NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

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

1 Technology

1.1 Description of the technology

The SherLock 3CG Tip Confirmation System (C.R. Bard) is designed to confirm the correct tip placement of a peripherally inserted central catheter (PICC)[1]. It integrates tip location and confirmation by enabling the magnetic and electrocardiographic real-time tracking of the PICC tip during insertion. This technology is intended to allow the person placing the PICC to immediately detect and correct any tip malposition. 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 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.

The SherLock comprises:

- a system console which includes a control processor with display interface

A PICC is inserted through one of the large veins in or near the arm (basilic, brachial or cephalic vein) rather than the neck or chest.[1]

- 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 sensor is positioned on the patient's sternum with 2 ECG leads placed to pick up the external ECG waveforms (1 ECG electrode is placed on the right upper chest and the other on the left side of the abdomen below the umbilicus). The PowerPICC SOLO catheter is inserted with the SherLock 3CG TPS stylet, which has permanent, passive magnets encapsulated within its tip. During insertion when the tip location mode is active, the magnets generate a field which is detected by the SherLock sensor, enabling tracking of the PICC to be visualised on the interface in real time. The SherLock sensor allows the placer to visualise if the PICC is tracking into the internal jugular vein or contra-lateral vein or is taking the correct path towards the cavo-atrial junction. A yellow depth marker on the interface indicates the depth of the PICC. The SherLock interface also simultaneously displays real-time ECG waveforms received from the patient's skin (baseline) and from the tip of the catheter (intravascular). Intravascular ECG is acquired from a column of saline injected into the PICC by the placer, prior to PICC placement. The P-wave changes on the ECG as the PICC tip moves towards the right atrium and right ventricle. By observing the displayed ECG P-wave, a clinician can determine the PICC tip location as it travels through the superior vena cava to the right atrial junction.

1.2 Regulatory status

The Sherlock 3CG TCS received a class I CE mark in December 2011 and this was updated in February 2013. The PowerPICC SOLO catheter with the

Sherlock 3CG TPS stylet received a class III CE mark in February 2012. The Sherlock 3CG TCS was launched in the UK in April 2013. The SherLock 3CG TCS was previously available as the SherLock TLS, SherLock II, SherLock 3CG TPS, Sapiens Tip Confirmation System (TCS) and SherLock II TLS. It was first available in the USA in 2006. SherLock 3CG TCS is the fifth generation device.

1.3 Claimed benefits

The benefits to patients claimed by the sponsor are:

- Better accuracy of PICC placement and better outcomes by reducing the incidence of catheter malposition and post procedural repositioning.
- Removes the need for a chest X-ray or fluoroscopy to confirm tip location after PICC insertion.
- Intra-procedural verification of the position of the PICC tip allows for the PICC to be used immediately after insertion thereby reducing treatment delays for the patient. Treatment delays have been reported to be up to 48 hours post PICC insertion.
- Provides a safe method for PICC tip placement with no associated adverse events or complications.
- PICC placement and tip confirmation are achieved during the same clinical procedure and this is easier for the patient and makes for a better patient experience (except for patients with altered cardiac rhythms, including patients where an ECG P-wave is not easily detectable such as in atrial fibrillation, rapid tachycardia and paced rhythm).
- Improves patient experience and increases the patient's confidence in the PICC placer as the rate of malpositioning and repositioning is reduced.

The benefits to the healthcare system claimed by the sponsor are:

- Process efficiency through reduced care pathway as no PICC tip confirmation using X-ray is required.
- Reduces staff requirements (radiologists/radiology nurses/radiographers/ radiology healthcare support workers) as PICC tip confirmation by X-ray is

reduced/eliminated; reduces the need for hospital porters to transfer patients between PICC placement setting to radiology for chest X-ray; reduces the need for doctors to confirm PICC X-ray before treatment can be initiated. All the staffing resources that are freed by the use of SherLock 3CG can be redirected to other areas of need.

- Potential reduction of bed occupancy due to reductions in delays of treatment initiation post-PICC insertion; delays caused by repositioning and malpositioning. This may lead to earlier discharge of hospital patients receiving intravenous therapy, enabling management in the community.
- Reduces costs of consequences of malpositioning.
- Reduces costs of using resource intensive departments such as radiology.

1.4 Relevant diseases and conditions

PICCs are used in a variety of clinical scenarios and there is no single source for the average annual number of insertions. A review in 1994 estimated that there were more than 200,000 central venous catheters (including PICCs) inserted in the UK annually. These were used for a variety of indications and diseases. The 1994 review identified the following circumstances as being suitable for PICCs:

- Intravenous access for drugs and fluids
  - Infusion of irritant drugs—for example, chemotherapy
  - Total parenteral nutrition
  - Long term administration of drugs such as antibiotics
- Monitoring or interventions
  - Central venous pressure
  - Repeated blood sampling
- Where there is poor peripheral access.

1.5 Current management

In current NHS clinical practice, PICCs are inserted by clinicians including intensive care consultants, anaesthetists, general physicians, nurse specialists, radiologists and radiographers. The clinical settings include operating theatres, emergency rooms, oncology, orthopaedic and other

wards, radiology departments, intensive care, high dependency units and outpatient clinics. A sterile environment is necessary, but can be achieved using a maximum barrier, sterile field at the bedside.

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

PICC placement

Different guidelines recommend different catheter tip positions. The European Society for Clinical Nutrition and Metabolism Guidelines on parenteral nutrition: central venous catheters indicate that the ideal position is in the lower third of the superior vena cava, at the atrio-caval junction, or in the upper portion of the right atrium. USA guidelines from the American Journal of Roentgenology: Central venous access: a primer for the diagnostic radiologist, favour the low superior vena cava or cava-atrial junction.

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

2 Reasons for developing guidance on the SherLock 3CG Tip Confirmation System for

placement of peripherally inserted central catheters

The Committee considered that SherLock 3CG TCS may offer benefits to patients by reducing the need for X-rays after insertion of the PICC lines, or fluoroscopy to guide placement. Additional benefits include the avoidance of delay in treatment and inconvenience of visiting the Radiology department.

The Committee considered that SherLock may offer benefits to the healthcare system by reducing both the costs associated with radiological confirmation of PICC location, and the rate of malpositioning of PICCs.

The Committee was advised that SherLock 3CG TCS should be evaluated relative to two comparators: PICC insertion with a confirmatory chest X-ray; and fluoroscopic-guided PICC insertion in a radiology department or operating theatre.

3 Statement of the decision problem

	Scope issued by NICE
Population	Adult patients undergoing PICC insertion
Intervention	SherLock 3CG Tip Confirmation System
Comparator(s)	•PICC insertion followed by chest X-ray to confirm tip placement •Fluoroscopy to guide PICC insertion and confirm tip placement
Outcomes	The outcome measures to consider include: •accuracy of catheter tip placement •incidence of catheter malposition •need for catheter re-positioning •impact of malposition-related complications such as infection/thrombosis •treatment delay following catheter placement •reduced staff time •reduced in-hospital stay •requirement for confirmatory chest X-ray •requirement for fluoroscopy to correctly place the PICC tip •time taken to insert PICC •PICC failure/re-insertion rates •patient experience measures •quality of life •device-related adverse events.
Cost analysis	The cost analysis will include both the standard method of PICC placement and fluoroscopic method as comparators. The use in different care settings (e.g. secondary, tertiary care) should be considered. This includes considering the difference between inpatient and outpatient costs. Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios where the use of SherLock removes the requirement for post-insertion confirmatory chest X-Ray.
Subgroups to be considered	None
Special considerations, specifically related to	Many patients requiring a PICC would be classed as disabled under the Equality Act 2010 but there are no equality issues with the use of SherLock 3CG TCS.

equality issues		
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

4 Related NICE guidance

Published

- Infection: Prevention and control of healthcare-associated infections in primary and community care. NICE Clinical Guideline, CG139, March 2012. Available from: http://guidance.nice.org.uk/CG139
- Nutrition support in adults: Oral nutrition support, enteral tube feeding and parenteral nutrition. NICE Clinical Guideline, CG32, February 2006. Available from: http://www.nice.org.uk/CG32
- Guidance on the use of ultrasound locating devices for placing central venous catheters. NICE Technology Appraisal, TA49, September 2002. Available from: http://www.nice.org.uk/guidance/TA49

Under development

None identified.

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Association of Surgeons in Primary Care
- British Cardiovascular Intervention Society
- British Cardiovascular Society
- Intensive Care Society

- The Royal College of Anaesthetists
- Royal College of Nursing
- Royal College of Physicians
- British Association of Critical Care Nurses
- Royal College of Radiologists
- National Infusion and Vascular Access Society

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Cancer Black Care
- Action Cancer - NI
- BME cancer.communities
- Cancer Equality
- Cancer of Unknown Primary (CUP) Foundation - Jo's Friends
- Cancer Research UK
- Cancer52
- CancerHelp UK
- Children with Cancer
- CLIC Sargent
- CRITpal
- Crohn’s and Colitis UK
- Helen Rollason Cancer Charity
- ICUSteps
- Independent Cancer Patients' Voice
- Macmillan Cancer Support
- Maggie’s Centres
- Marie Curie Cancer Care
- MRSA Action UK
- National Kidney Federation (NKF)
- PINNT (Patients on Intravenous and Nasogastric Nutrition Therapy)
- Rare Disease UK

- Rarer Cancers Foundation
- Sue Ryder
- Teenage Cancer Trust (TCT)
- Tenovus
- Together for Short Lives
- Ulcerative Colitis UK

5.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

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