NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Review Decision

Review of MTG24: The Sherlock 3CG Tip Confirmation System for placement of peripherally inserted central catheters

This guidance was issued in March 2015

NICE proposes an amendment of published guidance if there are no changes to the technology, clinical environment or evidence base which are likely to result in a change to the recommendations. However the recommendations may need revision to correct any inaccuracies, usually in relation to providing a more accurate estimate of the results of the cost modelling. The decision to consult on an amendment of published guidance depends on the impact of the proposed amendments and on NICE's perception of their likely acceptance with stakeholders. NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

1. Review decision

Amend the guidance to describe the current device platforms, including both the original stand-alone device and the new option of software incorporated in another device, and the estimated cost-savings based on updated prices for the devices and intervention in the pathway. Do not consult on the review proposal.

2. Original objective of guidance

To assess the case for adoption of the Sherlock 3CG Tip Confirmation System for placement of peripherally inserted central catheters.

3. Current guidance

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.

4. Rationale

Sherlock 3CG is still available as a stand-alone device. The company name and costs have changed. Sherlock 3CG is now also available as software on the Site Rite v8 ultrasound device. The new evidence supports the recommendations in the guidance and an update to the cost model shows the technology is still cost-saving. The proposal is to amend the guidance to reflect the current device options and the estimated cost-savings based on current prices.

5. New evidence

The search strategy from the original assessment report was re-run. References from July 2014 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

5.1 Technology availability and changes

The original technology is still available and has a CE mark. The manufacturing company has changed to BD since it acquired Bard in 2018. The price of the technology has increased to £10,653.97 (excluding VAT) from £9,990 in MTG24. The NHS supply chain price for the Sherlock 3CG system is [redacted].

A new version of the technology the Sherlock 3CG Diamond tip has been incorporated into the Site Rite v8 ultrasound system. The ultrasound system also manufactured by BD is used for the initial introduction of the peripherally inserted central catheter (PICC). This ultrasound-assisted identification of a vein would otherwise be done using a stand-alone device and was out of scope for the original guidance. The Sherlock 3CG Diamond tip device has the same mode of action as the original technology but includes an updated user interface with features to help with ECG P-wave identification and identification of the correct P-wave shape. The Site Rite v8 incorporating Sherlock 3CG Diamond tip technology is CE marked and available in the NHS at a cost of [redacted].

5.2 Clinical practice

According to 3 experts, there has been no change to clinical practice in the UK. People with atrial fibrillation are still required to undergo fluoroscopy assisted PICC placement or a confirmatory X-ray because of the lack of a consistent ECG P wave.

The NICE pathway is: Acutely ill patients in hospital overview

There have been no changes to the clinical pathway since the publication of the guidance.

5.3 NICE facilitated research

None.

5.4 New studies

The updated literature searches identified 16 peer-reviewed publications.

Cohort and prospective studies

Bloemen et al (2018) is a full paper describing a prospective non-randomised cohort study of either Sherlock 3CG (n=103) or fluoroscopy-guided (n=162) PICC placement in a hospital in the Netherlands during 2016. No significant difference was reported in clinical efficacy (98.5% of PICC insertions were described as having good positioning, 3 were malpositioned in the Sherlock 3CG cohort compared with 1 in the fluoroscopy group). Cost savings using Sherlock 3CG were reported as €122.14 per PICC in the first year and €189.60 in subsequent years.

Pittiruti (2015) is an abstract describing a prospective safety, feasibility and accuracy study on 130 PICC placements in an Oncology department. The geographical site was not given. 128 people had visible ECG P waves and tip location with Sherlock 3CG was possible in 120 of the 128. Placement was confirmed by X-ray. In 25 people there was poor or wrong visualisation of the

trajectory of the PICC tip. There were no safety-related complications. Feasibility with Sherlock 3CG was described as 81% and accuracy was 100%.

Observational studies

Bidgood (2016) is a full paper comparing positioning of PICCs (n=88) with Sherlock 3CG and X-ray confirmation in the NHS. 21 PICCs migrated into an incorrect location during placement and were corrected using Sherlock 3CG: 18 into the internal jugular vein; 1 to the opposite subclavian; 2 doubled back into the ipsilateral subclavian. The paper cites MTG24.

Lowrie et al (2016) is a conference poster abstract describing an observational study of the use of Sherlock 3CG for PICC placement in 49 people. 43 exhibited correct tip location when confirmed with X-ray; 6 PICCs were non-correlated with the ECG showing superior vena cava placement and the x-ray showing right atrium tip location. A reduction in time from placement to use of 8.63 hours was reported. The geographical site of the study was not given.

Tomaszewski et al (2017) is a full paper describing a cross-sectional observational study on 120 people divided into 60 with PICC placement using Sherlock 3CG and 60 with blind insertion and confirmatory X-ray arm across 4 centres in the USA. The mean time to IV therapy after the PICC was placed was 33.93 minutes in the Sherlock 3CG arm versus 176.32 minutes in the blind insertion and confirmatory X-ray arm. No malpositions were recorded for the Sherlock 3CG group whereas significantly more people had malpositions in the blind insertion and confirmatory X-ray arm (20% $p<0.001$). The paper cites NICE MTG24 and the associated paper from the EAC (Dale et al, 2016) and states that the analysis done in the study supports the comments made by the EAC.

Yamagishi et al (2018) is a full paper describing an observational study on people with PICC placements using Sherlock 3CG between October 2017 and February 2018 in Japan. 114 people were enrolled. The success rate was 97.3% (111/114). The level of training was found to influence the time taken to place the PICC, with the “beginner” group taking significantly more time (29.92 minutes) than the “skilled” group (22.34 minutes, $p = 0.00024$).

Audits

Bedford and Waterhouse (2017) is a full paper describing a nurse-led community-based service in the NHS for antibiotic delivery via PICC with placement using Sherlock 3CG. The technology had integrated ultrasound detection (Site Rite v8) to facilitate insertion of PICCs. 55 people had PICCs positioned while awake at an outpatient facility, with all attempts at insertion successful. Patient feedback was positive and described the procedure as less intimidating and less pressured than standard care. The service reduced

the need for secondary care intervention. People with atrial fibrillation were referred for midline insertion because the service did not have ready access to radiology for confirmation of PICC placement.

Cortes Rey et al (2018) is an abstract reporting an audit of PICC insertion with Sherlock 3CG from 2015 to 2017 at one site in Spain. 311 procedures were reported. Sherlock 3CG was reported as greater than 95% accurate in people with no ECG P-wave pathology.

Lelkes et al (2013) is a full paper describing a retrospective review of PICC placement at one site in the USA between December 2010 and December 2011. Records from 424 people were included. 97.7% of PICCs were described as appropriately placed using the Sherlock 3CG system.

Mundi et al (2016) was a retrospective review of the use of Sherlock 3CG to facilitate PICC insertion in a home environment for parenteral feeding. 17 people were in the review. 7 people (41%) had unsatisfactory PICC placement. The authors recommended that intravenous ECG tip confirmation should not be used without other methods for tip confirmation in people receiving PICCs for parenteral feeding since the requirement for accurate placement to deliver high osmolarity formula is critical.

Oliver and Jones (2016) is a full paper describing a case series of 60 patients and a retrospective audit of 4307 ECG-guided PICC placements in a UK NHS Foundation Trust comprising 5 hospitals. Sherlock ECG was not named in the paper. ECG-guided PICC placement was shown to be cost-saving and clinically-effective compared with PICC length estimation and X-ray confirmation. Clinical efficacy of the procedure was affected by: atrial fibrillation in 288 placements; presence of a permanent pacemaker in 55 placements; machine malfunction in 57 placements.

Patel et al (2018) is a full paper describing a retrospective before and after audit of 355 PICC placements in one hospital in the USA. The first group (n = 177, June-September 2015) comprised PICC placements using catheter length estimation with radiographic tip confirmation by X-ray: n=73 with no complication; n=27 malpositioned. The second group used Sherlock 3CG (178 October 2015 – February 2016): n=98 with no complication; n=1 malpositioned. The difference was significantly-different ($p<0.05$). The procedure was found to be cost-saving at $150 per person.

Rosche and Stehr W (2018) is a full paper describing an audit of 121 PICC placements (0-18 years old) with Sherlock 3CG in a US trauma centre. 112 (92.56%) were appropriately placed when confirmed by radiographic imaging. The total number of PICC placements was 144; 23 were excluded. Reasons

for exclusions were: difficulty in interpreting the ECG waveform (n=9); radiographic imaging errors (n=6); user errors (n=5); other reasons (n=3).

Van Elzen et al (2015) is an abstract that described an audit of Sherlock 3CG after introduction to a site in the USA. Cost savings of $55,476 were observed in 2014, with a reduction in chest X-rays from 50 per month to “less than 5 a month on average.”

The new clinical evidence supports the guidance. There is evidence (Bedford and Waterhouse, 2017) that X-ray and fluoroscopy free placement of PICCs has become adopted due to the use of Sherlock 3CG. No evidence was identified that has a material impact on the recommendations.

5.5 Cost update

The EAC produced a cost update (Dale et al, 2019). Main changes to the parameters were: the cost of ultrasound to locate PICC placement area; the unit cost of Sherlock 3CG; annual maintenance; operating theatre costs. Sherlock 3CG was associated with a cost increase of £9.45 per patient when compared with blind bedside insertion of PICCs. When compared with PICC insertion with fluoroscopy, Sherlock 3CG was associated with a cost saving £108.95 per patient.

In the intensive care unit, Sherlock 3CG with confirmatory X-ray was associated with a cost saving of £53.85 per patient when compared with blind insertion of PICCs with X-ray confirmation.

The results from the EAC cost update suggest that the general findings of the original guidance have not changed. The EAC considered one paper (Tomaszewski et al, 2017) including an economic analysis that had been published since the guidance and considered that the study did not affect the model.

Table 1: Results for the updated base case (from EAC report Dale et al, 2019)

	2014 cost per patient	Incremental cost of using Sherlock 3CG	2019 cost	Incremental cost of using 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 2: Results for the updated ICU scenario (from EAC report Dale et al, 2019)

	2014 cost	Incremental cost of using Sherlock 3CG	2019 cost	Incremental cost of using Sherlock 3CG
Sherlock with X-ray	£372.35	-	£449.34	-
Blind PICC placement with X-ray	£413.69	-£41.35	£503.19	-£53.85

The EAC considered the effect of purchasing Sherlock 3CG technology incorporated within the Site Rite v8 ultrasound device instead of a separate Sherlock 3CG and Site Rite v5. This was expected to result in a cost saving of £0.55 per patient. No changes in the clinical pathway were required to use Site Rite v8.

6. Summary of new information and implications for review

The new evidence supports the recommendations in the guidance. Incorporation of the Sherlock 3CG in the Site Rite platform has the potential for cost saving and

human factors benefits of having PICC insertion and tip localisation in the same platform without having to use separate devices.

7. Implications for other guidance producing programmes

None.

8. Implementation

The company has stated that 52 out of 64 sites using Sherlock 3CG in the NHS in England are X-ray free, inferring that confirmatory radiological investigations are not required. This compares with 9 X-ray free out of 14 sites before MTG24 was published.

The NICE Adoption and Impact team have provided information on the numbers of PICCs placed in the UK. This suggests that there has been an increase in the numbers of PICC placements.

A report shortlisted for a NICE shared learning award in 2019 from Southampton University Hospital suggests considerable cost and clinical advantages since the adoption of the recommendations in MTG24. The report cited Barton (2016) and Bidgood (2016) as evidence for the findings.

There are 507 reports on the FDA Maude database regarding Sherlock 3CG. 1 case was associated with cardiac arrest and death. Typical reports are incorrect positioning of the PICC because the ECG electrodes were incorrectly located.

Advice from 3 clinical experts who responded to NICE was positive:

One expert observed that the intravascular tip confirmation was not always reliably demonstrated by a change in colour from yellow. It was absent in many instances. The same expert indicated that Sherlock 3CG was used for all PICC insertions in Belfast Cancer Centre and at all cancer units in Northern Ireland.

One expert stated that use of Sherlock 3CG had resulted in reduced waiting. Prior to Sherlock 3CG, another department was used to insert a PICC. All line insertions are performed at the bedside using Sherlock 3CG (approximately 200 per year) for people with acute infections.

One expert stated that their site had purchased additional equipment since the publication of MTG24. The expert also mentioned the version change in the system (to Site Rite v8) as reported by the manufacturer. The expert has published a paper describing the use of Sherlock 3CG in a UK setting (Barton, 2016, described by the manufacturer as “not peer reviewed”).

The EAC contacted the clinical experts about their use of the Site Rite 8 incorporating Sherlock 3CG. They confirmed that they had previously used Site Rite

5 or an alternative ultrasound device for vein localisation and PICC insertion followed by the standalone Sherlock 3CG and no changes in the patient pathway were required to use Site Rite 8.

9. Equality issues

No equality or diversity issues were identified in the guidance. No new issues have been identified.

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below

Options	**Consequences**	**Selected – 'Yes/No'**
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	Yes
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	No
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

Appendix 2 – supporting information

Relevant Institute work

Published

TA49 “Ultrasonic locating devices for the placement of central venous lines” was reviewed in September 2016 and placed on the static list. TA49 stated that there was no evidence to support the use of ultrasound to facilitate PICC placement; all evidence and recommendations were for central line placement via central veins.

MIB6 “AccuVein AV400 for vein visualisation” was published in June 2014. MIB6 could be considered an alternative technology to the Site Rite ultrasound vein localisation system that now incorporates Sherlock 3CG technology.

In progress

None identified.

Registered and unpublished trials ***Ongoing studies*** Trial NCT03288766: SHERLOCK 3CG™ Diamond Tip Confirmation System (MODUS II)	Single-arm, prospective, multi-centre 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. Status: recruiting Expected enrolment: 605 Estimated primary completion date: December 2020. Location: United States
--- Trial NCT02929368: SHERLOCK 3CG vs. Fluoroscopy in Implantation of PICC-Line (3CG)	Randomized Controlled Noninferiority Study to Evaluate Safety and Efficacy of the Integrated Magnetic Tracking and ECG-guided Tip Location System (SHERLOCK 3CG) vs. Fluoroscopy in Implantation of Peripherally Inserted Central Catheter. Status: recruiting Primary comparator: PICC implantation under fluoroscopy Expected enrolment: 210 Estimated primary completion date: July 2017 Location: Germany
--- Trial NCT03652727: FX vs. ECG Guidance for PICC Insertion	Randomised, controlled trial investigating the appropriateness of replacing fluoroscopic guidance with ECG guidance in PICC Insertion. Status: recruiting Primary comparator: PICC insertion using fluoroscopic guidance Expected enrolment: 120 Estimated primary completion date: March 2019 Location: Switzerland
--- Trial JPRN-UMIN000033775: The accuracy of the position of peripheral intravenous central catheter using Sherlock 3CG system	Interventional, parallel randomized trial. Status: recruiting Primary comparator: none specified Expected enrolment: 20 Location: Japan

Appendix 3 – changes to guidance

Table 3: proposed amendments to original guidance

Section of MTG	Original MTG	Proposed amendment
p. 1 of 31, 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.	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 £109 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 £54 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. [2019]
p. 5 of 31, 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.	The Sherlock 3CG Tip Confirmation System (TCS; BD) 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). Sherlock 3CG is also available within the Site Rite ultrasound device (version 8). By using magnetic and electrocardiographic (ECG) real-time tracking of the PICC tip, Sherlock 3CG 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. [2019]
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.	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 £10,653.97 (excluding VAT). The cost of consumables associated with each insertion is £215.05, comprising primarily the cost of the PICC (including the stylet), sterile barrier and ECG leads. Maintenance costs associated with the technology are £840 per year per system console. [2019]
p.24 of 31, 5.22		For the guidance review, the external assessment centre revised the model to reflect 2019 costs (original guidance values given in brackets). The main parameter change was the cost of the Sherlock 3CG system £10654 (£9990). Results for the 2019 revised base case shows the cost saving associated with Sherlock 3CG was £109 (£106) when compared with fluoroscopy. In the ICU, use of the Sherlock 3CG system compared with blind PICC placement ICU with confirmatory X-ray was cost saving at £54 (£41) per patient. The external assessment centre considered the impact of purchasing Sherlock 3CG technology incorporated within the Site Rite v8 ultrasound device instead of a separate Sherlock 3CG and Site Rite v5. The cost model result is a cost saving of £0.55 per patient. No changes in the clinical pathway are required to use Site Rite v8. Further details of the 2017 revised model are in the revised model summary. [2019]

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