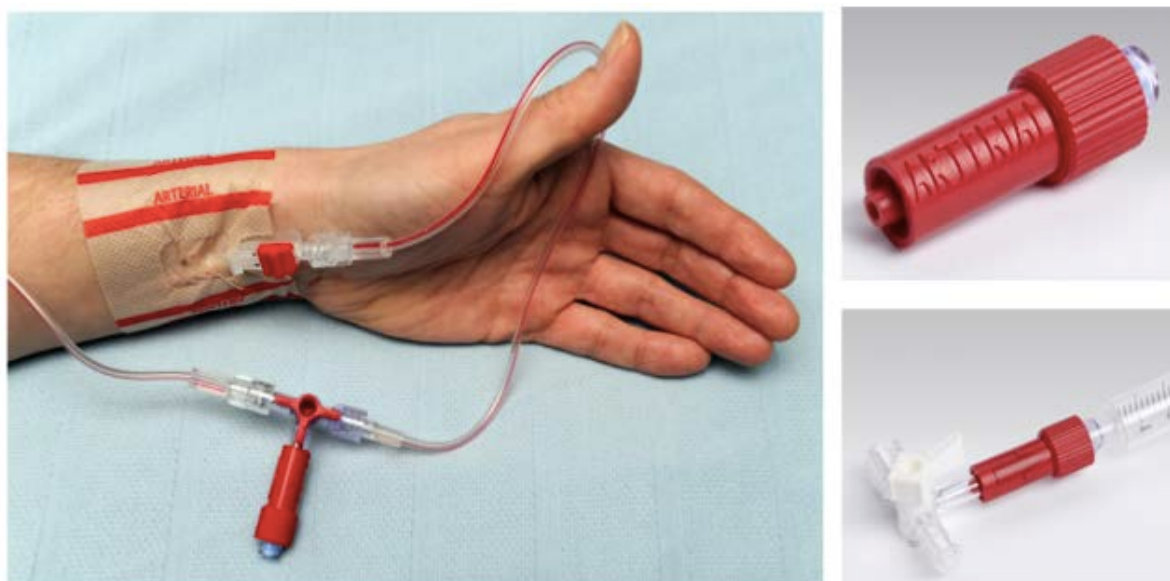


December 2013 – May 2015

## **The Non-injectable Arterial Connector (NIC)**

**A cost effectiveness assessment to improve arterial line safety**

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**The Eastern Academic Health Science Network  
Patient Safety Study, Number FC171013/11**

## **The Non – Injectable Arterial Connector (NIC)**

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## **Executive Summary**

### **The Non-injectable Arterial Connector (NIC)**

#### **Introduction**

In intensive care units (ICU) and operating theatres arterial lines are used to accurately measure a patient's blood pressure and take numerous and repetitive blood samples. In order to prevent bacterial contamination and blood spillage from the arterial line, red arterial connectors, which are closed cap coverings, are placed on the sampling port of the arterial line. It is estimated that around one million arterial line connectors used in the UK annually. The 2008 National Patient Safety Agency Rapid (NPSA) Response Report highlights problems with arterial lines that have led to patient harm, such as errors with sampling, the use of incorrect infusions, arterial line infection and confusion of arterial and venous lines.

The Non-Injectable Arterial Connector (NIC) addresses three of these errors:

- it eliminates accidental administration of medication into the arterial line (confusion of arterial and venous lines);
- it prevents bacterial contamination (arterial line infection);
- it prevents blood spillage during sampling (errors with sampling).

The NIC is an engineered patient safety solution, which eliminates a wrong route medication administration error (a serious adverse event). The NIC has a one-way valve in its internal chamber, which physically prevents staff accidentally giving medication via this route. When this error does occur, it can have devastating implications for the patient, the severest being amputation of the fingers or hand. The one-way valve mechanism also physically prevents bacterial contamination of the arterial line, excess blood spillage during sampling and blood loss if the three-way sampling port is accidentally left open, protecting healthcare workers and patients from blood borne infections. Adoption of the NIC requires minimal staff training.

There are several different types of arterial connectors available for use in the UK, these are often coloured red (but can be white) and it is possible to both aspirate and inject into the arterial line when these connectors are used clinically. The NIC, therefore, was manufactured in order to provide a physical barrier to the error of accidentally administering medication into the arterial line. The device does not interfere with normal clinical activities. When a member of staff accidentally attempts to make the error, the internal mechanism presents the barrier and prevents them from doing so. The NIC is the only arterial connector, available for clinical use, which prevents wrong route drug administration into an arterial line and meets the recommendations of the NPSA alert 2008/ RRR 006.

The NIC has been awarded the Association of Anaesthetists of Great Britain and Ireland Innovation in Anaesthesia Award (2015) and the National Patient Safety Care Award (2012).

**The aims of this study were to:**

1. eradicate accidental administration of medication into the arterial line and improve arterial line safety;
2. estimate the prevalence of wrong route arterial line drug errors;
3. conduct primary research;
4. implement the NIC in the East of England (minimum 6 acute Trusts);
5. assess cost effectiveness and the uptake of the NIC in the East of England;
6. understand the reasons for barriers to adoption.

**Prevalence of wrong route errors**

The incidence of arterial wrong route drug errors are low in the published literature, because they are rare events and because we believe there is under-reporting of the error. This may be because the clinical ramifications of resultant complications may be delayed by a number of hours and the accountable health care worker may not recognize or choose not to report the error.

*National survey*

In order to estimate the extent to which accidental administration of medication into arterial is occurring nationally, we conducted an anonymous survey of all ICUs asking the clinical directors whether an incident of accidental administration of medication had occurred in their unit in the last 5 years. 1/3 of the ICUs responded and 16/56 (28.5%) reported that they had experienced wrong route drug administration of medication into the arterial line in their ICU. This positive response indicates a minimal national incidence of around 9% and for a serious error, these numbers are too high. As only a single person's experience was surveyed in each unit we can assume these figures are an underestimate. Despite the recommendations made by the NPSA in 2008, intra-arterial injection is still a problem, which remains under-reported to NHS England. This highlights the necessity of engineered safety solutions, such as the NIC.

*Simulation study*

In order to understand why these errors occur in clinical practice, we conducted a simulation study, to determine the risk of accidental arterial line drug administration. Junior doctors, who were working on the ICU, were given a stressful and distracting scenario, as would normally occur in their clinical practice. When asked to urgently administer medication to the 'patient', we found that in their haste, 10/15 (66%) junior doctors accidentally gave the medication into the arterial line. Many of these doctors did not realise they had made the error, therefore, fail-safe solutions, such as the NIC, are needed to eliminate these errors.

**Primary Research**

Infection control in the ICU is of paramount importance, however the contribution of arterial lines to iatrogenic infections is not well understood. We

performed a clinical audit of standard arterial connectors in the ICU, which showed a 6% bacterial colonisation rate. This has the potential to be transmitted to the patient. Laboratory studies on the NIC show that the NIC does not become colonised with bacteria, and therefore, bacteria cannot be transmitted to the patient. Reductions in bacterial colonisation, infections and antibiotic treatment are also crucial to reducing antibiotic resistance which is continuously driven by nosocomial infections and suboptimal preventative strategies in hospitals.

### **Implementation Study**

The funding for this study has allowed the improvement of arterial line safety in 11 Trusts over a 6 month period in the East of England. 6 Trusts were originally requested to participate, however due to the popularity of the connector, the study was expanded to 11 Trusts. The study trusts were the Queen Elizabeth Hospital, Colchester General Hospital, Hinchingsbrooke Hospital, Ipswich Hospital, East and North Hertfordshire Hospital, The Luton and Dunstable Hospital, Papworth Hospital, The Norfolk and Norwich Hospital, Peterborough and Stamford Hospital, Watford General Hospital and West Suffolk Hospital.

The implementation study has been successful. The total number of arterial lines recorded during the study period was 3,421. The NIC was used on 2,881 of these lines, leading to 79% implementation rate across the region. Four Trusts achieved an implementation rate of greater than 95% during the study period, 4 Trusts achieved >80% implementation and 3 Trusts achieved between 36-66% implementation.

We surveyed the healthcare staff, nurses, doctors and operating department practitioners who used the NIC during the study period. 258 people responded to the survey across the region and it has been found that the NIC is well liked with some Trusts continuing to use the NIC after the study period.

98% of health care staff surveyed believed it was important to have a device that prevented wrong route drug administration and prevent arterial line infections.

28% of respondents said they have personally seen adverse events in their routine clinical practice when using standard arterial lines in the past and 93% believe these would have been prevented had the NIC been in use.

96.5% of staff said the NIC allows increased identification of the arterial line and >80% said that the NIC was easy to learn and use and is compatible with standard arterial line equipment.

81% wanted to use the connector after the study was completed and they felt that this was due to both ease of use and to promote patient safety.

## **Cost Effectiveness**

An independent report was commissioned from a Health Economist concluding

**“the use of the NIC is considered likely to be dominant in health economics terms, in that it delivers improved outcomes at lower overall costs, at both a unit and regional level.”**

The cost effectiveness of using the NIC was determined by comparison to the standard connector. This looked at 4 factors including: the staff time required to use the NIC, the number of process steps involved, the cost of additional consumables required and the potential costs of arterial line-associated bloodstream infections which may be avoided through the use of the NIC.

The NIC has been found to save time and reduce the average number of process steps required to take a blood gas sample. This leads to an opportunity cost saving of £1,091 per Trust and £20,560 in the East of England per annum.

Using the NIC has a cost benefit: the same NIC can be used over the lifetime of the arterial giving set, whereas standard arterial connectors require changing after each sample is taken. This leads to a direct cost saving of £285 per Trust and £5,131 across the East of England per annum.

The NIC prevents any accidental injection into an arterial line and bacterial contamination. When this does happen, it causes lasting harm to patients and requires additional healthcare costs. The NIC would save costs of several thousand pounds for every patient in whom such an error is averted (see full economic report).

Using the NIC is both cost beneficial and cost effective and leads to a total annual cost saving (opportunity and direct costs) of £1,376 per Trust and £25,691 across the East of England per annum.

## **Barriers to adoption**

It is widely known that even approved and mandated technology or techniques can take many years to be adopted fully. During the pre-implementation phase, in one study Trust (whilst they were clarifying the need in their setting), a near miss wrong route serious adverse incident occurred in the ICU. Following this, on inspection of local error reporting at the same Trust, two wrong route arterial error events were found to have been previously internally reported. Despite this evidence of previous error, the Trust took five months to agree to use the NIC, a certified device that was already approved for clinical use in the NHS. Measures should be taken to speed up adoption in individual Trusts, when certification and approvals are already in place.

All Trusts in the region were invited to participate in the study. In those Trusts that did not participate in the study, the ICU leads felt that accidental



administration of medication into the arterial line was not a problem in their hospital. It is likely that this is because it was a problem they had not personally experienced previously. This is a classical human factors error when considering rare events, which are uncommonly seen by individuals during their everyday practice, but are commonly occurring across healthcare systems. With some medical equipment or innovative techniques, implementation via a grass roots method is important to enable individual users to determine whether its use is appropriate for clinical practice in their environment. However, when considering patient safety, every individual clinician should not have to personally experience a serious albeit rare complication before changing their practice, if the problem has been identified on a wider scale throughout the NHS. Therefore in terms of rare and serious events, we believe there is a requirement for national leads to support and encourage best practice.

### **Patient Feedback**

The NIC is used in patients that are often anaesthetised and unconscious, and therefore will not be aware of the device. In order to seek patient's opinions on the NIC, we presented this work to the members of the East of England Citizens' Senate. Once the role of the device had been explained, we asked whether they would want the NIC to be used in the ICU and operating theatres for their benefit and that of their family. 100% of respondents (13/13) strongly agreed that the NIC should be used in ICUs and operating theatres for their benefit and that of their family.

Some comments from patients were that:

*"not using this device would seem like folly"*

*"making mistakes impossible keeps people alive and reduces cost per episode"*

*"why is this not part of normal practice?"*

*"From what I have heard, it is essential to good practice and economy"*

### **Conclusions**

This study has been highly successful by confirming the need for, and identifying the solution to, a serious adverse event affecting many patients across the NHS. The study has enabled the controlled implementation of an engineered patient safety solution that has arisen from grass roots innovation within the NHS, and has demonstrated the usability and efficacy of the device. The NIC study supports safer, integrated care with minimal additional training requirements - staff will only realise they cannot inject into the arterial line, if they try to do so. Patients who require an arterial line are critically ill, therefore, the prevention of any further accident, infection or injury by the use of the NIC supports the best patient outcomes. Patient safety has become a national priority in terms of

standards of healthcare throughout our hospitals. The NIC helps to improve areas of patient safety as described above, by removing an accidental injury pathway and contributing to infection control. Every Trust will have policies regarding arterial line use and care. The NIC will therefore complement and complete these existing standards. The study has demonstrated benefits to patients and staff, through improvement of practice and the development of a patient safety network, ERIN.

With the help of the EAHSN Board, the NIC now has the potential for widespread adoption across the UK, thereby eliminating a serious adverse event from the NHS. This would be a springboard to eliminating this serious adverse event and improving patient safety internationally. The NIC has been designed, licensed and manufactured in the UK and creates wealth for the UK in accordance with the national policy detailed in "Innovation for Health and Wealth (2011)."

The final phase of the study involves coordinating recommendations, through the EAHSN Board, the other 14 AHSNs and patient safety groups, directly to CEOs in the region and nationally to other appropriate bodies. The lead research fellow and the NIC device have also been awarded a place on the NHS National Innovation Accelerator (NIA) Programme, which supports rapid and wide scale diffusion of innovation across the NHS. We hope the support of the AHSNs and the NIA programme will lead to substantial improvements in patient safety for all patients requiring an arterial line across the NHS.

### **Recommendations of this report**

#### **The NIC should be introduced in all patients with arterial lines in the UK**

- **The NIC arterial connector enhances patient safety and should be introduced into clinical practice for the following indications:**
  - **engineering out a wrong route drug error;**
  - **enhancing infection control;**
  - **protecting staff and patients from blood spillage.**
- **Venous needle free solutions are now in routine practice across the NHS, due to the EU needle free directive. The introduction of the NIC now provides a credible arterial solution and should therefore be implemented to support this directive. Unlike the venous solution, it should not be possible to inject into an arterial needle free connector and the NIC meets this need.**
- **The recommendation for introduction of the needle free NIC arterial connector for all patients in the UK is supported by its endorsement by the national patient safety bodies (National Patient Safety Award, first prize winner 2012), national anaesthetic organisations (AAGBI first prize winner 2015), and the Eastern Academic Health Science Network following successful implementation trials in the East of England.**

- **Trust CEO's should cascade these recommendations to**
  - **Vascular access groups**
  - **Infection control leads**
  - **Patient safety leads**
  - **Medical directors**
  - **Nursing directors**
  - **Clinical Directors of Anaesthesia and Intensive Care**
  - **Practice development nurses and matrons (ICU and operating theatres)**
  - **Procurement leads**

### **Acknowledgements**

We are grateful to the EAHSN for their support during the study period. Their support for the NIC and translational research has allowed the uptake and adoption of a new technology at a scale and pace, not previously seen by independent researchers, within in the region. Through this funding we have fostered a supportive research collaboration, which has been constantly peer reviewed by the leading clinicians in each Trust and given the opportunity to more than 40 clinical staff to develop their research and improvement science skills. The EAHSN has also supported the lead clinical research fellow to undertake a Medical Doctorate at the University of Cambridge and ensures the publication of this work in peer reviewed journals.

Amdel Medical are a UK company who manufacture the product and the Queen Elizabeth Hospital NHS Foundation Trust and Health Enterprise East, the NHS Innovation agency, manage the IP under a revenue share arrangement with the inventors, Drs Young and Carter. This strategy is in accordance with the national policy as documented in "Innovation for Health and Wealth (2011)."

## Background

### Arterial lines, arterial connectors and complications

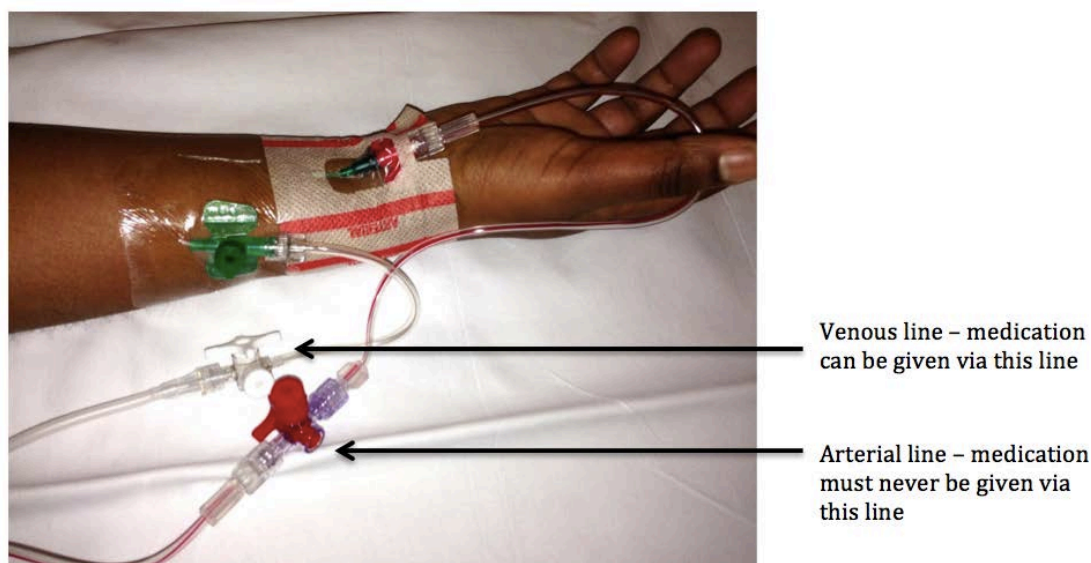
In intensive care units (ICU) and operating theatres arterial lines are used to accurately measure a patient's blood pressure and take numerous and repetitive blood samples.

The catheter of the arterial line, often placed in the radial artery, is connected to a continuous infusion and a pressure sensor via connector tubing. Within this system is a three-way connector tap (figure 1), where the side port (a female luer lock connection) is used for the aspiration of blood samples. The side port is commonly covered by an arterial connector, this is a closed covering that is used to prevent blood spillage and bacterial contamination of the arterial line. The annual estimated use of arterial connectors is around 1 million in the UK, 5 million in the US and 10 million in Europe. There are several different types of arterial connectors available for use in the UK (figure 1), these are often coloured red (but can be white) and it is possible to both aspirate and inject into the arterial line when these connectors are used clinically.



**Figure 1: Images showing various manufacturers' arterial connectors currently used in clinical practice. They are placed on the sampling port of the three-way tap and are closed coverings. It is possible to both aspirate and inject into the arterial line when these connectors are used clinically.**

The connector tubing, three-way connector tap and arterial connectors are conventionally coloured red to highlight the presence of an arterial line. This is to remind staff that medication should never be given via this line and to prevent confusion with a venous line. A venous line (figure 2) is placed in the vein. The connector tubing for the venous line is clear and it is used for giving medication or fluids. Arterial lines and venous lines can often be in close proximity to each other.



**Figure 1:** Showing an arterial line and a venous line in close proximity to each other. The arterial line is distinguished by the red stripe in the tubing. The lower arrow points to the red three-way connector port (luer lock system) of the arterial line from which blood samples are taken. The green cannula and white tubing shows the presence of a venous line. The higher arrow indicates the white three-way sampling port where medication can be infused into this line.

The 2008 National Patient Safety Agency (NPSA) Rapid Response and supporting information reports<sup>1,2</sup> highlight several problems that can occur with arterial lines such as:

- Bacterial contamination can occur from not adhering to strict cleaning prior to sampling.
  - a. This can lead to, at worst, bacteraemia, septicaemia. Contamination can drive antibiotic resistance or may cause local inflammation around the cannula insertion site and requiring the line to be re-sited.<sup>3,4,5</sup>
- Blood spillage during sampling or accidentally leaving the three way tap open
  - a. Bleeding from the line can lead to an infection risk to staff for blood borne infections.
- Confusing the arterial line with the venous line, leading to accidentally giving medication into the arterial line instead of the venous line due to use of conventional arterial connectors (figure 1).
  - a. This error can easily occur because of confusion due to the busy environments of ICUs and theatres, and often the need for rapid administration of medication to patients. When this error does occur it has the potential to cause serious damage to the arterial blood vessel and surrounding tissue. This can result in necrosis of the patient's hand and amputation.<sup>6</sup>

The NPSA report that these errors are due to sampling technique and human error. They recommend that manufacturers need to develop universal solutions to minimise risks, and until solutions are in place there should be better training in infection control, training in pre-procedure checks and management of samples.<sup>1,2</sup> In order to address the confusion of arterial lines and venous lines,

there should be colour coding, labelling, heightened awareness and clinical vigilance to mitigate errors.<sup>1,2</sup>

However, despite recommendations made by the NPSA, intra-arterial injection is still a problem. Importantly, accidental misadministration of medication into the arterial line, although rare, is an under-reported problem. Under reporting may occur because resultant complications may be delayed by a number of hours and the accountable health care worker may not recognize or may not choose to report the error.

During this study, we conducted an anonymous national survey of all ICUs asking the clinical directors whether an incident of accidental administration of medication had occurred in their unit in the last 5 years. 1/3 of the ICUs responded and 16 (28.5%) reported that they had experienced wrong route drug administration of medication into the arterial line in their ICU. This positive response indicates a minimal national incidence of around 9% and for a serious error, these numbers are too high. As only a single person's experience was surveyed in each unit we can assume these figures are an underestimate.<sup>7</sup> Despite the recommendations made by the NPSA in 2008, intra-arterial injection is still a problem, it remains under-reported to NHS England and highlights the necessity of fail-safe safety solutions.

### **The Non-Injectable Arterial Connector**

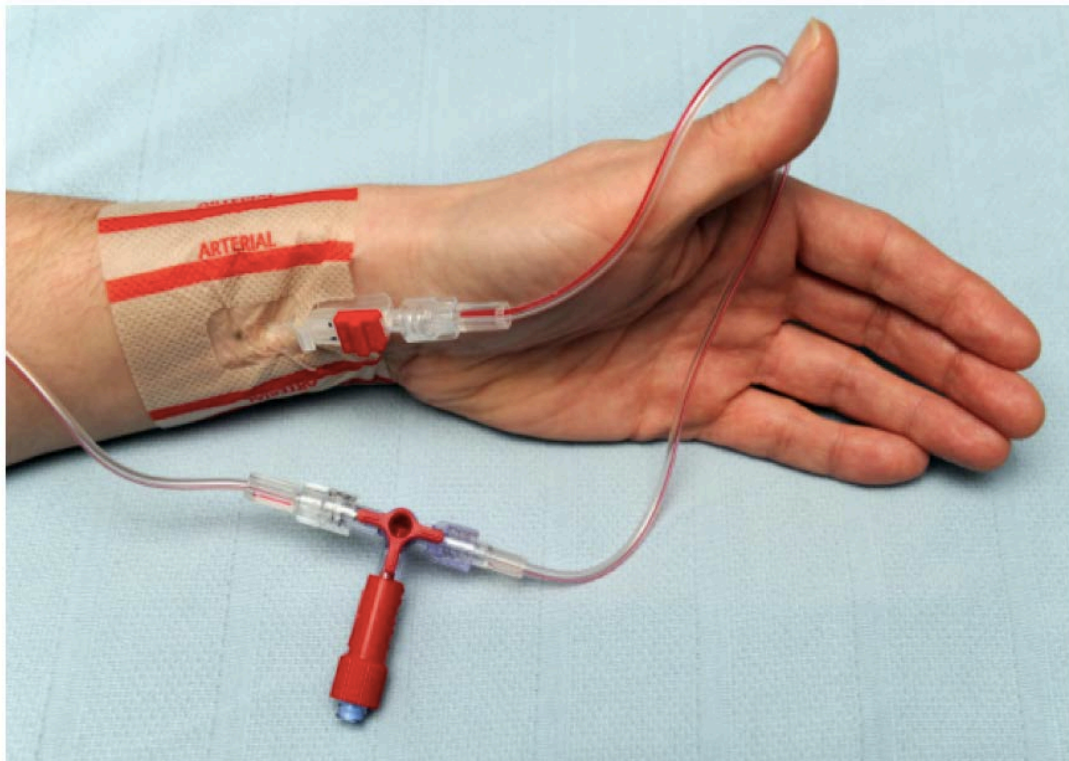
The non-injectable arterial connector (NIC) is an engineered solution designed to eradicate the problem of accidental administration of medication into the arterial line. The NIC meets the recommendations of the NPSA alert 2008/ RRR 006<sup>1,2</sup> on “problems with infusions and sampling from arterial lines” and is a manufactured solution designed to prevent these errors.

The NIC is an engineered patient safety solution which eliminates the serious adverse event of wrong route medication administration, with minimal effort and staff training. The NIC has a one-way valve in its internal chamber, which physically prevents staff accidentally giving medication via this route. The device does not interfere with normal clinical activities. When a member of staff accidentally attempts to make the error, the internal mechanism presents the barrier and prevents them from doing so. The NIC is the only arterial connector, available for clinical use, which prevents wrong route drug administration into the arterial line.

The one-way valve mechanism also physically prevents bacterial contamination of the arterial line, excess blood spillage during sampling and blood loss if the three-way sampling port is accidentally left open, protecting healthcare workers and patients from blood borne infections.

The NIC connects to the sampling port of the three-way connector in the same fashion (luer lock) as other arterial connectors, is coloured red with the words arterial inscribed on the connector to clearly indicate it's purpose (figure 3). The

NIC is CE marked and by virtue of the luer lock mechanism, it is compatible with all arterial lines (giving sets) currently used in ICUs and theatres, allowing easy and immediate implementation, with minimal staff training.



**Figure 2: A: Showing the standard arterial line with a NIC attached to the sampling port of the three way tap.**

### **Why is the NIC important for patient safety?**

The NIC supports safer, integrated care with minimal additional training requirements - staff will only realise they cannot inject into the arterial line, should they try to do so. Patients who require an arterial line are critically ill, therefore, the prevention of any further accident, infection or injury by the use of the NIC supports the best patient outcomes. Incidents related to arterial line mis-administration are rare but consequences are often very severe, so although outcome measures will be limited in terms of the decrease we see in serious errors, widespread use of the NIC eradicates the possibility of such an event occurring in the first place.

Patient safety has become a national priority in terms of standards of healthcare throughout our hospitals and care homes. This NIC helps to improve areas of patient safety as described above, by removing an accidental injury pathway and contributing to infection control. Every Trust will have policies regarding arterial line use and care. The NIC will therefore complement and complete these existing standards.

**The aims of this study were to:**

1. eradicate accidental administration of medication into the arterial line and improve arterial line safety;
2. estimate the prevalence of wrong route arterial line drug errors;
3. conduct primary research;
4. implement the NIC in the East of England (minimum 6 acute Trusts);
5. assess cost effectiveness and the uptake of the NIC in the East of England;
6. understand the reasons for barriers to adoption.



## **Methods**

There were eight elements to this study. Our primary data provided the evidence to manufacture the NIC for clinical use. It has gained CE marking and passed regulatory approvals and therefore this was an implementation study, looking at the use of the connector in clinical practice.

### **1. Preliminary Research**

Our primary evidence was formed of three studies:

1. a clinical audit to determine the rate of bacterial contamination of standard arterial connectors;
2. a laboratory study comparing bacterial contamination rates of the NIC and standard arterial connectors and determine the potential onward transmission of bacteria to the patient;
3. a simulation study where 15 junior doctors were tested in a high pressure simulated emergency to determine the risk of error.

### **2. National Survey**

In order to estimate the extent to which accidental administration of medication into arterial is occurring nationally, we conducted an anonymous postal survey was conducted of all ICUs and anaesthetic departments. The survey asked the clinical director of each department whether an incident of accidental administration of medication had occurred in their unit in the last 5 years (Appendix 1).

### **3. Observational Use Study**

In each Trust, we determined the number of process steps required to perform a blood gas sample comparing the NIC and the standard connector. Observations were made of nurses taking a blood gas sample when either the NIC or a standard connector was used.

### **4. Time Study**

We compared the total time taken to perform an arterial blood gas sample comparing the NIC and a standard arterial connector.

### **5. Usability Study**

Nurses were asked to compare the ease of use of each connector on a visual analogue score, where 0 was very easy to use and 10 was very hard to use and a difference of 2 was deemed as significantly different.

### **6. Implementation Study**

It was necessary for senior clinicians and management to support the study and implement the use of the NIC. Therefore the Chief Executive, Nursing Director,

Medical Director and Intensive Care Clinical Director of each acute Trust in the region were contacted and the study was explained. The East Anglian Intensive Care Group and the Critical Care Network meetings were attended and the research proposal presented to the ICU leads of the Trusts.

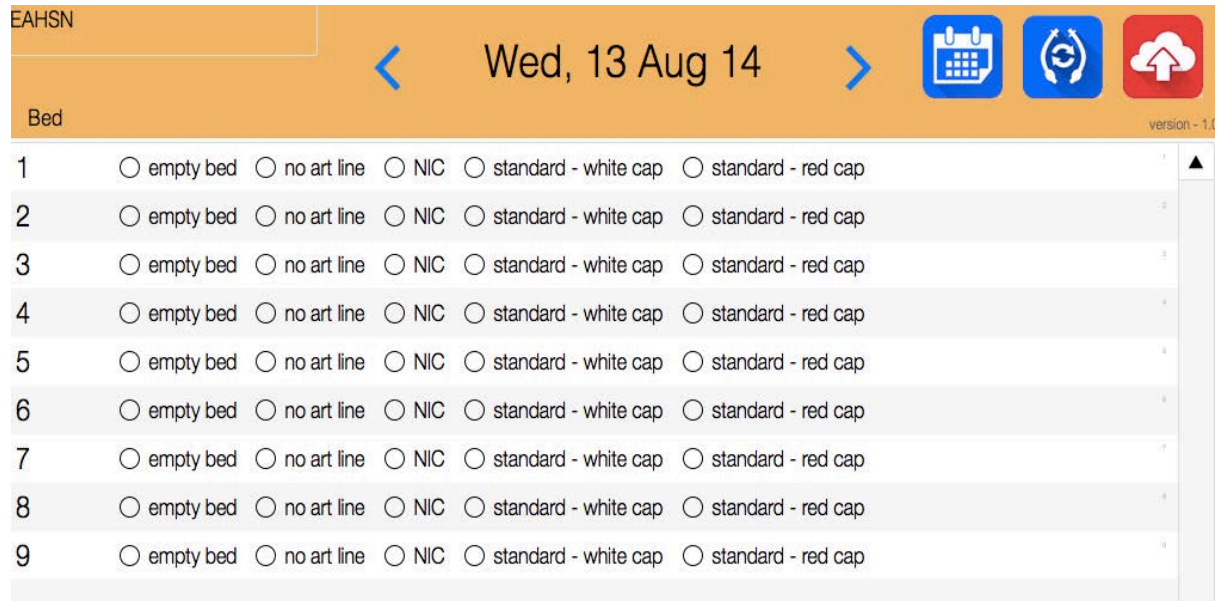
Data collection was required to understand the uptake of the NIC during implementation. Therefore junior doctors were recruited to undertake the data collection. Staff and associate specialist (SAS) doctors were initially recruited by approaching the regional SAS Tutors and the SAS doctors at their meetings to encourage participation in the study. SAS doctors were chosen due to their permanency in the department and the individual Trust over the length of the study.

All interested ICU leads, senior nurses and junior doctors from the Trusts were invited to an introductory meeting at BMA House in London. The meeting was accredited with CPD points, approved by the Royal College of Anaesthetists. Lectures were given by the clinical team on arterial line safety, the NIC, how it was to be used and the reasons for implementation (Appendix 2). A novel method to allow data collection was developed via an application designed by the study co-lead. This application was made using the programme filemaker and was loaded onto an iPad. Attendees were shown how to use the programme and undertake data collection.

In order to establish a research platform to enable the study over a large area the Eastern Research and Innovations Network was established (an accompanying website was also created: [www.erinuk.com](http://www.erinuk.com)). This allowed all members (ICU leads, junior doctors and nurses) to engage with each other and formed a research community for the study. As data collection was being performed by individuals at each study site, it was necessary to ensure that they would be appreciated for the work undertaken. We ensured that data collectors would be rewarded for their participation in the study by actively supporting their career development. Data collectors would have ownership of their own Trust's data, and this would be provided in an easy format to allow presentations of the clinical audit in their own hospital.

All participating Trusts were asked to register the study with their hospital audit department. Once this confirmation was received, each Trust was given the NIC for use in the ICU and theatres. An iPad, with a specially designed application tailored for each individual hospital, was sent to the Trusts in order to perform data collection. A research nurse visited each Trust and showed the healthcare staff how to use the connector and the iPad application. A video was made demonstrating sampling technique, instructions for use of the device, and posters of the NIC were made and distributed to each Trust and a copy was loaded onto the iPad for subsequent use and teaching (appendix 3).

The study team were asked to use the NIC on all of the patients admitted to the ICU (and theatres if able). They were asked to perform data collection twice a week. Each time they were required to input how many patients had a NIC, a standard connector, no arterial line or no patient in the bed, figure 5.



**Figure 5: A screen shot of the data collection app from the iPad. Each application was tailor made for each Trust. The figure shows the data points collected. After data collection data collectors would press the red button in the top right hand corner, which would then automatically send the data to the centralised server.**

Each iPad was loaded with a sim card and the collected data returned to a centralised secure server, which collated all of the information and presented a percentage NIC use for each Trust, figure 6.

DATE	Day	Count	Week	NIC	Other	NICRatio	
08 August	Friday	2	32	7	0	100.0%	QEH >
04 August	Monday	2	32	10	0	100.0%	QEH >
02 August	Saturday	3	31				QEH >
01 August	Friday	3	31	8	0	100.0%	QEH >
28 July	Monday	3	31	10	0	100.0%	QEH >
27 July	Sunday	4	30	9	0	100.0%	QEH >
24 July	Thursday	4	30	7	0	100.0%	QEH >
23 July	Wednesday	4	30				QEH >
21 July	Monday	4	30	10	0	100.0%	QEH >
20 July	Sunday	1	29				QEH >

Figure 6: The centralised server view, demonstrating the use of the NIC by date of data collection performed.

It was possible to transmit this data over a non NHS server as this information had no patient identifiable data. Despite this, we sought and were granted the appropriate clearances from the Caldicott Guardian, the head of research and development, and IT from the QEH hospital, Kings Lynn.

The data received during the study period was reviewed daily by a research assistant. This allowed us to quickly detect errors or problems in the data collection. If a problem was identified, the Trusts were contacted and helped to manage any problems that were preventing implementation or data collection at the time. When required, a research nurse travelled to the Trust to address problems in person.

## 7. Regional Survey

At the end of the study Trusts were asked to complete a survey assessing the use of the NIC and to gain feedback on the study (appendix 4).

## 8. Health Economic Evaluation

A health economic evaluation was also performed in order to determine to cost effectiveness of introducing the NIC within the East of England.

## Results

This study assessed the implementation and clinical use of the NIC in the East of England. The awarded funding requested a minimum of six study sites, however, due to the popularity of the study, the NIC was implemented in 11 Trusts throughout the region, however, this meant that not all Trusts completed a full six month evaluation period. Participating Trusts included the Queen Elizabeth Hospital, Colchester General Hospital, Hinchingsbrooke Hospital, Ipswich Hospital, East and North Hertfordshire Hospital, The Luton and Dunstable Hospital, Papworth Hospital, The Norfolk and Norwich Hospital, Peterborough and Stamford Hospital, Watford General Hospital and West Suffolk Hospital.

### 1. Preliminary Research

Infection control in the ICU is of paramount importance, however the contribution of arterial lines to iatrogenic infections is not well understood, therefore a clinical audit was conducted at the Queen Elizabeth Hospital, Kings Lynn over a six month period to determine the incidence of infection in standard arterial connectors. On day three of the arterial line being in situ, and prior to replacement, the arterial line hubs were swabbed with (Aimes swabs) and delivered to the microbiology department. Swabs were plated onto Columbia Agar plates and incubated for 48 hours at 35 degrees. The resultant growth was analysed by a microbiologist. Of the 87 arterial lines swabbed, 6% were colonised with bacteria.

A laboratory study was conducted looking at the potential onward transmission of bacteria to the patient, comparing the standard arterial connector to the NIC. A closed circuit was designed under sterile conditions to replicate an arterial system and a patient's circulation. A standard blood gas sample was taken, where the syringe tip used for taking the waste sample was coated with bacteria and inserted into the arterial hub. The normal method of taking an arterial sample was performed and arterial line was flushed using a transducer. The flush, which would normally go into the patient's circulation, was collected in a sterile container. A swab was inserted into the flush sample and was plated onto Agar plates as above. The connectors were also swabbed to determine bacterial contamination. The study was repeated 20 times with the NIC and with the standard arterial connector. A blinded microbiologist analysed the results. Swabbing of the arterial connectors showed 100% bacterial contamination in the standard group (20/20) and 0% contamination of the NIC (0/20). The progression of bacterial to the potential patient was found to be 85% (17/20) in the standard connector and 0% (0/20) in the NIC.

In order to understand why these errors occur in clinical practice, a stressful simulation study using a sim man simulator was designed in a critical care environment. 15 doctors were recruited to the study and asked to manage an arrest situation. The sim man had a central venous line, peripheral venous line and an arterial line, with a standard arterial connector. The participants were asked to urgently give atropine or adrenaline to the 'patient' after a bradycardia.

We found that 66% (10/15) of participants injected directly into the arterial connector.

This data has been published (Anaesthesia 2015).<sup>8</sup>

## **2. National Survey**

In order to estimate the extent to which accidental administration of medication into arterial is occurring, a national survey was sent to the clinical lead of both the Intensive Care Units and the Anaesthetic Departments of every acute Trust in the UK. They were asked whether they were aware of an incident of accidental administration of medication into the arterial line in the last 5 years.

1/3 of ICU clinical directors responded and 16/56 (28.5%) reported that they had experienced mis-administration of medication into the arterial line.

1/3 of Anaesthetic clinical directors responded and 8/55 (14.5%) reported that they had experienced mis-administration of medication into the arterial line.

As only a single person's experience was surveyed in each unit we can assume that these figures of 28.5% and 14.5% are underestimates. These positive responses indicate a minimal national incidence of around 9% and 5% respectively, and for a serious error these numbers are too high.

This data has been published (Critical Care Medicine 2015).<sup>7</sup>

## **3. Observational Use Study**

When implementing the NIC, staff were shown how to use the connector and instructions for use were provided. However, we found, most Trusts did not change their method of blood gas sampling. As techniques differ in each Trust, the time taken to perform a blood gas sample and the number of process steps required to perform the procedure varied.

We found that the average number of process steps required to take a blood gas sample with the NIC was either fewer or the same when compared with the standard arterial connector. The NIC had a mean number of 17 process steps (range 12-19) compared with the standard arterial connector of 18.7, (range 15-28). The results show that no significant change in practice was required in the Trusts in order to use the NIC. However, using the NIC affords the opportunity for a shorter procedure, fewer process steps and therefore a reduction in potential errors.

## **4. Time Study**

11 nurses participated in the timing study, 3 of the nurses had not been formally taught by the research nurse but had been shown how to take a blood sample using the NIC by a colleague.

When comparing the NIC and the standard arterial connector it was found that there was no difference in the time taken to perform a blood gas sample. Average time NIC = 60 seconds and standard connector = 61 seconds,  $P = 0.78$ . We can determine that the NIC is easy and quick to use, even when staff have not been formally taught by a research nurse.

## **5. Usability Study**

11 nurses were asked to compare the ease of use of the NIC against the standard connector. The mean visual analogue score was 1.12 compared to 1.41 for the NIC and standard connector respectively,  $P = 0.73$ . We can determine that there is no difference in using the NIC compared to the standard connector.

## **6. Implementation Data by Region**

The awarded funding for this study has allowed the improvement of arterial line safety in 11 Trusts for six months in the East of England. The funding body originally requested six study sites, however due to the popularity of the study, this was expanded to 11 Trusts. Therefore, not all Trusts will have completed a full six month study period. The results also show variation in the number of arterial lines placed per year due to the differing sizes of each ICU.

The implementation study has been successful. The NIC has been used in patients in 11 Trusts with the percentage use shown in table seven. The study period totalled 269 weeks (24 weeks on average per Trust).

The total number of arterial lines recorded during the study period was 3,421, of which the NIC was used on 2,881 of these lines. This gives an implementation rate of 79% across the region.

Four Trusts achieved an implementation rate of greater than 95% during the study period, four Trusts achieved >80% implementation and three Trusts achieved between 36-66% implementation. (Table 1, Figure 7).

### Limitations

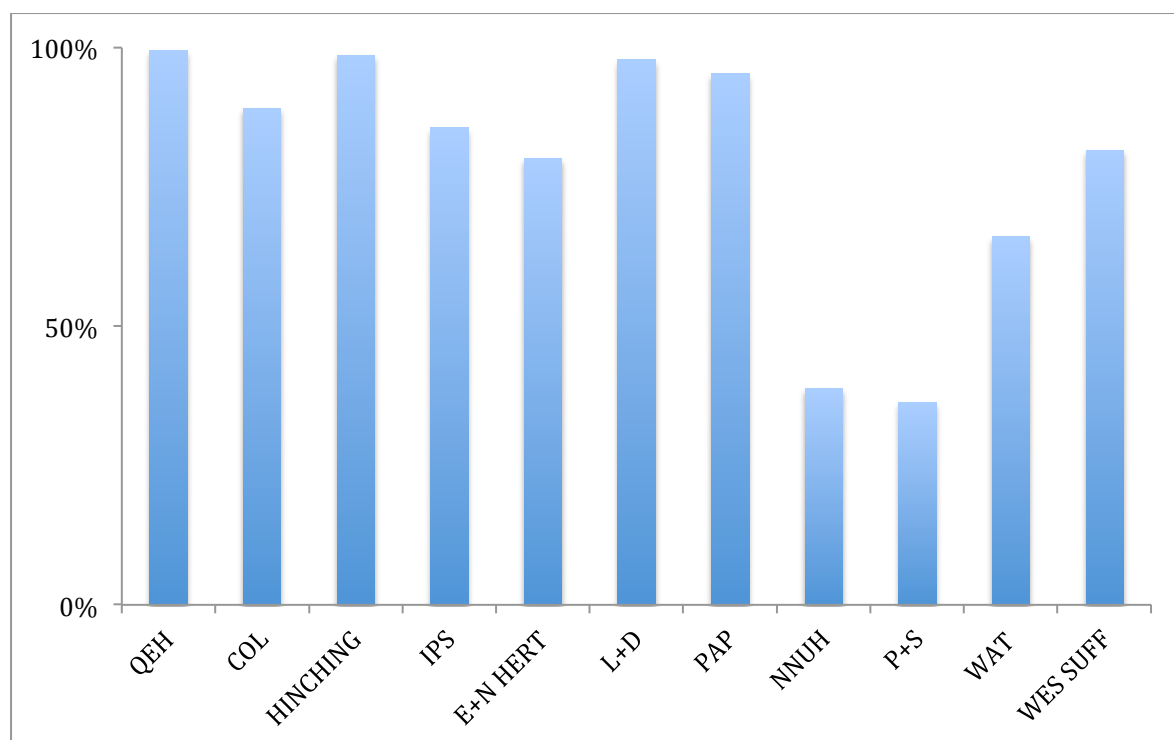
We can state this incidence of use is likely to be an underestimate. Data collection was performed only twice a week. The movement of patients through the ICU is more frequent than the data collection was capable of recording and arterial lines may be changed for various clinical reasons. Therefore, this data will not record exact numbers and will show an underestimated use.

These results are also dependent on data being collated accurately. Although, it was requested that data collection was completed twice a week over the study period, there were times when this was not done in some of the Trusts, mainly due to absence of the data collectors in the Trusts, during annual leave. NIC data could not be collected retrospectively, therefore again this data maybe an underestimate.

**Table 1: Showing the recorded no of arterial lines in the study and NIC usage.**

Trust	No of beds	No. of weeks	Total Number of arterial lines	No. of NIC used	No. of standard connectors used	Use of NIC over study period
The Queen Elizabeth Hospital	13	31	465	463	2	<b>99.5%</b>
Colchester General Hospital	14	15	189	168	21	<b>89.1%</b>
Hinchingbrooke Hospital	9	31	224	221	3	<b>98.6%</b>
Ipswich Hospital	15	18	228	197	31	<b>85.6%</b>
East and North Hertfordshire Hospital	20	24	268	215	53	<b>80.1%</b>
Luton and Dunstable Hospital	7	29	189	185	4	<b>97.8%</b>
Papworth Hospital	33	19	903	859	44	<b>95.3%</b>
Norfolk and Norwich Hospital	20	22	235	92	143	<b>38.8%</b>
Peterborough and Stamford Hospital	16	26	178	67	111	<b>36.3%</b>
Watford General Hospital	19	21	222	145	77	<b>66.1%</b>
West Suffolk Hospital	11	33	320	269	51	<b>81.6%</b>
<b>Total</b>		<b>269</b>	<b>3421</b>	<b>2881</b>	<b>540</b>	<b>79%</b>





**Figure 7: Graph showing percentage implementation of the NIC across the East of England.**

### *Implementation by Trust*

Individual Trust usage graphs are attached as appendix 5.

#### The Queen Elizabeth Hospital – 99.5% implementation

Implementation was 99.5% at this Trust. The connector was designed at the Queen Elizabeth Hospital and preliminary trials of the connector were performed at this Trust. Therefore implementation and use of the connector was easily achieved.

#### Colchester General Hospital – 89.1% implementation

The NICs were provided at the beginning of the study period. However, implementation was started later at this Trust than other study sites due to a requirement of the device to go through the new medical devices committee. This committee took 5 months to agree to allow the NIC to be used during the study period.

During this time on the ICU a junior nurse had near miss event where she attempted to give the medication Ondansetron into the arterial line. She was only stopped because a senior nurse spotted what she was doing and prevented her. This incident was entered into the Datix hospital reporting system. On further inspection it was found that there had been two previous incidents of accidental administration into the arterial line recorded at this Trust.

On implementation of the NIC and training in using the NIC, many of the nurses reported the near miss serious adverse incident to the research team. They were

keen to implement the NIC and explained that had they been able to implement the NIC sooner this incident could have been avoided.

Implementation of the connector was well achieved at this Trust and was well supported by the medical and senior nursing staff as, given their recent incidents, it was thought to be a good idea.

#### Hinchingbrooke Hospital – 98.6% implementation

The NIC study was a success at this Trust. During the training and study period staff were engaged and took full opportunity to use the device. Training and implementation was well supported by the senior nursing staff.

They have decided to continue to use the NIC after the study period.

#### Ipswich Hospital – 85.6% implementation

This study was successful at this Trust. On initial training to use the NIC, it was found that three different arterial line sets were used concurrently at the Trust. All of which required varying techniques and practices in order to be able to use and take samples from the arterial line. By participating in the study, the ICU were able to correct some technical issues and make their practice uniform. Use of the NIC was well implemented and supported by the senior nursing staff.

It was found that some of the NIC delivered to the Trust were out of date. Whilst this was being corrected, there was a gap in the use of the NIC, which reduced the Trust's rate of use.

#### East and North Hertfordshire Hospital – 80.1% implementation

This study was well implemented and supported by the senior nursing staff. Training was easy and feedback was positive. Staff felt that the NIC was easy to use.

#### The Luton and Dunstable Hospital – 97.8% implementation

This study was implemented by the professional development nurse and supported by the senior nursing staff. Staff were engaged and interested in the study. Training sessions showed the NIC was easy to use and no problems were reported during the study.

#### Papworth Hospital – 95.3% implementation

The NIC study has been successful at this Trust. The introduction of the NIC was co-ordinated, well organised and supported by the senior nursing staff. They have decided to continue to use the NIC after the study period.

A few issues were mentioned regarding the manufacturing of the NIC as a couple were easily damaged during use. This has been reported to the manufacturer.

#### The Norfolk and Norwich Hospital – 38.8% implementation

Implementation of the study at this Trust was difficult due to various reasons. Despite excellent engagement of the medical lead and local research nurse, there was substantial resistance from a few key senior nursing staff on the ICU which became embedded.

The initial training was well received, however, later it was found that staff were reluctant to use the NIC. On support visits to the Trust, it was found that the technique using the NIC was not correct leading to errors. This error was quickly addressed by the research team, however, there still remained strong resistance to using the connector.

On visiting the Trust and attending a senior ICU nursing meeting, it was established that a number of key decision making senior nurses thought that there was no need for the NIC, as they had never seen this problem previously and though the NIC was therefore not required. It was understood that this was at odds with opinion of the medical team.

At the meeting, it was stated that 'when the doctors go around and put on a NIC, we go around again taking them off and putting them in the bin.' In view of the strength of resistance, it was suggested that the study should be stopped early. However, senior nursing staff felt that they should continue until the end of the study period. There was some improvement in trialling the use of the NIC, however, the study was prematurely stopped 1 month prior to completion by the ICU.

Despite this some of the junior nursing staff stated that they did not have a problem with connector and would be happy to use it during the study period.

It appears that low implementation rate at this Trust, may have been due to interactions and differences of opinion between staff groups locally and a lack of confidence in the study. During the study set up, we as the senior investigators take a responsibility for failing to ensure initial approval to commence with the key senior nursing staff on the ICU. We think that this omission may have led to an entrenched resistance against the initiative.

A lesson we have learnt from this is that the implementation of patient safety devices at a ward based level may depend on individual personal opinions and interpersonal interactions and this may have a overbearing impact depending on the influence and authority of the individual decision makers.

#### Peterborough and Stamford Hospital – 36.3%

Implementation at this Trust not as successful as other Trusts. There are number of reasons as to why this might be the case.

Despite responses from the nursing staff showing that they liked the NIC, thought it was a good idea, and that it was easy to use, it was found that nursing staff needed to be reminded, each day the data was collected, to use the NIC as understandably, this was not the highest priority during their clinical practice.

However, the main issue at this Trust was organising the introduction of the connector, a fault of the central research team. It was later learned that some Trusts, in order to combat this issue, removed the standard connector completely, from the stock during the study period. In this way all nurses were

reminded to use the connector during the study period and this allowed a complete evaluation of the NIC to be undertaken.

Another reason for a lower implementation rate was incomplete data collection. There were large gaps in the data due to various reasons and therefore the reported use is likely to be lower than actual use.

#### Watford General Hospital – 66.1%

The training was easy to instigate and nurses seemed to find the NIC easy to use. There was good support from the senior nursing team.

Implementation in this Trust although lower than some Trusts, was successful during the study period. When we look at the graph (appendix 5) of usage in this Trust, when the data was collected here the percentage use on average was not low. The main reason for apparent lower implementation here is due to difficulties in data collection during the study period. As we can only base the usage on the data received, we have to report this figure.

#### West Suffolk Hospital – 81.6%

The NIC in this Trust was well received and the nurses were easily trained. There was senior support to introduce the NIC from both the medical and nursing sides.

One issue that the Trust had with data collection, was that one of the data collectors started pressing the wrong button on the app which meant the implementation rate became 0%. However, as the study group were checking the data on a daily basis, we were able to address this problem quickly and able to correct the data on the final results. This highlights the importance of checking the data on a daily basis to ensure appropriate data is collected.

## **7. Regional Survey Results**

A survey of the healthcare staff, nurses, doctors and operating department practitioners, using the NIC was conducted. 258 people responded to the survey across the region and it has been found that the NIC is well liked with some Trusts continuing to use the NIC after the study period.

98.0% of health care staff surveyed believed it was important to have a device that prevented wrong route drug administration and prevent arterial line infections. 94.9% believed it was important to prevent blood spillage during sampling.

28.0% of respondents said they have personally seen adverse events in their routine clinical practice when using standard arterial lines in the past and 93.0% believe these would have been prevented had the NIC been in use. Most commonly these were: accidental administration of medication into the arterial line, three way tap accidentally left open and patient bleeding, re-attaching the wrong lines after the patient is moved.

81.0% wanted to use the connector after the study was completed and they felt that this was due to both ease of use and to promote patient safety.

70.9% believed that simply using the standard connector was enough to identify an arterial line. However, 96.5% of staff said the NIC allows increased identification of the arterial line and >80.0% said that the NIC was easy to learn and use and compatible with standard arterial line equipment.

73.5% stated that using the NIC is no different in terms of nursing procedures to using the standard connector, which supports the time and usage data from our study.

61.2% said that the NIC was a workable size, however, 35.0% believed it is was too big and easy to grab by confused patients. 85.2% of staff mentioned that the NIC was easy to remove from the three-way tap and 80.6% of staff preferred this.

22.0% mentioned problems with the NIC, this was most commonly that the connector developed blood clots and that there was some blood spillage during sampling. This was addressed by ensuring that the nurses were flushing the line appropriately and that care was taken when the syringe was inserted and removed to prevent spillage.

84.4% believed that the study and use of the connector was well explained and was easy for them to understand their use. Only 66.0% of staff believed that they were supported by the research team, and most said that they were taught by their own research nurses, professional development nurses and senior sisters, who were in turn supported by the research team. However, this highlights the ease of learning and use of the NIC.

## **8. Health Economic Evaluation**

Independently commissioned from Anna Crispe, a Health Economist with a background in clinical and managerial critical care practice.

### Introduction and Summary

It is estimated that there are 1 million arterial line connectors used in the UK annually, with 8 million in the US and 10 million across Europe. This paper summarises the findings of a study funded by the Eastern Academic Health Science Network to assess the clinical benefits and cost effectiveness of introducing a new type of non-injectable connector (NIC) for arterial lines. 11 Hospital Trusts in the East of England Region took part in the study, which ran over a period of six months.

The cost-effectiveness of the NIC was assessed by considering:

- The staff time required to use it, compared to current connectors;
- The process steps required to use the NIC;
- The additional consumables used in conjunction with the NIC and with current connectors;

- The potential costs of erroneous injections into arterial lines, avoidable with the NIC;
- The potential costs of arterial line-associated bloodstream infections, potentially reducible with the NIC.

The NIC was found to save staff time, and reduce the process steps required to sample arterial blood gas. A small increase in the costs of associated consumables was observed, but this is not required as part of the NIC in-use protocol. As the NIC does not have to be changed with every sample taken, although its unit cost is higher, at the level of cost per bed day it is cheaper than current connectors, and because of this, its use would save critical care units money over the course of a year. The NIC completely prevents any accidental injection into an arterial line, an occurrence, which although rare, can lead to significant, lasting harm to patients, and additional healthcare costs of several thousand pounds per patient. Finally, an estimate was made of the current costs of arterial line-associated bloodstream infections, which the NIC is studied to reduce; this has the potential to reduce costs substantially.

#### Purpose of the Non-Injectable Connector

Patients in critical care often require arterial access lines to provide beat by beat blood pressure monitoring, blood samples, and to facilitate the collection of numerous and repetitive arterial blood gas readings. The use of arterial lines therefore provides numerous clinical benefits, but is also associated with a number of problems.

These include:

- Accidental injection of medication intended for intravenous administration into the arterial line, with the potential to cause serious damage to the vessel and surrounding tissue, and wider systemic harm to the patient;
- The arterial line becoming colonised with bacteria, and acting as a source of catheter-associated blood stream infection in patients;
- Blood loss from the three way tap during sampling, posing infection risk for healthcare staff (seen more commonly with junior medical staff, not often with nursing staff)
- Complex processes involving numerous steps and other consumable equipment to use the line safely, which may have to be repeated up to four times a day for every patient

The non-injectable connector (NIC) has been designed to address these areas of risk, and improve patient safety in the critical care environment.

#### Assessing the Cost-Effectiveness of the Non-Injectable Connector

The non-injectable connector has been piloted in 11 Trusts in the East of England over a period of seven months during summer 2014 to January 2015.

This has allowed the direct assessment of a number of aspects of cost-effectiveness, including the cost of the device itself, other consumables which are required to be used in conjunction with it, the impact of the device on staff time and the processes staff are required to follow to ensure safe practice, and the views of staff as to its possible advantages, disadvantages and usability. In addition, risk databases in the pilot Trusts have been interrogated for information on accidental injections into arterial lines, a clinical simulation has been conducted to assess the likelihood of accidental injection into the arterial line when under pressure, and a national survey has been conducted exploring the observed incidence of this event. Finally, the literature on the incidence and cost of arterial line bloodstream infections has been reviewed and used to calculate a possible cost of these events in the East of England. This report analyses much of that data, and provides an assessment as to whether the NIC is likely to be cost-effective in use in the NHS. A number of categories are considered in detail below: staff time; process and consumables; the prevention of error; and the prevention of infection.

### Staff time

New medical devices can face a barrier to adoption if they require significant increases in staff time to operate. Staff time, particularly in a high cost setting such as critical care, is at a premium and must be used effectively. For the NIC to be cost-effective in terms of staff time, it must therefore be possible to perform standard tasks in the same amount of time currently taken (cost-neutral), or in less time (cost-effective).

A study was undertaken to ascertain whether the NIC made a difference to the amount of time it took staff to complete a common task involving the arterial line, withdrawing arterial blood for sampling. Nurses were asked to complete this task while being timed and observed. In a unit where the NIC has been in use for several months, 10 nurses were asked to perform an arterial blood gas sample with a dummy arm using the NIC to sample. The nurses were asked to repeat this process with a standard arterial connector. The mean and median times for the observations including NIC, and for those without NIC, were calculated.

The differences in timing were compared. Separate data was gathered on the nursing skill mix of the critical care units in the NIC pilot, focused particularly on the proportion of band five and band six nurses. Different units in the study have different skill mixes between band five and band six staff, and a slight difference was found between the time taken by band five and band six staff to complete the procedure, so this was factored into the analysis. The cost of Band five and Band six nursing time was calculated using the hourly costs by band, including training, published by the Personal and Social Services Research Unit for 2013.<sup>9</sup>

The observations showed that the procedure using the NIC was, on average, two seconds faster than using other connectors. At a unit level, assuming 16 critical

care beds and each patient having four arterial blood withdrawals per day, this could save 10 hours of nursing time over the course of a year. Using the regional average skill mix between Band five and Band six staff, this translates into cost savings of £1,091 over the year, and savings for the whole region of £20,560 over a year.

It is important to note that these savings are most likely to be in the form of “opportunity costs” – i.e. the time taken to complete arterial blood withdrawals cannot be spent on other tasks, or “opportunities”. Those foregone opportunities represent the “opportunity cost” of the task. Reducing the time required to complete an individual task is therefore unlikely to result in cash savings for a Trust, as overall staff numbers cannot be reduced on this basis, but it will release time for other activities, be that patient care, training and education or perhaps audit to support service improvement. These are all valuable activities in the context of critical care nursing staff.

On the basis of the observational study it appears that use of the NIC will be cost-effective with regard to staff time, as the time taken to complete the most common task using an arterial line was reduced by 10 hours per unit per annum, on average.

#### Process and consumables

It was also important to measure whether use of the NIC also required the use of other consumables which would add to the overall cost of the procedure. To assess this, all the Trusts in the pilot were asked to map the process they would use to complete an arterial blood gas sample using a giving set with a NIC connected; and a giving set with a standard connector. Each process step taken was recorded, along with any additional consumables required for each step. These additional consumables were then costed.

The process maps from the 11 pilot Trusts showed some variation both in the process steps taken during this task, and in the additional consumables used. Analysis of the results indicated that using the NIC reduced the mean number of process steps to 17, compared to a mean of 19 for the giving sets not using a NIC. This could have implications for increased patient safety, as reducing the length and complexity of care processes generally decreases the possibility of infection, inter-operative process variation, and process error.<sup>10</sup>

The results also demonstrated that 0.7 fewer additional consumables per procedure were required when using a NIC. This was not however reflected in the costs of additional consumables, which were increased by a mean of £0.90 per bed per year when the NIC was used, assuming four blood gas samples per patient per day. The main reason for this slight cost increase is the use of a 5ml syringe in conjunction with the NIC, whereas previously a 10ml syringe was typically used, which increases the overall costs by a small amount. For an average unit with 16 beds, this will increase costs by £14 per year. There is no reason why this larger and more expensive syringe should be used with the NIC,



so this apparent cost increase could be reversed with further training and clearer guidance on product usage.

Set against this are the costs of the NIC itself. Data gathered from the pilot Trusts indicates that the standard connectors in use prior to the NIC study cost between £0.04 and £0.79 each, with a mean cost of £0.18. A non-injectable connector currently costs £2.00, a price that may fall once the connector is being produced at volume. Using the current price, it can be seen that a NIC costs an additional £1.82 in comparison to the mean cost of a standard connector, but a NIC can remain in situ for 72 hours, and only requires changing at the same time the whole giving set is changed. Standard connectors are replaced every time a sample is taken, which occurs on average four times per patient per day. Over the course of one week, 28 standard connectors would be used, at a mean cost of £0.18 each, giving a total cost of £5.04, £0.37 higher than the comparable NIC costs over the same time period. Across a region such as the East of England, with 277 arterial line beds, this could save approximately £5,400 per year, or £299 per average Trust. This saving clearly outweighs the additional £14 per Trust per year required for additional consumables, giving a net annual cash saving of approximately £285 per Trust, or £5,100 per region. On this basis, the NIC is likely to be cost-effective in comparison to the use of standard connectors and associated consumables.

#### Prevention of error

The administration of medication via an arterial line is not advised, and almost never carried out because of the potential to cause serious harm to patients. This harm can include limb necrosis so severe that major amputations can be required. However, given the busy clinical environment usually surrounding a patient with an arterial line, the accidental injection of intravenous medication into arterial lines does sometimes occur.

Because the frequency of this error occurring is very low, any reduction in the risk of it occurring is difficult to value. Approaches such as calculating the number of NIC needing to be used to avoid a harm caused by error are not possible to employ without a valid initial estimate of risk.

Therefore, the study has attempted to assess the risk of these events occurring in a number of ways:

- A national survey of Consultant Anaesthetists and Consultant Intensivists was conducted, asking whether they were aware of unintended arterial line injections in their hospital in the last five years;
- A training simulation was conducted with junior medical staff being put into a pressurised clinical situation, and asked to inject medication intra-venously, with the IV line purposely hidden under the bed sheet.

The study has then gone on to estimate the direct healthcare costs of three known incidents involving an unintended arterial line injection, and a recommended care pathway for patients who have suffered in intra-arterial injection<sup>6</sup>:

- A near miss which occurred in a pilot Trust during the study period;
- An incident which occurred in one of the pilot Trusts, where the patient did not sustain lasting harm;
- An incident from the literature where the patient did suffer lasting harm.

Assessing the frequency of inadvertent arterial line injection is difficult; because it is much lower than 1%, the use of arterial lines is generally considered to be safe. However, the presence in the literature of recommended treatment algorithms for when such an event does occur, indicates that, while the event may be rare, it does happen.<sup>6</sup>

This finding is supported by the responses to a national survey of 55 Consultant Anaesthetists, and 56 Critical Care Consultants. 14.5% of the Anaesthetists stated that they were aware of such an incident in their Trust in the last five years; amongst the Critical Care Consultants, the proportion was even higher at 28.5%.<sup>7</sup>

One of the pilot Trusts conducted a simulation study, where 15 doctors were asked to look after a critically ill patient. The participants were suddenly stressed when the patient was given a bradycardia which they were instructed to manage. When asked to treat the patient, 15/15 elected to give atropine, however, due to the stressful situation 66% accidentally administered the medication into the arterial line, despite the presence of a red and clearly marked arterial line, a visible central line and partially hidden IV line. Perhaps even more worryingly, none of the doctors who made the error realised what they had done until it was pointed out to them, perhaps suggesting that these incidents are only recognised when witnessed by another clinician or when the patient complains of symptoms.<sup>8</sup>

Considering these three findings together, while it is not possible to estimate the incidence of this error from this data, they may indicate that it occurs more frequently than widely assumed.

Costing the consequences of this error also entails estimation. Three scenarios were developed from the risk reports from a pilot Trust, and from reported cases in the literature, and were then clinically reviewed: a “near-miss” in a pilot Trust during the study period where the injection did not actually occur; an injection which did occur in a pilot Trust and which resulted in transient harm to the patient; and a reported incident from the literature resulting in permanent harm to the patient concerned.<sup>11</sup> Using staff costs from the PSSRU, procedure and investigation costs from the 2014-15 National Tariff for England, and drug costs from the British National Formulary and the Pharmacy Department at one of the pilot Trusts, the direct additional healthcare costs of each scenario have been estimated.

The additional costs of the near-miss relate to the time taken to report and document the incident, and are estimated to be £57. The additional costs of the incident where the patient sustained temporary harm include additional time in critical care, additional medication, vascular surgery review and outpatient follow up, an ultrasound scan and additional nursing time. These costs are estimated to be at least £2,230. The third scenario, where the patient sustained lasting harm, includes additional medication, follow-up and review, and is estimated to have cost in excess of £4,000.

In addition to these costed clinical scenarios, it should also be noted that patients occasionally require an amputation after an inadvertent arterial line injection. Using the NHS England Reference Costs for 2013/14, it can be seen that the average unit price for an amputation of a single limb with a complication score of 1-9 (code YQ22B) was £10,174. Further critical care costs would be additional to this, as would the costs of follow up and rehabilitation for these patients, which can be substantial. So it can be seen that in the most serious cases, direct healthcare costs in excess of £10,000 per patient are likely to be sustained. These analyses also do not include the ongoing costs and dis-benefits to the patient concerned, which may be very high due to the permanent reduction in their quality of life.

When considering whether an intervention is likely to be cost-effective, the following calculation is often used: the cost of the error, multiplied by the likelihood of the error, indicates what level of spending would be cost effective to prevent that error. So we can see that for an error with healthcare costs of £10,000, such as an amputation, and a likelihood of 1/5000, it would be cost-effective to spend up to £1 to prevent that error; using the NIC actually generates savings of 16p per bed over a 72 hour period. As the data from the study does not provide us with a robust estimate of incidence, it is not appropriate to simply multiply the various estimates of incidence by the estimates of cost to assess the level of cost-effective spending on prevention. It can however be concluded that these incidents clearly do occur locally, and that the direct healthcare costs associated with them are likely to range from less than £100, to in excess of £10,000, per patient.

**All these incidents would be completely preventable if all giving sets used the non-injectable arterial connector. As demonstrated above, use of the non-injectable connector is also cost-saving, at a predicted level of £285 per year, per average Trust. Use of this device can therefore be considered dominant in health economics terms, as it delivers improved patient outcomes at reduced cost.**

#### Prevention of infection

The final area considered in relation to the cost-effectiveness of the NIC is that of infection prevention. While the incidence of blood stream infection related to a central venous catheter is well recognised, and widely measured and monitored, the incidence of blood stream infection associated with an arterial line is less

widely captured, mainly due to difficulties in the attribution of the infection. Lucet *et al.*, have published data suggesting that the infectious risk associated with arterial catheters is broadly equivalent to that of central venous catheters.<sup>3</sup> They reported colonisation rates of arterial catheters of 7.9% (11.4/1000 catheter days) and of central venous catheters of 9.6% (11.1/1000 catheter days). Infection rates were again similar, with 0.68% (1.0/1000 catheter days) for arterial catheters, and 0.94% (1.09/1000 catheter days) for central venous ones. Similar rates of colonisation (6%) have been found in a study at one of the NIC pilot Trusts,<sup>8</sup> and similar rates of infection are reported in a systematic review and meta-analysis of the prevalence of blood stream infections associated with arterial catheters.<sup>4,5</sup>

Catheter related blood stream infections have severe consequences, which can include, from the patient's perspective, an increased risk of mortality and morbidity. Complications can include site pseudoaneurysms, septic thromboarthritis and arterial rupture, and can require surgical intervention.<sup>5</sup> These patients correspondingly require considerably greater healthcare resources, with additional average costs of £10,593 per patient reported in the BMJ review of the "Matching Michigan" study,<sup>12</sup> additional costs in excess of £15,800 reported by NHS Patient Safety First,<sup>13</sup> and even higher additional costs of up to £37,900 reported in other studies.<sup>14,15</sup>

The design of the NIC means that it prevents bacteria from contaminating sampling lines downstream of the three-way tap, hence reducing the potential for infection.<sup>8</sup> While further work is required to evidence this theory, if correct, it would improve patient outcomes by reducing arterial line-associated bloodstream infections, and reduce the costs of these infections at the same time.

The impact of these cost reductions have been estimated for the East of England region, which contains 18 critical care units, using the incidence of colonisation and infection reported by Lucet *et al.*, and using an average of the additional costs per patient reported in the BMJ and by Patient Safety First. The data on the numbers of critical care beds and the prevalence of arterial lines for critical care patients were obtained from the study, and extrapolated to represent 18 units over the time period of one year. It has been assumed that use of the NIC reduces the reported incidence of arterial line-associated bloodstream infections by 25%.

On this basis, without use of the NIC, the East of England region can expect 34 patients to develop an arterial-line related bloodstream infection every year, costing over £444,000 per year in additional treatment costs and leading to a number of excess deaths amongst those patients affected. Assuming use of the NIC leads to a 25% reduction in the incidence of arterial-line related bloodstream infections, nine infections would be avoided each year in the region, saving £111,000, in addition to the clinical improvements realised.

Using the current reported infection incidence rate of 0.68%<sup>3</sup> and an assumption that that rate will fall to 0.51% with the use of NIC, it is possible to calculate the number needed to harm. Subtracting the control event rate (0.68%) from the intervention event rate (0.51%) gives a measure of the absolute risk increase

associated with not implementing the intervention. From this absolute risk increase, the number needed to harm (i.e. the number of patients who would need to be treated in the standard way for 1 to be harmed, compared to treating them using a NIC) can be calculated. For the infection rates being considered here, that number is 588. Given that an estimated 20,000 patients are treated using arterial lines in critical care units in the East of England every year, clearly that number is significantly exceeded, again suggesting that this intervention available at a marginal saving of £0.37 per bed, per week, is likely to be cost effective and dominant.

### Conclusion

The study has considered the whether the NIC is likely to be cost-effective in use in the NHS. Considering the East of England region, it is likely to be cost-effective in releasing staff opportunity costs in the order of £20,500 per year, which could be used for other purposes. It is also likely to be cost-effective in cash terms by reducing the requirement for additional consumables to be used in routine tasks, amounting to a saving of £26,000 per year. While the incidence of serious errors involving unintended arterial line injection is very low, the study has demonstrated that such events do occur, and that they can entail significant healthcare costs and harm to patients, which would be entirely prevented by the use of the NIC. In addition, the NIC is likely to be cost-effective in avoiding a proportion of arterial catheter-related blood stream infections, saving the region £111,000 every year in costs driven by arterial line related infections. On this basis, the use of the NIC is considered likely to be dominant in health economics terms, in that it delivers improved outcomes at lower overall costs, at both a unit and regional level.

## **Barriers to adoption encountered during the study**

### *Implementation*

Implementation was mainly successful. However, there were some barriers to adoption encountered in some of the Trusts.

All hospitals in the region were invited to participate. In those Trusts that did not participate in this study, the ICU leads felt that accidental administration into the arterial line was not a problem at their hospital. It is likely that this is because it was a problem they had not personally experienced previously. This is a typical human factors error when considering rare events, which are uncommonly seen by individuals during their everyday practice, but which do occur frequently across healthcare systems.

From the preliminary data and national survey, we see that accidental administration of medication via the wrong route does occur, and more commonly than reported.<sup>7,8</sup> We know that the numbers reported in our national survey is dependent on the recollection of a single person, from this we can say that the result is an underestimate. Therefore, implementing a safety device in a hospital should not be dependent on the opinion of a single person, but on the recommendations of a relevant group, such as the vascular access or patient safety group.

During the pre-implementation phase, in a single Trust (whilst they were clarifying the need in their setting), a near miss wrong route serious adverse incident occurred in the ICU. Following this, on inspection of local error reporting at the same Trust, 2 previous wrong route arterial serious adverse events were found to have been internally reported. Despite previous instances of error, the Trust took 5 months to approve the NIC, a certified device that was already used in the NHS. Measures should be taken to speed up adoption in individual Trusts, when certification and approvals are already in place in the wider NHS.

Another barrier to adoption is the cost of new technology. Patient safety should be paramount in the NHS. When devices are also proven to be cost effective, this should remove the barriers to adoption. The independent health economic analysis has shown that the NIC is cost effective and improves patient safety.

With some medical equipment or innovation, implementation via a grass roots method is important to enable individual users to determine whether its use is appropriate for clinical practice in their environment. However, in terms of patient safety, every individual clinician should not have to personally experience a serious albeit rare complication before changing their practice, if the problem has been identified on a wider scale throughout the NHS. Therefore in terms of rare and serious events, we believe there is a requirement for national leads to support and encourage best practice.

## **Problems encountered during the study**

### *NIC*

One reason for poor implementation in some Trusts was due to an un-unified introduction of the NIC. This is the fault of the research team. Although attempts at this were made, there were unforeseen barriers and differences in clinical practice between Trusts, which prevented this. These lessons have now been learnt, and will be utilised during wide scale adoption.

Some of the NICs delivered to some of the hospital were out of date. This therefore led to a pause in the study, and staff reverted to previous practice until new NICs were delivered. This problem caused a drop in the percentage implementation. After discussions with the manufacturer, it was found that newly created devices have an initial shelf life of 6 months. Once the devices have passed tests for prolonged periods of time, the shelf life can be extended. The NIC will now have a longer and more appropriate shelf life.

Some nurses mentioned that during clinical use, the NIC developed blood clots and that there was some blood spillage during sampling. This was addressed by ensuring that the nurses were flushing the line appropriately and ensuring that care was taken when the syringe was inserted and removed to prevent spillage. This information has also been relayed to the manufacturer.

### *Data Collection*

The data collection was made as simple as possible and was done in a way that would not greatly inconvenience staff, but would still allow the appropriate data to be collected. The greatest difficulty was collecting data when the main data collectors were unable to do it, such as when they were on annual leave. As this data cannot be collected retrospectively, we found that this led to gaps in the data collection.

## **Lessons learnt from the study**

For this study, we found that Trusts that had strong support from the senior nurses also had a higher implementation rate. If this study were repeated, the senior nurses, research nurses and professional development nurses in the ICU would be engaged and taught how to use the connector first. When they are taught and trained, it is much easier for them to teach the other nurses that work on the ICU. An average ICU would have minimum of 40 nurses, and it was impossible for one research nurse to teach every nurse how to use the NIC. Therefore the best way to increase adoption, for this study, was to use the senior nursing network to support the new device, particularly the research and professional development nurses. As mentioned in the last section, the study team now has a better understanding of the barriers to adoption and potential differences in practice, to allow a more uniform approach to adoption as we seek to do this nationally.

At the start of the study, initial contact and explanation of the study should have included the vascular access groups, infection control groups, patient safety lead and the new medical devices committee, as well as the chief executive, nursing director, medical director and ICU leads. It is therefore, a recommendation of this report that CEOs of individual Trusts cascade their recommendations to these groups.

The success of the study depends on the work of many individuals across many different Trusts, it is important to ensure that data collectors have a real stake in the outcome, feel genuinely appreciated, can share in the credit and enhance their own careers as a result. We therefore credit all data collectors for the study at the beginning of this report and will be returning their data to them allow local presentations of their work.

It is also important to ensure that the data collection is monitored on a daily basis to address problems and issues that may arise from the Trusts. These issues need to be addressed quickly, which may be done by a telephone call or a visit to the hospital in order to manage problems, so that the study site feels supported.



## **Patient Feedback**

The NIC is used in patients in ICUs and operating theatres. These patients are often anaesthetised and unconscious, and therefore will not be aware of the device.

In order to seek patient's opinions on the NIC, we presented this work to the members of the East of England Citizens' Senate. Once the role of the device had been explained to them, we asked whether:

1. they would want the NIC to be used in the ICU and operating theatres for their benefit and that of their family;
2. whether they would give their opinion of the device.

100% of respondents (13/13) strongly agreed that the NIC should be used in ICUs and operating theatres for their benefit and that of their family.

Respondent's feedback were as follows:

***"Excellent idea, feel confident this would benefit my family, myself and the NHS"***

***"Not using this device would seem like folly."***

***"This device is critical to patient safety. We must collectively influence the commissioners to invest in this."***

***"This is clearly a device which increases patient safety and prevents an injection of noxious agents intravenously."***

***"A wonderful idea that removes all the risk of injecting into an arterial line"***

***"Seems desirable for patients. Bring it on!! How can we help spread the word as it is hard to reach procurement level in Trusts?"***

***"Why oh why is this not part of normal practice? As much patient voice should be used to pressurise CCGs and Trusts etc."***

***"Making mistakes impossible keeps people alive and reduces cost per episode."***

***"From what I have heard today, it is essential to good practice and economy."***

***"NIC is highly innovative of 1<sup>st</sup> stage design to alleviate costs to problems caused commonly in ICU situation and which improves patient quality of care"***

***"Appears to be good value for money and increased patient safety"***

## **Conclusions**

We are grateful to the EAHSN for funding this study, and believe the EAHSN has made a tangible difference to the progress of eliminating a wrong route drug error in the Eastern region, the NHS, and indeed world-wide.

This study has been highly successful. It has confirmed the need for, and identified a solution to a wrong route drug administration serious adverse event affecting many patients across the NHS.

The study has enabled a controlled implementation, showing both usability and efficacy, both clinical and cost, of a new, innovative, engineered, patient safety solution that has arisen from grass roots innovation within the NHS. This study has demonstrated benefits to patients and staff, through the improvement of practice and the development of a patient safety network, ERIN.

With the help of the EAHSN Board, the NIC now has the potential for widespread implementation across the UK, thereby eliminating a serious adverse event from the NHS. This would be a springboard to eliminating this serious adverse event internationally thereby improving patient safety and creating wealth in the UK, in accordance with national policy as documented in, Innovation for Health and Wealth (2011).<sup>16</sup> The NIC is manufactured by Amdel Medical, a UK company. The Queen Elizabeth Hospital NHS Foundation Trust and Health Enterprise East, the NHS Innovation agency, manage the IP under a revenue share arrangement with the inventors, Drs Young and Carter.

The final phase of the study involves coordinating recommendations through the EAHSN Board, with NHS England, Patient Safety groups, other AHSNs, directly to CEOs in the region and other appropriate bodies.

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## **Appendix 1: National Survey Questionnaire**

Name  
Job title  
Hospital  
Address 1  
Address 2  
Address 3  
Address 4

Xth June 2014

Dear Colleague,

Thank you for completing this survey concerning your department's experience of specific never events.

The aim of the survey is to elucidate whether these events are nationally under-reported. All responses will of course be treated confidentially.

We would be grateful if you could answer the following questions and return the completed form in the stamped addressed envelope provided.

1) In the last 5 years are you aware of any unintentional arterial line injections occurred in your hospital?

- Yes  
 No

Many thanks for your time.

Kind regards,

Peter Young

## Appendix 2: Research Programme

# Eastern Research and Innovations Network

## Academic Health Science Network Patient Safety Projects

2<sup>nd</sup> April 2014  
BMA House, London

### Programme

10:00-10:15: Registration and Refreshments

10:15 – 10:30: Introduction – Dr Peter Young

10:30 – 11:00: Prevention of VAP: Implementing subglottic secretion drainage – Dr Peter Young and Dr Gayathri Wijewardena

11:00 – 11:20: Drug trolley Security: Introducing the Limpet Alarm – Dr Maryanne Mariyaselvam

11:20 – 12:00: Preventing accidental intra-arterial injection: Introducing the Arterial Non-injectable Connector – Dr Joseph Carter

12:30 – 14:00: Lunch

14:00 – 16:00: Practical Sessions – Dr Mark Blunt and Dr John Gibson

- Demonstrating data collection methods
- Questions/Discussion
- Confirming contact details



Approved by the Royal College Anaesthetists 5 CPD Credits

**Appendix 3:****Needle-Free Non-Injectable Connector (NIC) for Arterial Luer Hubs**  
**Instructions for use.**

Product part number :- AMD0031086.

Ensure that the Non-Injectable Arterial Connector (NIC) is only applied to arterial systems – it will prevent injection and therefore should not be used for intravenous connections. There is a semi-irreversible connection once the NIC is attached which will make it difficult to remove reducing the chances of inadvertent intra-arterial injection.

**Description/indication,**

The NIC is a device which, when connected to an Arterial Line via the sampling port of a three-way tap allows for blood samples to be taken, whilst:

- **Preventing intra-arterial injection**
- **Reducing the chance of transmission of microbial contaminants into the patient**
- **Simplifying the process of blood gas sampling from an arterial system**
- **Minimising accidental blood spillage and arterial bleeding from the hub**

**Where to Put the NIC**

1. Normally the NIC is placed on the three-way tap close to the patient.



2. For additional safety another NIC can be placed on the female luer hub at the arterial transducer pinch valve.



This may be desirable when there is difficult access to the patient (i.e. under drapes in the operating room) and the anaesthetist may be at risk of accidental injection into the arterial transducer pinch valve hub when the intention is to administer the injection through the central venous transducer pinch valve hub.

#### Applying the NIC

Remove the NIC from the packaging.

Remove the cap from the three-way tap that is provided with the transducer set.



Place the NIC onto the female luer connection of the three-way tap (the directional arrow on the Arterial Connector will point AWAY from the three-way tap).

Once in place turn the NIC clockwise until a secure attachment is achieved.

Check that the NIC is not easily removed with finger grip alone – if it is tighten further (with the assistance of forceps if necessary) to achieve sufficient grip onto the luer port.



### Disinfection

Prior to placement of the NIC the female luer hub of the three-way tap should be disinfected according to hospital policy (this commonly involves wiping with an approved disinfectant agent wipe)

Tighten the NIC on keeping the fluid path sterile.

Disinfect the Arterial Connector during use as per hospital policy (note that the NIC provides an additional antibacterial barrier to the arterial flush system and in laboratory studies it was not possible to introduce bacteria into the three-way tap during normal use).

### Sampling

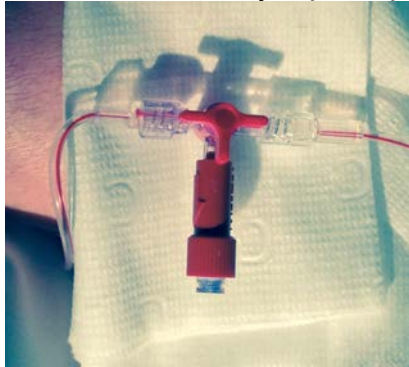
Blood should always be treated as infection risk to staff and precautions taken regarding splashing and contamination as per hospital policy. Protective attire should be worn such as gloves and eye-wear. When syringes are connected and disconnected a gauze swab or similar should be used to cover the disconnection site to prevent accidental splashing of blood. All blood should be disposed of safely as per hospital policy.

Equipment:

1. Discard/dead-space syringe - 10 ml luer syringe (luer-lock recommended)
2. Arterial blood sampling syringe - commonly 2ml luer syringe

### **Technique**

Turn the three-way tap to open to the NIC.



Place the discard/dead-space syringe over the sampling port of the NIC arterial connector, apply pressure to connect the luer tip through the blue stop-valve. Turn in a clockwise direction if a luer-lock syringe is used.

This will allow entry into the port and compress the silicone seal.



Withdraw dead-space and waste blood from the system using clinical judgement (normally approx. 5mL to achieve an undiluted sample).



Disconnect the discard syringe and connect arterial blood sampling syringe.

Aspirate required sample(s) into the blood sampling syringe(s).



To flush, connect the same discard/dead-space syringe if sufficient capacity remains for flushing (e.g. 5 mL) or a new discard/dead-space syringe to the NIC.

Flush the arterial system with approx. 5mL of fluid from the pressurised bag using the transducer pinch valve. This will fill the discard/dead-space syringe.



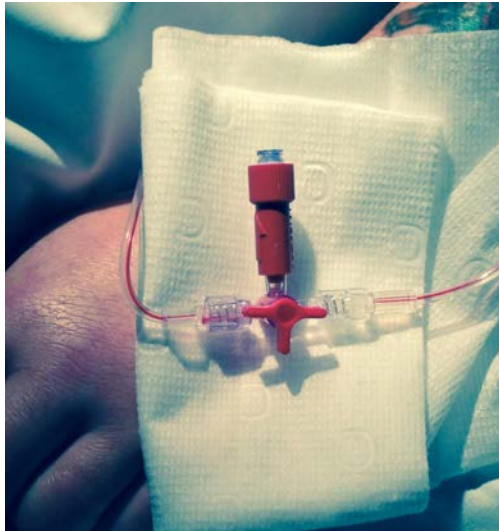
Before it is full, remove the discard/dead-space syringe and dispose of it.



Flush transducer pinch valve to clear the tubing of blood (into the patient).



Return the three-way tap to OFF to close the NIC.



### Removing the NIC

Note that the NIC is intended to reduce the risk of inadvertent arterial injection when it is correctly fitted. If removed the luer hub is no longer protected against injection and bacterial colonisation

Removing the NIC is possible and desirable in some situations, for example:

1. If manual flushing of the line with saline is required this can be done preferably from the transducer port but also by removing the NIC temporarily.
2. For calibration of cardiac output devices

### Procedure

Tight gripping of the NIC may result in removal if sufficient force can be generated

Suitable metal forceps may be used if this is not possible.

Aseptic technique should be used as per hospital policy to avoid contamination of the hub or the sterile portion of the inside of the NIC.

Replace with a new NIC if the NIC is de-sterilised or damaged during the removal process.

### When to change the NIC

The NIC can be changed when the arterial transducer set is changed.

### Precautions,

Use NIC only with Arterial pressure monitoring systems.

**Single use only. Do not re-sterilise or re-use.**

Do not use needles with the NIC.

Do not use if the packaging is damaged, this could compromise device integrity and/or sterility.

Do not use after the use by date.

Do not use the product if it is damaged upon opening of the packaging or during use.

## Appendix 4: Regional Survey Questionnaire

1

### Evaluation of the Non-Injectable Arterial Connector

**Thank you for your support in trialling the NIC connector. For the final part of the study, please could you take the time to fill in this survey. All your responses are anonymous.**

The National Patient Safety Agency reports that sampling errors occur due to problems when “taking and managing the sample, contamination by inadequate flushing and confusing arterial with venous lines.”

Therefore

“arterial infusion lines must be clearly identified. This means labelling or use of other safety solutions such as marked red lines thought out the line.”

Given the above statement:

#### Appearance

1. Do you think your previous arterial sampling set was adequate enough to identify it as an arterial line?  Yes  No
2. Does the appearance of the NIC connector allow you to visually differentiate it from a venous connector or any current standard arterial connectors (red or white: universal plug, comb lock, swan lock)?  Yes  No
3. Do you find that practically the NIC connector is  Too big  Too small  A workable size

#### Using the connector

4. Did you find learning to use the NIC connector  Easy  Intuitive  Difficult
5. Do you find taking a blood sample with the NIC connector  Easy  Difficult
6. Compared to the previous method, is using the NIC connector  Easier  Harder  No difference
7. Compared to the previous method, is using the NIC connector  Faster  Slower  No difference

#### Connector qualities

8. Are you aware that the NIC connector:
 

Prevents accidental administration of medication into the arterial line?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Do you think this is important?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Prevents bacterial contamination of the arterial line?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Do you think this is important?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Prevents blood spillage during arterial line sampling?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Do you think this is important?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
9. Do you find the NIC easy to use with your standard arterial line equipment?  Yes  No
10. Do you find the NIC connector easy to remove?  Yes  No
11. Would you prefer to be able or unable to disconnect the NIC from the three way tap?  Able  Unable

PTO

**Adverse Events**

1. When using the previous arterial connector, are you aware of any adverse events that occurred with the arterial line? Yes No

12a. Please describe the event \_\_\_\_\_  
\_\_\_\_\_

12b. If Yes, do you think using the NIC connector would have prevented this incident? Yes No

2. When using the NIC connector have you **personally** experienced any adverse events? Yes No

13a. If Yes, please describe: \_\_\_\_\_  
\_\_\_\_\_

3. Are you aware of any adverse events using the NIC connector that **your colleagues** have experienced? Yes No

14a. If Yes, please describe: \_\_\_\_\_  
\_\_\_\_\_

**General comments**

4. Do you have any suggestions for improvements for the NIC connector?  
Appearance \_\_\_\_\_  
\_\_\_\_\_

Usability \_\_\_\_\_  
\_\_\_\_\_

Function \_\_\_\_\_  
\_\_\_\_\_

5. Was the science and reasoning behind the NIC adequately explained? Yes No

6. If given the choice would you continue to use the NIC connector? Yes No

17a If Yes, is this to Promote Patient Safety Ease of use Both

7. Are you Medical or Nursing Staff?

8. Do you feel you have been supported by the research team during the study? Yes No

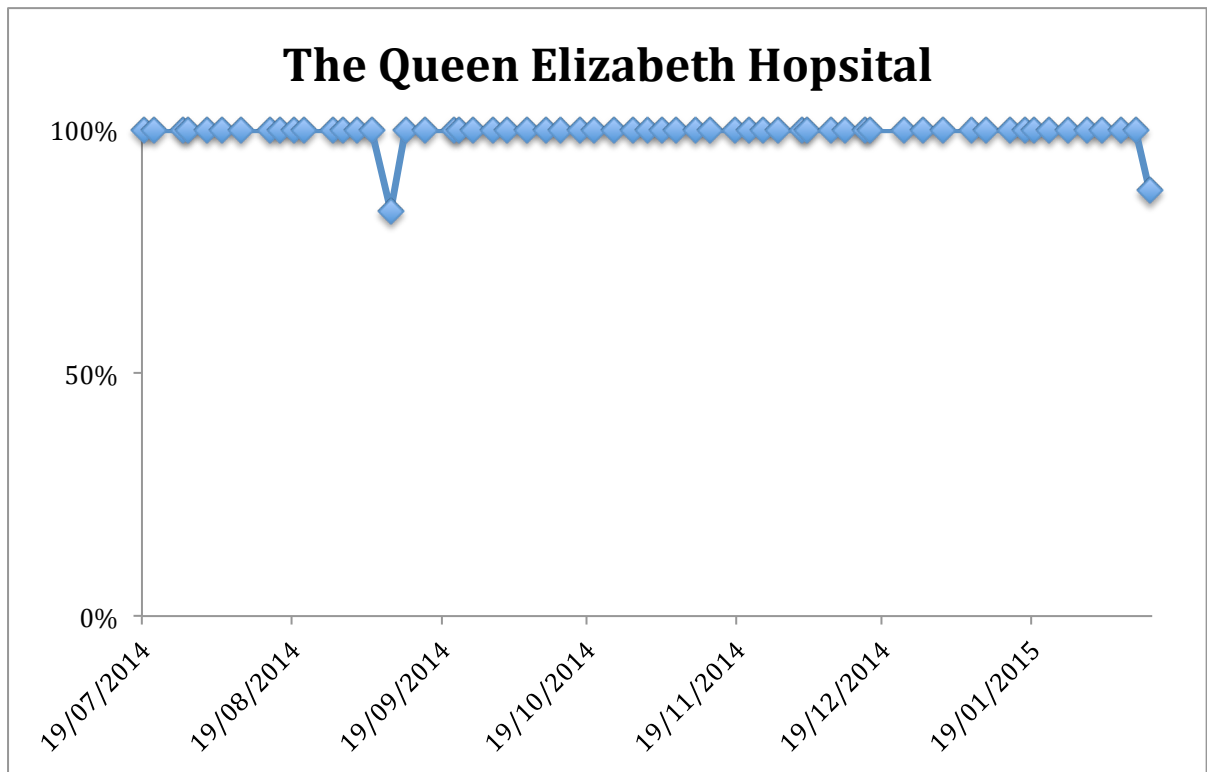
19a. If no, please give any suggestions for improvement \_\_\_\_\_  
\_\_\_\_\_

9. Do you have any general comments about the connector or the study that have not been addressed above? \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Thank you for taking the time to complete this survey, your feedback is valuable and will help to develop and continue the work on the NIC connector.**

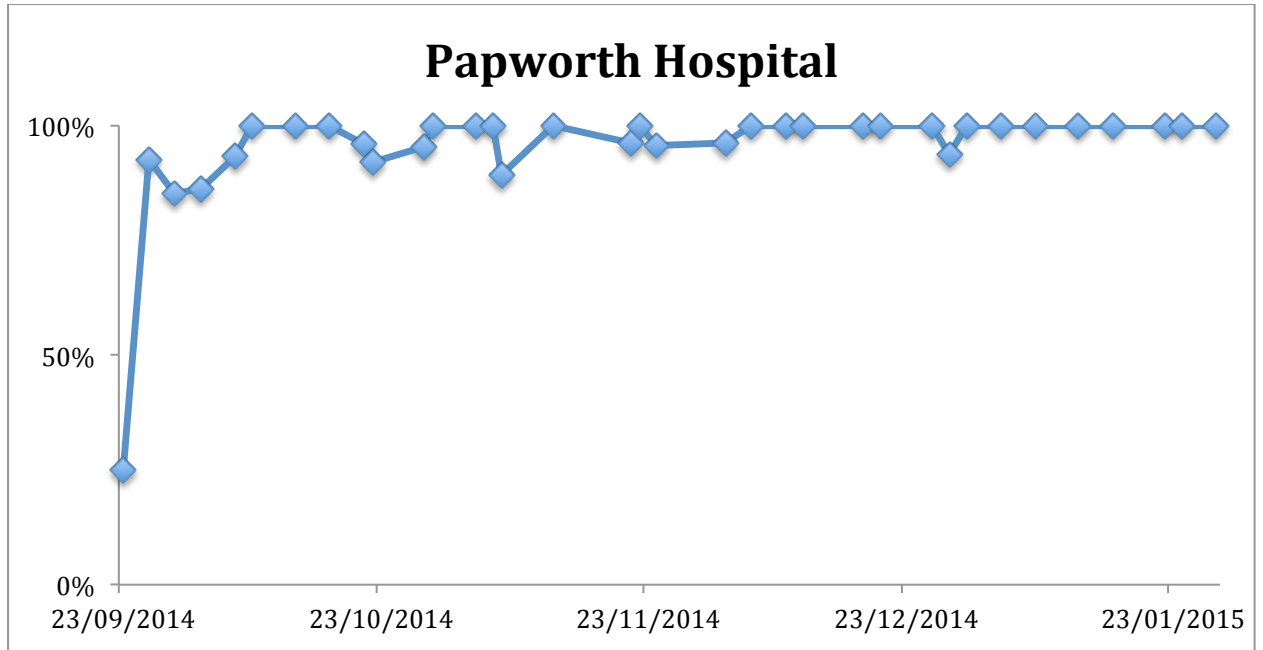


**Appendix 5: Individual implementation data by Trust.**

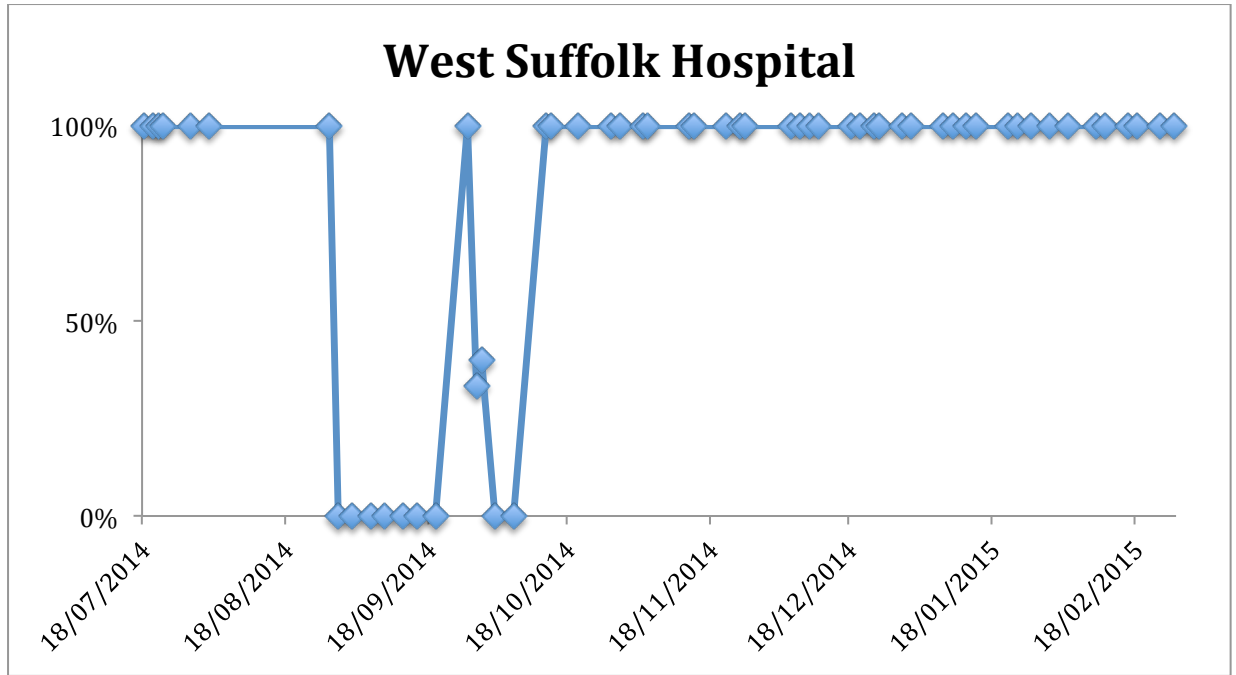












## **Appendix 6: Promotion of Work: Awards, Publications and Presentations**

This research has been promoted and presented at international, national and regional conferences in order to improve arterial line safety.

### Awards

2015 Winner, Association of Anaesthetist of Great Britain and Ireland Innovation in Anaesthesia, Critical Care and Pain Award: The NIC

2012 Winner, National Patient Safety Award Safety Arterial Connector

2009 Winner, NHS Innovation Competition, Health Enterprise East

### Publications

M Mariyaselvam, R Heij, D Laba, J Richardson, E Hodges, C Maduakor, J Carter, P Young. Description of a new non-injectable connector to reduce the complications of arterial blood sampling. *Anaesthesia* 2015; 70(1): 51-55

M Mariyaselvam, E Fawzy, P Young. Innovation in the NHS. *Anaesthesia News. The Newsletter of the Association of Great Britain and Ireland* May Issue, 2015; No.334, ISSN 0959-2962

### *Abstracts*

M Mariyaselvam, A Hutton, P Young. Accidental intra-arterial injection: an under-reported preventable never event. *Critical Care* 2015; Supplement A441

M Mariyaselvam, G Wijewardena, A Hutton and P Young. Complications of accidental intra-arterial injections *Anaesthesia* 2014, 69(Suppl. 4), 11-88. No 136, p78

M Mariyaselvam, R Heij, D Laba, J Richardson, E Hodges, C Maduakor, J Carter, P Young. The Problems of Arterial Cannula Sampling: Introducing the Non-Injectable Connector. *BMJ Quality Improvement Reports* 2014; Volume 3, Agents for Change Supplement.

D Laba, M Mariyaselvam, R Heij, P Young. Introducing an arterial non-injectable connector into clinical practice *Critical Care* 2014, 18: Supplement 1:P88

James Richardson, Maryanne Mariyaselvam, Chinedu Maduakor, Richard Windsor, Emily Hodges, Peter Young. The non-injectable connector: a novel solution preventing bacterial contamination of arterial lines. *Journal of Infection Prevention*. 2013, 14: S3. Abstract ID: 2574, pS35

### Presentations

*Invited Speaker Presentations**National*

M Mariyaselvam, The Non-injectable Arterial Connector. Innovation Prize Presentation. Association of Anaesthetists of Great Britain and Ireland Winter Scientific Meeting, QE2 Centre, Westminster, London, January 2015

M Mariyaselvam, The Non-injectable Arterial Connector. The Infection Prevention Society, 4th Annual IV Forum Conference, Kings Gate Conference Centre, Peterborough, November 2014

*Regional*

M Mariyaselvam, The Eastern Region Academic Health Sciences Network Update. The East Anglia Intensive Care Group, Ravenwood Hall, Rougham, November 2014.

M Mariyaselvam, Recent Innovations in Nosocomial Infections in the ICU. British Association of Critical Care Nurses, Anglia Region Study Event. Bury St Edmunds Hospital, Suffolk, October 2014

M Mariyaselvam, The Eastern Region Academic Health Sciences Network Update. The East Anglia Intensive Care Group, Hinston Cambridge, May 2014.

M Mariyaselvam, The Eastern Region Academic Health Sciences Network Introduction. Regional Critical Care Network ODN Meeting, February 2014.

*Oral Presentations National*

M Mariyaselvam, The Problems of Arterial Cannula Sampling: introducing the Non-Injectable Connector. The Agents for Change Conference, BMJ House, London, June, 2014

<https://www.youtube.com/watch?v=f22LesgXi0o>

Poster Presentation*International*

M Mariyaselvam, Accidental intra-arterial injection: an under-reported preventable never event. International Symposium on Intensive Care and Emergency Medicine, Brussels, March 2015.

Introducing an arterial Non-injectable Connector (NIC) into clinical practice. International Symposium on Intensive Care and Emergency Medicine, Brussels, March 2014.

*National*

M Mariyaselvam, The Non-Injectable Arterial Connector: Improving Arterial Line Safety. International Forum on Quality and Safety in Healthcare. Excel, London, April 2015



M Mariyaselvam, Complications of accidental intra-arterial injections. The Association of Anaesthetists of Great Britain and Ireland, International Conference Centre, Harrogate, September 2014

M Mariyaselvam, The Non Injectable Connector: A novel solution preventing bacterial contamination of arterial lines. The Infection Prevention Society, London, September 2013.

#### Exhibition stands

The Clinical Human Factors Group, Human Factors, Design and Safety Equipment Conference, Birmingham, March 2014

CARE conference, Warwick, June 2014

The International Quality and Patient Safety Forum in Health, Paris 2014

The Patient Safety Congress, Liverpool, May 2014

Kent Surrey Sussex AHSN, Exposition, London, January 2015

Medtec UK, Health Care Technologies, London, March 2015,

Medtech Europe, Health Care Technologies, Stuttgart, Germany, April 2015

Innovation Scouts Network, Health Enterprise East, Cambridge, May 2015

NHS Confederation Conference, Liverpool, June, 2015

The Patient Safety Congress, Birmingham, July 2015