

To Ms Devonish
Assistant Coroner

Patient Safety
NHS Improvement
Skipton House, Area 6C
80 London Road
SE1 6LH

(Sent by email)

<https://www.improvement.nhs.uk>

Monday 8th August 2016

Dear Ms Devonish,

**Regulation 28 Report to Prevent Future Deaths following the inquest of
Patricia Steer who died on 21 June 2015**

I am writing to you to respond to the concerns raised by your investigation into the circumstances surrounding the tragic death of Patricia Steer.

For clarity, and because of the legal responsibilities attached to the organisations that Regulation 28 letters are addressed to, I do need to briefly explain why I am responding.

Your original Regulation letter had been addressed to Simon Stevens at NHS England and to the National Patient Safety Alerting System, NHS England and sent by you on 25th May 2016. I understand NHS England contacted your team to explain that some key responsibilities related to patient safety, including delivery of the National Patient Safety Alerting System, had shifted to another NHS body, NHS Improvement, earlier in 2016.¹

¹ More detail on the transfer of functions to NHS Improvement and on the National Patient safety Alerting System can be found here:

https://improvement.nhs.uk/uploads/documents/Patient_Safety_Alert_Stage_2_-_Patient_Safety_transfer_to_NHS_Improvement.pdf

Your PA then forwarded the original Regulation 28 letter to us via email. We contacted her to explain that it would be helpful if it could be more formally redirected to NHS Improvement. We then received another copy of the Regulation 28 letter that you had kindly re-dated, but where the requirement to act remained directed to the National Patient Safety Alerting System, NHS England. We have assumed you intended the requirement to act to prevent future deaths to be directed at the patient safety team within NHS Improvement, and we have responded accordingly.

From your report we understand that Patricia Steer died after the clamp was briefly left open on a central venous catheter port resulting in air embolization and cerebral infarction.

Your main concerns were that

- nursing staff were not aware of the risk of air embolization when leaving a central venous catheter port uncapped and unclamped; and that
- it had not been possible to locate any literature or guidance regarding the risk of air entry if the clamp is left open during the use of the catheter.

The patient safety team is aware of risks associated with central lines and has undertaken a range of work to improve safety in this area before. I have attached an outline of this wider work as an appendix to this letter.

In relation to your specific concerns, we have been able to identify that appropriate guidance on this risk for nurses has been established. There are two key sources:

Royal College of Nursing (2010) *Standards for infusion therapy*

Page 22: Under no circumstances should devices be left with caps open or exposed.

We understand that these standards are currently being updated but we anticipate this risk will continue to be emphasised when revised standards are published on the RCN website.

Critical Care Network/ National Nurse Leads - *National Competency Framework for Adult Critical Care Nurses*

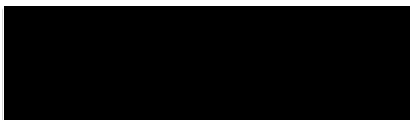
Page 20 - You must be able to demonstrate through discussion essential knowledge of (and its application to your supervised practice): Associated hazards and complications of central venous catheters and systems

<http://www.cc3n.org.uk/competency-framework/4577977310>

We have discussed the issue with the Safe Anaesthesia Liaison Group (SALG), which includes representatives from the Royal College of Anaesthetists (RCoA), the Association of Anaesthetists of Great Britain and Ireland (AAGBI), the Medicines and Healthcare Products Regulatory Agency (MHRA), the Faculty of Intensive Care Medicine and the College of Operating Department Practitioners (CODP). Their belief is that the risk is widely appreciated and is routinely covered in local training and protocols but they accept that the findings of your inquest indicate this was not the case in at least one organisation. These organisations have undertaken to raise awareness amongst their members about the risk of leaving a CVC line uncapped during use. These are the organisations best placed to take that message to the staff which provide professional leadership, training, and supervision as well as to staff providing direct care to patients with central lines.

We are very grateful to you for bringing your findings from your investigation of Mrs Steer's death to our attention and giving us the opportunity to work with others to reduce the risk of future deaths.

Please accept my best wishes,



NHS National Director of Patient Safety
NHS Improvement

Appendix:

Summary of wider work to improve the safety of central lines

The key themes identified from reviews of patient safety incidents were:

- *Insertion* related incidents (e.g. inadvertent placement into artery, perforation of vessel causing haemorrhage, injury to the lung causing pneumothorax)
- *Removal* related incidents (e.g. patient harm/ air embolus due to incorrect removal technique (sitting up), disconnection/ accidental removal)
- *Other* (e.g. central line infections, extravasation injuries, retained guide wires, anaphylactic reaction)

Work undertaken by the **patient safety team** to minimise risks associated with central lines:

General:

- Central line infections - Matching Michigan Project
- *Intravenous Heparin Flush Solutions* – Rapid response Report April 2008
<http://www.nrls.npsa.nhs.uk/resources/?entryid45=59892>
- *Extravasation injuries* - SIGNALS September 2009 and February 2010
- *Risk of harm from retained guidewires following central venous access* | Signal
September 2011 <http://www.nrls.npsa.nhs.uk/resources/?entryid45=132829>

Air embolism

- *Risk of air embolism when removing central lines* - Signal, September 2011
<http://www.nrls.npsa.nhs.uk/resources/?entryid45=132830>
- *Nursing Times (2011) Avoiding air embolism when removing CVCs*
<http://www.nursingtimes.net/clinical-archive/patient-safety/avoiding-air-embolism-when-removing-cvcs/5037174.fullarticle>

Work undertaken by **other national organisations** to minimise risks associated with central lines:

General:

NICE (2002) *Guidance on the use of ultrasound locating devices for placing central venous catheters* <https://www.nice.org.uk/guidance/ta49>

MHRA (2013) *Infusion systems*

<https://www.gov.uk/government/publications/infusion-systems>

We understand that these standards are currently being updated but this is more about the infusion devices themselves, rather than the clinical risks associated for the accessories such as catheters and central lines.

Please see the main body of our reply for work with direct bearing on the issue of caps left open and lines unclamped on central lines.