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The Royal Wolverhampton
NHS Trust

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PRIVATE AND CONFIDENTIAL –
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Mr Daniel Howe
HM Area Coroner
Staffordshire and Stoke-on-Trent Coroner's Service
H M Coroner's Office
Stoke Town Hall,
Kingsway,
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ST4 1HH

Email: [redacted]

24 December 2024

Dear Coroner Howe

Re: In the matter of Regulation 28, Prevention of Future Death Report - Gemma Ralph - response due by 3 January 2025

Following the inquest on 3 October 2024, you raised the following concerns in relation to this trust:

1. That bottles of sevoflurane, whether unopened or partially used after theatre, does not appear to be robustly monitored to the degree that it was possible for a bottle of sevoflurane to be removed from Cannock Chase Hospital without this being flagged by the auditing system.

2. That the trust was unable to confirm or refute that the bottle found at the deceased's home address originated from Cannock Chase Hospital.

It is important to note that no witnesses from the trust called to attend court and evidence provided by the trust was read, there was therefore no opportunity for the trust to present or clarify any contextual matters that may have arisen during the inquest hearing.

This letter sets out the trust's response to the Regulation 28 notice received on 8 November 2024.

For context:

Inhaled sevoflurane is used to cause general anaesthesia (loss of consciousness) before and during surgery. It belongs to the group of medicines known as general anaesthetics.

There are a range of general anaesthetics available in theatre for anaesthetists to choose based on the specific need of the case.

Some are delivered via an intravenous (IV) route (directly into a vein), but most are delivered via an inhaled route (breathed in) and are known as Anaesthetic Gases, those in common used across the country are nitrous oxide, halothane, isoflurane, desflurane and sevoflurane. They are administered as primary therapy for preoperative sedation and adjunctive anaesthesia maintenance to intravenous (IV) anaesthetic agents such as midazolam and propofol in the perioperative setting.

The Anaesthetic Gases are delivered by an anaesthetic machine through a breathing circuit (pipes) attached to the patients airway, The types of device to secure the airway can range from open, semi closed and closed, this means the exact amount given to each patient is difficult to record with precision because it is varied throughout the surgical procedure to lighten or deepen the anaesthetic based on a number of patient and surgical factors and circuit leakage can be variable dependent on the type of airway securing device chosen. They are usually administered by and under the direct supervision of a trained anaesthesia professional. This is normal practice across England.

Staff who are permitted legitimate role-based access to all drugs are trusted across England to use these drugs appropriately, this is conventional and established current practice in all departments where drugs are used to treat patients.

The bottom line is that, in reality, any drug in the right quantity can end life. The system in place in England is that only drugs classified under the Controlled Drugs (Supervision of management and use) Regulations 2013 etc are required to be recorded from production to end use (patient or disposal). There is no such requirement for other drugs.

This presents complexity and difficulty for the trust in delivering meaningful compliance with the request in the Regulation 28 report, however the trust can and will make improvements which are summarised at the end of this letter. The trust complies with the guidance required as presented in my report presented to the inquest (attached).

As already mentioned, there is opportunity for the trust to take some form of action in relation to this Regulation 28 notice but this will not address any risk that sits outside of the trust (the whole of England) so any action taken by the trust, in context, will provide limited risk reduction across the country.

Addressing the concerns that you have presented specifically to the trust.

1. **That bottles of sevoflurane, whether unopened or partially used after theatre, does not appear to be robustly monitored to the degree that it was possible for a bottle of sevoflurane to be removed from Cannock Chase Hospital without this being flagged by the auditing system.**

The context of this is explained in the narrative above, this risk contextually applies to any drug of any type that does not fall under the controlled drugs legislation. If the trust were to take some form of action in relation to sevoflurane specifically it would not close the risk of any person taking a fatal dose of any other drug that they have legitimate access to as part of their role. To take action to address this risk in all drugs would be disproportionate to the risk, would create different risks and most likely be operationally impractical and unaffordable.

2. **That the trust was unable to confirm or refute that the bottle found at the deceased's home address originated from Cannock Chase Hospital.**

The trust has not been provided with the batch number of the sevoflurane found in Gemma's home, even if it had been provided with the batch number it would still not evidence that the sevoflurane used by Gemma was obtained from the trust. The manufactured batches are large and supplied to many organisations. Therefore, confirming or refuting where Gemma obtained it from

would only be possible if there were a trust specific permanent marker on the bottle, again this is not usual practice.

There have been a number of professionals involved up to now in the consideration of the practicalities of taking action in relation to this Regulation 28 notice, this includes [redacted], Clinical Director Anaesthesia, Perioperative & Pain Medicine Directorate and [redacted], Clinical Director of Pharmacy and Medicines Optimisation, Controlled Drugs Accountable Officer.

There is nothing, including making a medicine a controlled drug, that will prevent someone taking a medicine if they are intent to do so. We do not believe that it would have been possible or practical to have put anything in place to completely prevent the removal of a bottle of sevoflurane (or any other medicine), we can only make it more difficult to do this and therefore reduce the risks.

<u>Actions that require national consideration / are outside of the control of the Trust</u>

- Sevoflurane is one of many drugs that has potential to be abused or misused but is not classified as a controlled drug. Only controlled drugs have strict laws around storage and documentation. The government would need to determine whether on balance of risk and evidence from this Regulation 28 notice, sevoflurane should be made a controlled drug.
- The Royal College of Anaesthetists determines that on a risk basis the medicine cupboards of theatres which are in use may be left open to enable emergency access, the only exception to this being controlled drugs. The Royal College may want to review their position on this and/or determine whether there are any further exceptions.

<u>Actions that are partly within the control of the Trust</u>

- Scan4Safety is an NHS initiative that involves end to end barcoding of healthcare products, including medicines. It can track movement of medicines from manufacturer to patient, therefore increasing accountability and reducing the potential for fraud/diversion. We are not aware of how mature the systems are, and which Trusts in England have implemented this. If this was found to offer the potential to reduce risk, unless mandated nationally it would have limited impact on risk reduction.
- Making sevoflurane a controlled drug and/or implementing Scan4Safety are the only ways we think the Trust may have been able to identify, with a degree of certainty, that a single bottle of sevoflurane was unaccounted for. The Trust could consider managing sevoflurane as a controlled drug (we do this for Oramorph for example) but the practicalities of this are likely to outweigh the current risk of diversion.
    - These considerations are:
        - Staff capacity to manage sevoflurane as a Controlled Drug
        - How volume would be measured because of the characteristics of administration – possibly have to measure in full bottles and part bottles, rather than in ml.
        - Space in CD cupboards to store

<u>Actions that the Trust could consider to improve audit and / or restrict access to sevoflurane to authorised registered staff only are listed below.</u>

These measures would improve on what we already have but would not necessarily identify if someone was diverting small volumes of sevoflurane and therefore deliver limited effect on risk reduction.

- Introduce daily stock counts of full bottles, part bottles and empty bottles to ensure all are accounted for. NB. Raises the question that if we did this for sevoflurane why wouldn't we do it for all other non-controlled drugs that could be abused. Unless this is made a national requirement it would **deliver limited effect on risk reduction across England.**
- Ensure sevoflurane is in a locked cupboard unless under direct physical supervision of the anaesthetist. No sevoflurane to be stored in anaesthetic room cupboards that are left open during a theatre list. Unless this is made a national requirement it would **deliver limited effect on risk reduction across England.**

- Implement auditable locks (swipe card / biometric) on drug storage cupboards (bulk and anaesthetic room) and ensure locked at all times (even when theatre is in use). This should mean that staff can access in an emergency without having to find keys but would provide greater security. These types of locks also allow audit of who has been accessing the cupboards. Unless this is made a national requirement it would **deliver limited effect on risk reduction across England.**
- Implement automated medicines cabinets for bulk storage and auditable locks or Abloy keys for drug storage cupboards in anaesthetic rooms. Unless this is made a national requirement it would **deliver limited effect on risk reduction across England.**

We have discussed the Regulation 28 notice with the Regional Chief Pharmacist, and he is in agreement with the above. We will however look at risk reduction strategies e.g. improved use of automation, ensuring our storage, recording and audit processes are robust.

The plan and timescales for what is within the trusts control and is reasonably practicable is set out below.

Action	Lead	Timescale	Comments
Sevoflurane bottles to be in a locked drug cupboard unless under the direct supervision of the anaesthetist.	[redacted]	Complete	• The amount of sevoflurane stored in each theatre has been reduced to 2 bottles; the in-use bottle and 1 spare bottle. Both bottles are under the direct supervision of the anaesthetist and are locked away at the end of the theatre session. • Bulk supply of sevoflurane is in the theatres bulk drug storage areas in locked cupboards which are only accessible to authorised and registered healthcare professionals. Compliance is monitored as part of the pharmacy-led annual medicines storage audit.
To submit a business case to the Trust Board and Black Country ICB for capital monies to purchase and install automated medicines storage cabinets for bulk storage of drugs and auditable locks for drug cupboards.	[redacted]	Q1 2025/26	• Collaborative work has commenced within the Black Country Provider Collaborative Pharmacy Network to write a systemwide business case to purchase and install automated medicines storage cabinets at RWT, DGFT and WHT, with agreement within the network that theatres will be a priority area. There is significant variation within the Black Country ICS as SWB have fully implemented automated medicines storage cabinets across the new MMUH, and therefore if approved, the business case will bring all Black Country Trusts to a similar standard of inventory control. • There is a significant risk that a business case will not be approved due to lack of capital monies within the Trust and Black Country ICS, therefore as an interim measure RWT have commenced discussions with the provider of existing automated storage cabinets used for storage of dressings and medical devices in theatres, as to whether it is possible to repurpose these for medicine storage. Early conversations indicate they may not be suitable for medicines storage, thus requiring new cabinets to be purchased.

Yours sincerely

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[redacted]
Group Director of Assurance