions, the EAC 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. With a cost update of these parameters (table 5), use of the Sherlock 3CG TCS without X-ray compared with blind bedside insertion was associated with a cost saving of £1.62 per patient

Tables 3,4 and 5 demonstrate that there have been cost increases for both the intervention and all the comparators. The cost difference has decreased slightly for Sherlock 3CG TCS without x-ray compared to blind PICC in the base case, and

increased slightly for all other comparisons. These are very small adjustments and do not alter the general findings of the published guidance.

Table 3: Results for the updated base case

	2014 Cost	Incremental cost saving due to Sherlock 3CG	2019 Cost	Incremental cost saving due to Sherlock 3CG
Sherlock without X-ray	£302.63	-	£366.16	-
Blind PICC placement with X-ray	£293.26	-£9.37	£356.71	-£9.45
Fluoroscopy	£408.75	+£106.12	£475.11	+£108.95

Table 4: Results for the updated ICU scenario

	2014 Cost	Incremental cost saving due to Sherlock 3CG	2019 Cost	Incremental cost saving due to Sherlock 3CG
Sherlock with X-ray	£372.35	-	£449.34	-
Blind PICC placement with X-ray	£413.69	+41.35	£503.19	+£53.85

Table 5: Results for the scenario discussed at MTAC with reduced nurse time for Sherlock, and including porter time for X-ray

	2014 Cost	Incremental cost saving due to Sherlock 3CG	2019 Cost	Incremental cost saving due to Sherlock 3CG
Sherlock without X-ray	£297.71	-	£360.85	-
Blind PICC placement with X-ray	£298.87	+1.16	£362.46	+1.62

8. Impact of changes in technology

Sherlock 3CG is available as a combined system together with the SiteRite8 ultrasound machine. Purchase of the combined system rather than a standalone Sherlock 3CG and SiteRite5 ultrasound device would result in a slightly reduced purchase cost. This would be expected to reduce the modelled cost of Sherlock 3CG by approximately 55p per patient, in the base case, compared with new purchase of separate devices, if it were assumed that maintenance costs applicable to Sherlock 3CG remained the same. Users may already have an adequate ultrasound device in use, or choose to purchase a different type of ultrasound device either of which would change the cost implications.

Three clinical experts advised that their sites use SiteRite8 incorporating Sherlock 3CG technology, and that previously they had used SiteRite devices with standalone Sherlock 3CG TCS with SiteRite5 or an alternative ultrasound machine. No changes in the patient pathway were required to use SiteRite8.

9. Conclusion

Updated costs suggest that Sherlock 3CG without x-ray remains around cost neutral in comparison to blind PICC insertion at the bedside. In comparison to insertion of PICCs using fluoroscopy, Sherlock 3CG without x-ray remains cost-saving. The updated costs have had only a small impact on the previous findings. Two experts advise that SiteRite8 can be used without changes in the patient pathway. The impact on costs will depend on the ultrasound currently used, and if it is due for replacement.

The manufacturer submitted information on the use of Sherlock 3CG in UK hospitals, which shows widespread acceptance of Sherlock 3CG technology without confirmatory x-rays to confirm placement.

10. References

The Sherlock 3CG Tip Confirmation System for placement of peripherally inserted central catheters NICE MTG24 (2015)

Department of Health Pay & Price Series 2015/16 http://www.info.doh.gov.uk/doh/finman.nsf/af3d43e36a4c8f8500256722005b77f8/360a47827991d10a80258036002d8d9f/$FILE/2015.16%20Pay%20&%20Price%20series.xlsx [last accessed 20 February 2019]

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Boiza A, Cellupica M et al. (2015) A prospective study of placement and confirmation of Peripheral Inserted Central Catheters (PICC) tip position using a new tracking and electrographic method (Sherlock 3CG, BARD). AVA 2015. Poster available from: http://static1.squarespace.com/static/5463e914e4b06e75cf10a427/t/55fdd43ae4b09b900d020b7c/1442698298107/Rosay+98006.pdf

Johnston A, Bishop SM, Martin L et al. (2014). Defining peripherally inserted central catheter tip position and an evaluation of insertions in one unit. Anaesthesia, 2013, 68, 484–491

Johnston A, Holder A, Bishop SM et al. (2014). Evaluation of the Sherlock 3CG Tip Confirmation System on peripherally inserted central catheter malposition rates. Anaesthesia epub ahead of print (accessed 13 July 2014)

Appendix A

Trial Number &	Summary	Status	Impact
NCT01275430	Phase I: Non randomised, considering PICC placement – to determine the location of the peripherally inserted central catheter (PICC) tip upon observation of maximum p-wave amplitude Phase II: To determine the precision of PICC placement in the Sherlock 3CG group versus the standard PICC placement. This would have been randomised and included longer term outcomes. *Primary Outcome* Phase I - Location of the PICC Tip Upon Observation of Maximum P-wave Amplitude Using Sherlock 3CG. [Time Frame: Time of PICC placement (Day 0)] Mean distance (mm) from the PICC tip to the upper cavoatrial junction (CAJ) upon observation of maximum p-wave amplitude when using Sherlock 3CG. All subjects were assigned to Sherlock 3CG in Phase I. Randomization was to have occurred in Phase II, but Phase II was not initiated due to termination of the study.	Phase 1 completed, Phase 2 terminated	Results for Phase 1 posted July 2016 We mentioned this in AR, but no results had been reported yet. Phase 1 probably of limited interest, phase 2 would have been more so, adds a little about
NCT03288766	A single-arm, prospective, multi-center study to assess clinical performance of the SHERLOCK 3CG Diamond Tip Confirmation System (TCS) with MODUS II software for confirming correct tip position of peripherally inserted central catheters (PICCs) in adult subjects with altered cardiac rhythm. *Primary Outcome* Rate of successful tip placement	Recruiting	December 2020 Of little interest
NCT01969981	Prospective, single centre, observational study. No follow up. 571 patients enrolled. Results online	Completed	April 2014
NCT03028090	Observational, prospective, non-comparative study to assess development of software package. Gather real-time ECG data through the use of the SHERLOCK 3CG™ Tip Confirmation System (TCS), an electrocardiogram (ECG)-based peripherally-inserted central catheter (PICC) tip confirmation	Completed	January 2017 (Actual study completion was March 2014)

	technology. The study was to promote the development of a software package (MODUS) that can accurately define the maximum P-wave on an ECG waveform. All study participants received PICCs as their standard of care. *Primary Outcome* Percent agreement between maximum P-wave assessments of PICC nurse clinicians and the MODUS software during PICC insertion [Time Frame: The PICC insertion procedure is 60-90 mins in duration] The measurement used will be percent agreement between clinician and MODUS software. Agreement of 95% between the nurse clinician and software assessments will be used to validate the study hypothesis.		No results posted
NCT02929368	RCT, fluoroscopy vs Sherlock for PICC placement. 210 participants, single centre, Germany. No follow-up past discharge from hospital. Peripherally inserted central catheters, or PICC lines, has now been successfully in use for many years, especially in the chemotherapeutic treatment of oncologic patients or in parenertal nutrition. The implantation of PICC lines is mostly performed under x-ray (fluoroscopy). The aim of the clinical study is to assess the safety and the efficacy of the SHERLOCK-Systems eliminating the confirmatory chest x-ray exposure. Additionally, the SHERLOCK-System immediately confirms the PICC tip position even at the bedside of the patient, thus, saving costs and time. *Primary Outcome* Tip Placement efficiency measured by chest radiograph [Time Frame: through study completion, an average of 2 years] Correct placement through anatomic evaluation of chest x-ray measuring catheter tip max. two vertebral bodies under carina	Recruiting	March 2018

NCT02498821	Observational study, non-randomised, comparative. Blind PICC with x-ray vs Sherlock 3CG without x-ray. No follow up past final tip confirmation. To evaluate differences in the time and costs between Sherlock 3CG® TCS and Chest X-ray to confirm the location of a Peripherally Inserted Central Catheter (PICC). *Primary Outcome* Time From Initiation of Procedure (Opening of PICC Kit) to Catheter Tip Confirmation (Release for IV Therapy). [Time Frame: Usually ranges from 0 to 300 minutes from initiation of procedure] Results published by Tomaszewski and include an economic model.	Completed (has results)	May 2016
NCT03652727	RCT study of fluoroscopy vs Sherlock for PICC placement to determine accuracy of placement. Both confirmed by chest x-ray. 120 participants, Switzerland	Recruiting	March 2019