NHS England

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Senior Coroner
Newcastle and North Tyneside
Coroner's Court
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Barras Bridge
Newcastle upon Tyne
NE1 8QH

National Medical Director
NHS England
Wellington House
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28 August 2024

Dear Coroner,

Re: Regulation 28 Report to Prevent Future Deaths – Michael Trevor Walton who died on 13 July 2023.

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 4 July 2024 concerning the death of Michael Trevor Walton on 13 July 2023. In advance of responding to the specific concerns raised in your Report, I would like to express my deep condolences to Michael's family and loved ones. NHS England are keen to assure the family and the Coroner that the concerns raised about Michael's care have been listened to and reflected upon.

Your Report raised the concern over the risk posed to patients by medical equipment shortages and the use of sub-optimal medical equipment. In Michael's case, you raised that the operating surgeon's preferred choice of cannula was not available due to supply issues, and this resulted in a cannula with a shorter tip being used, which ultimately contributed to its dislodgement and to Michael's death.

Nationally, NHS Resilience gets involved in supply disruptions where they receive an escalation. These come in from either NHS Trusts (via NHS England's Emergency Preparedness, Resilience and Response (EPRR) Teams), the Department of Health and Social Care's (DHSC's) National Supply Disruption Response (NSDR) Team or, less frequently, from NHS Supply Chain or NHS England's Patient Safety Team.

Whilst defined triggers for our NHS Resilience involvement are in development and are not available to share, we consider (on a case-by-case basis) the potential risks to patients and the operational delivery of NHS services of a break in supply, how imminently supply disruption will occur, and the availability of alternative products, before potentially stepping up incident management arrangements – in the form of either a full Incident Management Team (IMT) or a working group approach. Where NHS Resilience lead meetings, clinical input is used to help devise guidance on the use of alternative devices, the preservation of existing stock through changes to practice, and to help coordinate national mutual aid, as required.

Regarding this specific case and the Medtronic cannula product that was unavailable, NHS England does not believe (from a search dating back to 2021) that there was any escalation of a shortage to the national team, nor a referral from DHSC's NSDR

function stating that an inability to source this product was causing operational or patient safety risks.

NHS Supply Chain colleagues have also been sighted on your Report. Many organisations order products through NHS Supply Chain, who aim to ensure adequate supply for demand and will link to alternative products where a product may be unavailable. Where there are shortages, these are communicated through an Important Customer Notice (ICN). All NHS Supply Chain shortages are tabled at a Supply Management Oversight Group (SMOG) which is chaired by DHSC.

ICN 1832 was published on 26 October 2022, detailing transportation and logistical delays impacting availability across 56 Medtronic perfusion products. These impacted products were detailed in a product listing, with alternative products added for consideration. The ICN detailed that customers needed to undertake appropriate due diligence to determine the suitability of alternatives listed. The 71424 (NPC FXA418) cannula, the preferred cannula of the operating surgeon in this case, had the following alternative product codes listed - FXA413, FXA355, FXA206. The 72224 (NPC FXA572) which was used was not listed as an alternative product for FXA418 by NHS Supply Chain in the ICN. It is however noted that the two cannulas are very similar in size, design and intended use.

NHS Supply Chain's listing of alternative products is limited in scope and does not constitute advice. Decisions on the use of alternative products must be taken at local level.

NHS England has engaged with Newcastle upon Tyne Hospitals NHS Foundation Trust on the concerns raised in your Report. We note that they state they were unable to determine the exact cause of the aortic cannula becoming dislodged, and that the default cannula choice was made for an operation of this nature. We note, however, that following Michael's death, the Theatre Department have permanently suspended use of the cannula.

I would also like to provide further assurances on the national NHS England work taking place around the Reports to Prevent Future Deaths. All reports received are discussed by the Regulation 28 Working Group, comprising Regional Medical Directors, and other clinical and quality colleagues from across the regions. This ensures that key learnings and insights around events, such as the sad death of Michael, are shared across the NHS at both a national and regional level and helps us to pay close attention to any emerging trends that may require further review and action.

Thank you for bringing these important patient safety issues to my attention and please do not hesitate to contact me should you need any further information.

Yours sincerely,

National Medical Director