Department of Health & Social Care

[redacted]
Minister of State for Health (Secondary Care)

39 Victoria Street
London
SW1H 0EU

Our ref: [redacted]

HM Coroner Georgina Nolan
Newcastle and North Tyneside Coroners Court
Lower Ground Floor
Block 1
Civic Centre
Barras Bridge
Newcastle upon Tyne
NE1 8QH

By email: [redacted]

18th September 2024

Dear Ms Nolan,

Thank you for the Regulation 28 Report of 4 July 2024 regarding the death of Michael Trevor Walton**.** I am replying as the Minister with responsibility for supply threats and disruption within the Department of Health and Social Care.

I would like to say how saddened I am to read of the circumstances of Mr Walton's death, and I offer my sincere condolences to his family and loved ones. The circumstances your report describes are concerning and I am grateful to you for bringing these matters to my attention.

Matters of Concern

Your report outlines a number of matters of concern, including that the surgeon's preferred choice of cannula was not available for the procedure due to supply issues; that the cannula type contributed to its dislodgement from the lumen of the aorta, and to Mr Walton's death; and, that using sub-optimal medical equipment poses an avoidable risk to patients of significant harm including death.

Thank you for the additional time provided to the Department to provide a response to the concerns raised in the report. In preparing this response, Departmental officials have made enquiries with NHS England (NHSE), the Medicines and Healthcare products Regulatory Agency (MHRA) and the Care Quality Commission (CQC). I understand that you have also requested a response from NHS England, which will provide information on the specific actions taken by the Newcastle upon Tyne Hospitals NHS Foundation Trust following the concerns you have raised about Mr Walton's death.

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Medical Supply

Medical supply chains are complex, global and highly regulated, making them vulnerable to a variety of shocks. Whilst we cannot always prevent supply disruption from occurring, there are a range of well-established processes and tools in place to help manage them when they do arise, and to help mitigate risks to patients.

Guidance[1] published in June 2024 by NHS England and available to all NHS Trusts sets out how to report potential supply disruptions of medical equipment and includes the escalation processes that NHS Trusts can follow in the event of a disruption. This guidance outlines that, in the event that an NHS Trust is not able to resolve supply disruption via local activity, the Trust can report the disruption to the Department's National Supply Disruption Response (NSDR)[2].

The NSDR has been in place since December 2019 and acts as a single point of contact when an NHS Trust is experiencing supply disruption and has not been able to mitigate the disruption. Once a disruption has been reported to the NSDR, the Department will then work to help resolve the matter, including by:

- liaising with the manufacturer of the product in question for details of the disruption and any recovery plans;
- contacting NHS Supply Chain or other distributors/wholesalers that stock the product to determine whether any stock can be released to fulfil the NHS Trust's immediate need; and,
- investigating alternative products and liaising with suppliers.

From a review of our records, we can confirm that supply disruption of the preferred choice of cannula for Mr Walton's procedure was not escalated to the NSDR for support.

Product Safety:

I understand from the MHRA that central arterial cannula are acceptably safe when used as intended. Unfortunately, rare complications do still occur during interventional procedures. The MHRA have analysed available data and past records up to and including 17 July 2024 and are not aware of any excess risk with the cannula used for Mr Walton's procedure. For all devices on the UK market, the manufacturer must submit vigilance reports to the MHRA when reportable incidents that involve their device occur in the UK. The manufacturer must also take appropriate safety action when required and ensure their device meets appropriate standards of safety and performance for as long as it is in use.

[1] NHS England » Reporting potential supply disruptions of medical equipment and consumables
[2] Reporting to the National Supply Disruption Response (NSDR) - GOV.UK (www.gov.uk)

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Next Steps:

The CQC have confirmed with my Department that they were made aware of Mr Walton's death by the Trust and will be reviewing this information in line with their specific incident process. They are requesting further information from the Trust accordingly.

The CQC inspected the cardiothoracic department at Freeman Hospital in September 2023 due to multiple concerns raised. The NHS Trust subsequently produced an action plan, and a quality improvement plan is now in place. As part of CQC's ongoing regular engagement with the Trust, they will continue to monitor progress made.

I hope this response is helpful. Thank you again for bringing these concerns to my attention.

Yours sincerely,

[redacted]

[redacted]