NICE advice

Needle-free arterial non-injectable connector

Medtech innovation briefing
Published: 26 October 2016

www.nice.org.uk/guidance/mib85

Summary

- The **technology** described in this briefing is the needle-free arterial non-injectable connector (NIC), which is connected to the sampling port of an arterial line and through which blood samples can be collected.
- The **innovative aspect** is a safety feature that stops inappropriate injection into the arterial line. It may also help to prevent bacterial contamination of the arterial line and blood loss during sample collection.
- The intended **place in therapy** is instead of arterial connectors currently used in adults with arterial lines in critical care facilities, operating theatres, and emergency departments. It is not licensed for use in children.
- The **key points from the evidence** summarised in this briefing are from a laboratory study showing that NIC prevents bacterial transfer from a syringe into a 3-way port; a user survey (n=258) showing that most users wanted to continue using the NIC after an implementation study finished; and a cost-effectiveness study, which concluded that using the NIC instead of standard connectors could save £285 per year in an

average NHS trust. No evidence was available to show that using the NIC prevented inappropriate injections or blood loss in clinical practice, but the rarity of such events makes such a study unfeasible.

- A **key uncertainty** around the evidence is whether there would be savings associated with using the NIC for NHS organisations that adopt this technology.
- One single-use NIC **costs** £1.95 (including VAT).

The technology

The needle-free arterial non-injectable connector (NIC; Amdel Medical) is connected to the sampling port of a standard 3-way tap in an arterial line using a Luer connection. The NIC is red in colour to help identify the arterial line. An internal 1-way valve in the NIC allows fluid to only flow from the arterial line to the sampling syringe. This valve closes completely when pushed downward thereby preventing accidental injection into the patient. The locking Luer connecting the NIC to the 3-way tap makes it hard to remove the NIC, which also reduces the risk of inadvertent injection into the artery. The NIC injection port has a silicone compressible bung with a central slit, which seals against back pressure but opens when the Luer tip of a sampling syringe is pushed against it. The seal closes once the syringe has been removed, preventing accidental blood loss. The manufacturer of the NIC states that bacterial contamination is also prevented because of the design and configuration of the device. The NIC is intended for single-patient use only.

The innovation

The NIC is the only needle-free arterial connector for the sampling port of a 3-way tap that can stop intravenous fluids or treatments from being inappropriately given through the arterial line. The NIC may also help to prevent bacterial contamination and blood loss during blood sample collection.

NICE is not aware of any other CE-marked devices that have a similar function to the NIC.

Other needle-free connectors or caps are available that have closed coverings to prevent blood spillage and bacterial contamination of the arterial line, but these do not specifically stop accidental injection into the arterial line.

Current NHS pathway

Arterial lines are regularly used for adults in critical care units and operating theatres for sampling arterial blood to measure blood gases, glucose and electrolytes, and for monitoring blood pressure. Different types of arterial connectors can be used on the sampling port of the arterial line but these are not designed to prevent inappropriate injection of fluids or drugs intended for administration into a vein. Inappropriate injections into an artery are rare but can have life threatening or life changing consequences. The accidental administration of intravenous medication can cause serious injury (including skin loss, tissue necrosis and loss of limb) and all incidents resulting in severe harm and death must be reported to the National Reporting and Learning System. In 2008, the National Patient Safety Agency recommended that in addition to raising awareness amongst staff, training and the development of local systems to identify arterial lines and infusates, longer-term design solutions are needed to minimise the risks associated with using arterial lines.

Population, setting and intended user

The NIC is intended to replace needle-free connectors or caps currently used in the NHS to cover the sampling port of the arterial line.

The NIC can be used for any adult with an arterial line, but it is not licensed for use in children. It is intended for use in hospital settings where arterial lines are in place (for example, operating theatres and critical care facilities).

The device would be used by the same staff who currently use needle-free connectors or caps on arterial lines. Minimal training is needed to use the NIC.

Costs

Device costs

Each NIC costs £1.95 (including VAT). It is sterile packed and sold in boxes of 25 units.

The device is for single-patient use. It is changed when the giving set is replaced, usually every 48 to 72 hours.

Costs of standard care

Costs for other arterial needle-free connectors currently in use range from £0.18 to £1.50 each (NHS Supply Chain, March 2016). They are single-use devices that should be replaced after each blood sample is taken.

Resource consequences

The NIC is currently used in 13 hospitals in England and 1 hospital in Northern Ireland.

No changes to the way that current services are organised or delivered would be needed. No additional facilities or technologies would be needed to use the NIC, although minimal training may be neccesary.

Regulatory information

The needle-free arterial non-injectable connector (NIC) was CE marked as a class IIa medical device in November 2013.

A search of the Medicines and Healthcare products Regulatory Agency website revealed that no manufacturer Field Safety Notices or Medical Device Alerts have been issued for this technology.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

The needle-free arterial non-injectable connector (NIC) would be used for patients needing arterial lines, who may be critically ill. Older people may have more critical care periods than younger people (Health and Social Care Information Centre 2016). The NIC is

not currently licensed for use in children. Age is a protected characteristic under the Equality Act (2010).

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the published process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting MIBs@nice.org.uk

Published evidence

Two publications (table 1) are summarised in this briefing. The first publication (Mariyaselvam et al. 2015a) reported the following evidence:

- a clinical audit of bacterial contamination of standard 3-way taps in a single intensive care unit in the UK
- a manikin simulation study using standard 3-way tap ports to determine the likelihood of accidental arterial injection by 'time-pressured' junior doctors in an intensive care unit in the UK
- a laboratory study to determine the protection offered by the needle-free arterial non-injectable connector (NIC) against transmission of bacteria.

Evidence from the clinical audit and manikin study was not included in this briefing, because it does not provide direct evidence on the NIC.

The second publication (Mariyaselvam et al. 2015b) reported the following evidence:

- Results of a national survey sent to every acute NHS trust in the UK (where the NIC was not in use) to gather information on the incidence of accidental administration into an arterial line in the past 5 years.
- A regional survey carried out across 11 trusts in the east of England to gather information on the acceptability of the NIC to 258 users (including nurses, doctors, operating department practitioners and other healthcare staff) after a 6-month

implementation study. Further details of the respondents were not reported.

- A cost-effectiveness assessment of the NIC which was also based on information gathered from the 6-month implementation study of the NIC in 11 trusts in the east of England.

Findings from the national survey on accidental administration into an arterial line were not included in this briefing because it does not provide evidence in relation to the NIC.

Table 1 summarises the included evidence as well as its strengths and limitations.

Table 1: Summary of clinical evidence

Study	Details of intervention and comparator	Outcomes	Strengths and limitations
Mariyaselvam, Heij, Laba et al. (2015a) UK-based laboratory simulation study to determine the protection offered by the NIC against transmission of bacteria.	An artificial system was prepared to imitate arterial blood sampling and the flushing sequence through a 3-way arterial connector. A syringe that was intentionally heavily contaminated with bacteria was connected to a standard 3-way arterial connector (n=20) or to the NIC (n=20). Downstream flush samples and swabs of the 3-way tap ports were collected.	Bacterial growth was found in 85% and 100% of samples and swabs respectively, when using standard 3-way arterial connectors. No bacterial growth was found in any samples or swabs when the NIC was used.	The researchers used a syringe that was more heavily contaminated than would be expected in normal clinical practice, and showed that even when bacterial contamination is excessively high, it is not transmitted to the port or the arterial blood sample. This was done in an artificial system designed to imitate arterial blood sampling and flushing in real-life, because it would be unethical to do such a test in patients. However, transmission rates using standard connectors may be much lower in clinical practice than when used with a heavily contaminated syringe and it is not known whether there would be a clinically or statistically significant difference in a real-world situation. Outcome assessors were not blinded to the type of connector, and 2 of the investigators have a profit share arrangement for the device.

Study	Details of intervention and comparator	Outcomes	Strengths and limitations
Mariyaselvam, Blunt, Young (2015b) Implementation study carried out in 11 NHS trusts in the east of England that had been using the NIC for 6 months.	Cost-effectiveness assessment, comparing the NIC with a standard arterial connector, based on: estimates of staff time; process steps and consumables; costs of erroneous injections; and costs of bloodstream infections. Survey of 258 staff who had used the NIC, comparing the NIC with a standard arterial connector.	Use of the NIC could lead to better outcomes at lower costs, saving £285 per year for an average trust. Acceptability for users: 96.5% said the NIC made it easier to identify the arterial line, although 70.9% thought that the standard connector was adequate for identifying an arterial line 81% wanted to continue using NIC after the study ended 22% noted problems with using the NIC.	Cost-effectiveness estimates were derived from real-world use of the NIC in NHS settings. Uncertainties around the parameters and assumptions used were not explored. Insufficient details about the methods of the analysis were reported to allow judgement of whether the cost savings are likely to be realised elsewhere. The study has not yet been peer-reviewed as part of a publication process. The survey was based on real-world use of the NIC in NHS settings. Insufficient details were reported to determine if the survey used was valid. One of the investigators on implementation study has a profit share arrangement for the device. The study has not yet been peer-reviewed as part of a publication process.

Abbreviation: NIC, needle-free arterial non-injectable connector.

Strengths and limitations of the evidence

The evidence to support the NIC is from laboratory studies and user experience surveys. Any clinical study designed to show that the NIC prevents accidental injection into or blood loss from arterial lines would need to be very large, in order to be adequately powered to show a reduction in the incidence of these rare events. The evidence for prevention of bacterial contamination is limited to a small laboratory study and the benefit of the NIC in a clinical situation is unknown. The NIC was compared with 1 type of connector, so the benefit compared with the various types of connectors currently used in the NHS is also unclear.

The evidence on acceptability to users in this MIB is from a representative group of NHS staff, and indicates that most users would choose to continue using the NIC. The NIC offers a safety feature not found in currently used arterial connectors that could also lead to cost savings. However, there is uncertainty about whether the estimated cost savings are accurate, and so these could be greater or less than estimated if it is adopted more widely in the NHS.

Recent and ongoing studies

No ongoing or in-development trials on the NIC were identified.

Specialist commentator comments

One specialist commentator stated that although accidental injection into the arterial line is uncommon, its potential consequences are devastating, and the needle-free arterial non-injectable connector (NIC) could make accidental injection less likely. They also thought that accidental blood loss as a result of leaving the tap open was uncommon.

One specialist commentator stated that bacterial contamination during sampling from an arterial line is very common, although the consequences are negligible and sub-clinical. They accepted that NIC has the potential to reduce bacterial contamination.

One specialist commentator stated that they had not experienced any issues with arterial lines (accidental injection, bacterial contamination or accidental blood loss) in the past 12 months, but they expected that the NIC would help eliminate such potential problems. The specialist commentator had previously used the NIC in their unit, but it is not currently

in use. They noted that there had been some issues with using the NIC, including its size, which made it cumbersome to use, and problems with flushing or changing the device too frequently, but they thought that these could be overcome with appropriate training. Another specialist commentator thought the NIC should be simple to use. One specialist commentator noted that they would not introduce the NIC in their own centre, based on the current evidence on infection rates and cost savings.

Specialist commentators

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

The following clinicians contributed to this briefing:

- Peter-Marc Fortune, Consultant Paediatric Intensivist, Associate Clinical Head, Royal Manchester Children's Hospital, no conflicts of interest declared
- Tim Meek, Consultant in Anaesthetics and Theatres, South Tees NHS Trust, no conflicts of interest declared
- Beverley Ann Hobson, Ward Manager, Adult Intensive Care Unit, University Hospital of South Manchester NHS Foundation Trust, no conflicts of interest declared

Development of this briefing

This briefing was developed for NICE by Birmingham and Brunel Consortium. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality assured and approved for publication.

ISBN: 978-1-4731-1961-1