Improving safety of blood sampling

A novel device, invented by two consultants from The Queen Elizabeth Hospital King's Lynn NHS Trust, was designed to help prevent known risks associated with conventional arterial lines.

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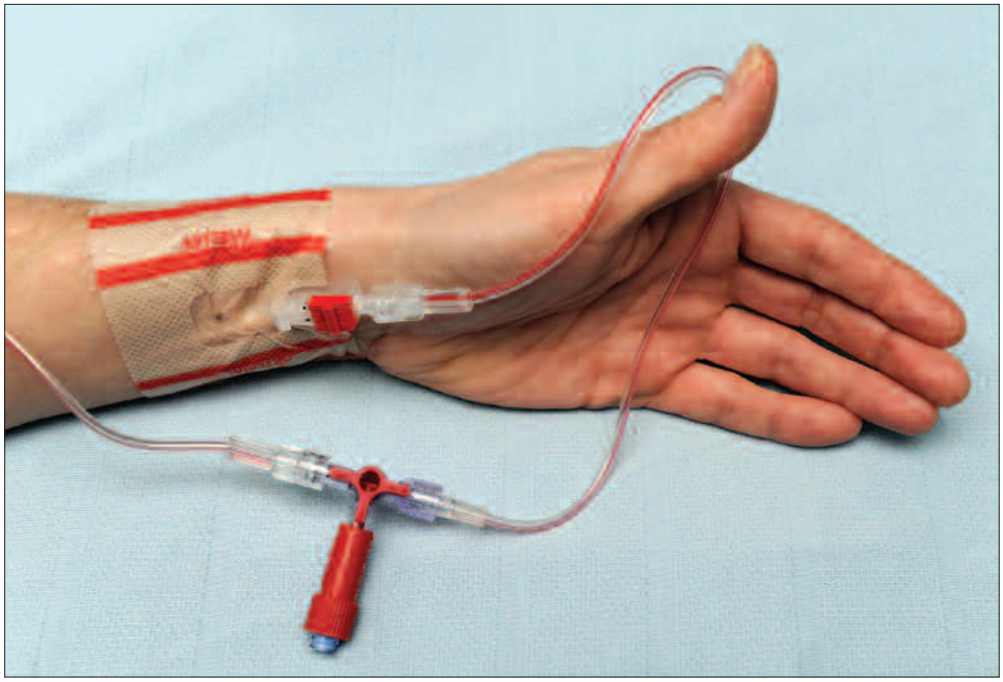
Arterial lines are routinely used in critical care areas for sampling arterial blood to measure blood gases, glucose and electrolytes. However, safety risks have been identified when using conventional arterial lines, prompting the issue of a Rapid Response Report by the NHS National Patient Safety Agency, in July 2008.

Current arterial line systems do not prevent intra-arterial injection of drugs and this has been a reported complication which can result in dramatic consequences such as skin loss, tissue necrosis, loss of a limb or potentially loss of life.

In response to this problem, two consultants from The Queen Elizabeth Hospital King's Lynn NHS Trust (QEH) invented a novel device which increases the safety of patients undergoing blood sampling. Now in commercial production, the Non-Injectable Connector for Arterial System was devised by Dr Joseph Carter and Dr Peter Young, with help from Health Enterprise East (HEE), the NHS Innovation Hub for the East of England.

The Non-injectable Connector (NIC) has a unique design incorporating a one-way valve, so that it only allows removal of the blood and prevents anything from being injected into the arterial line. It also stops blood from leaking out of the system should the three-way tap be accidentally left open. Intra-arterial cannulae and monitoring systems are frequently used to facilitate beat-to-beat monitoring of blood pressure and to allow blood sampling.

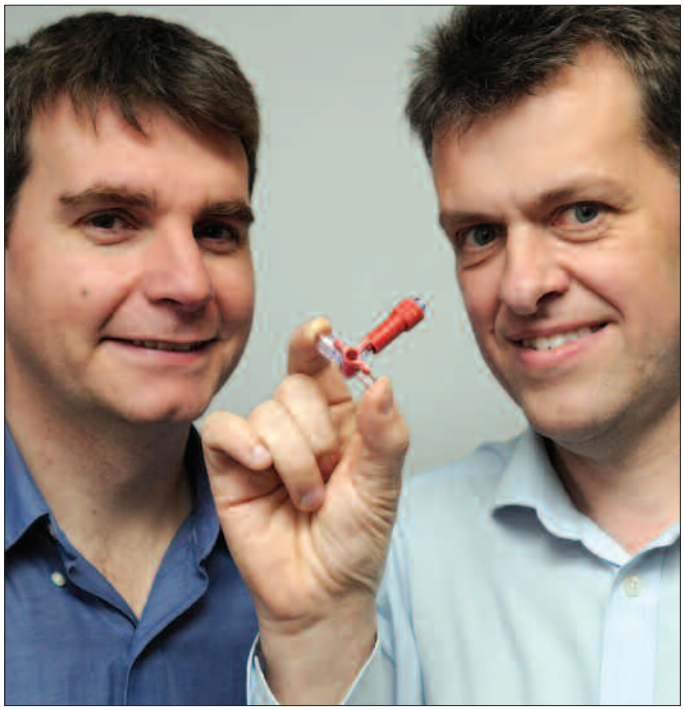
The innovation won the Siemens Healthcare Diagnostics Award for Medical Technology in the 2009 Innovation Competition organised by HEE. It was also recognised in the National 2011 Patient Safety Awards.



Addressing the problem

Dr Carter, one of the inventors said: "Dr Young and I first had the idea for the NIC in 2008 when we were working on some other equipment relating to wrong route injections. As consultants in intensive care at QEH in King's Lynn, we were commonly exposed to patients with arterial lines in place and were aware that wrong route injection here was a problem.

"As a result, we had both come across instances of intra-arterial injection which have had serious consequences and were aware that the current steps to try and prevent it were not sufficient. Colour coding has been shown not to be useful in situations of low light such as in the operating theatre and on the ICU at night. It is common



Dr Joe Carter (left) with co-inventor Dr Peter Young.

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Stuart Thomson.

among anaesthetists to put some tape over the tap to try and remind oneself not to inject.

"When acting under stress, junior doctors in unfamiliar environments may inject drugs directly into the arterial system. The only preventative strategies to distinguish an arterial line at present are colour coding and labelling which are not always instituted and may, in some instances, be accidentally removed. Our new NIC is an engineered solution to make this complication impossible."

Dr Carter and Dr Young developed a prototype from equipment that was routinely available and then undertook a study to show that this was an effective and safe option. They went on to approach HEE to ask for its help in taking the concept forward.

The HEE team responded by helping to protect the idea with a patent, funded proof of concept development and supported clinical evaluation at QEH. It also identified a suitable commercial partner – Amdel Medical – and negotiated the exclusive licence with them.

Stuart Thomson, head of medical technology at HEE said: "This innovative design has huge potential in terms of increasing patient safety and we are delighted that we have played a part in its development and commercialisation. As with many successful ideas coming from the NHS, it has been created by frontline staff who have seen how existing equipment could be improved for patient benefit."

In a survey of clinicians, 95% said that they would recommend the use of the non-injectable connector. It is estimated that around one million non-injectable connectors could be used in the UK annually and at least five million per year throughout the US.

James Lyon, managing director, Amdel Medical, based in Liverpool, added: "This award-winning device is a perfect fit with our current portfolio of innovative products that are already being used to increase quality of care and efficiency across the UK.

"It was clear from the outset that this product needed a company with in-depth knowledge and experience of taking it from the product development stage to market. Initially we have a patent granted for all areas within Europe and currently have a patent pending for the US market.

"Importantly we have a CE marked product, manufactured in the UK, ready for market, with huge potential in terms of take-up and sales."

Health Enterprise East (HEE)

As the NHS Innovation Hub for the Eastern Region, HEE can:

- Assist NHS staff to identify and evaluate innovative new ideas.
- Provide advice and practical support to move ideas forward.
- Protect ideas – for example, filing patent and design applications and advice on copyright.
- Give access to a Development Fund to assist further development.
- Negotiate commercial deals with manufacturers and distributors.
- Facilitate the development of partnerships between the NHS and healthcare companies.

Operating within the NHS, HEE also provides consultancy services to technology-based companies looking to access the UK market and works with clinical key opinion leaders and senior NHS managerial, commissioning and procurement staff on a daily basis. Its NHS market assessments provide vital information for companies to ensure that their products are well targeted to the technical and business needs of the NHS, speeding up adoption of new technology by the NHS.

Non-injectable connector

- Contains a unique valve mechanism which allows blood sampling but prevents anything else being injected into the arterial line.
- Design prevents blood from leaking out of the system should the three-way be accidentally left open.
- One-way valve is also shown to prevent the possibility of bacterial infection which can occur with arterial devices and may be passed onto the patient.