Department of Health & Social Care

From Maria Caulfield MP
Parliamentary Under Secretary of State for Primary Care and Patient Safety

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[redacted]

Dr Sean Cummings
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HM Coroner's Office
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12 January 2022

Dear Dr Cummings,

Thank you for your letter of 6 September 2021 to [redacted], Chief Medical Officer for England, about the death of Glenda May Logsdail. I am replying as Minister with portfolio responsibility for patient safety and I am grateful for the additional time in which to do so.

Firstly, I would like to say how deeply shocked and saddened I was to read of the circumstances of Mrs Logsdail's death and I offer my heartfelt condolences to Mrs Logsdail's family and loved ones. That Mrs Logsdail's death was avoidable must be particularly distressing and it is essential we do all we can to ensure such failings in care do not occur again.

I expect the Milton Keynes University Hospital NHS Foundation Trust and the Royal College of Anaesthetists (RCA) respectively, to address your concerns about the specific circumstances and failings described, and awareness of the Royal College's campaign on capnography in cardiac arrest ('No Trace, Wrong Place').

My response will comment on the national level aspects in relation to your concerns, in particular, training in relation to multi-disciplinary team working in an emergency situation, and display configurations on anaesthetic machines and multiparameter monitors. In preparing this response, my officials have taken advice from Health Education England (HEE); NHS England and NHS Improvement (NHSEI); and the Medicines and Healthcare products Regulatory Agency (MHRA).

Multi-disciplinary team working and training for an emergency situation

In relation to your concerns about multi-disciplinary team working in an emergency situation, you may wish to note that specific simulation-based training for emergency skills and team-based drills in specialised areas of clinical practice, such as the operating theatre, is the responsibility of, and delivered by, individual NHS trusts, based on the

availability of appropriate simulation resources and time for clinical trainers to support this practice.

At a national level, HEE is taking a number of proactive steps to strengthen multi-professional supervision, with a view to delivering consistent quality standards across the system and breaking down silos between clinical professions.

HEE, via its Technology Enhanced Learning (TEL) programme is currently implementing a specialty training recovery project that is seeking to enhance the use of simulation-based training across all postgraduate specialties. One specific theme within this work, is developing professional capabilities that support team-based practice in complex or life-threatening situations. These capabilities will be based on individual specialty curricula and the national patient safety syllabus. They will include clinical leadership, decision making, and developing effective teamworking skills and behaviours.

As part of TEL, HEE is also seeking to develop standards in simulation-based education and training that will help ensure high quality practice across different providers. This includes a national development programme that can be accessed by educators and practitioners from all specialities and professions. Specific learning outcomes within this programme will include transferrable skills of observing and supervising performance and debriefing clinical colleagues and multi-professional teams in the clinical setting. These attributes are fundamental when creating trust and respect within teams and hence critical to delivering safe, effective team-based care in life threatening situations.

HEE is also piloting a unique simulation and competency assessment methodology that is applicable to multi-professional team training for high risk clinical settings. This will offer the opportunity to create personalised development plans for individual participants and local teams. This will also provide more objective assurance of meeting these needs for clinical service leaders.

You may wish to note that in May 2020, the Academy of Medical Royal Colleges (AoMRC) published guidance on developing professional identity within multi-professional teams. The principles outlined in the AoMRC document shape the work of specialty schools and faculties in developing training environments. Specific elements of this training are offered to multi-professional participants and address team-based skills and behaviours that are important in responding to acute medical emergencies.

Variable configurations in relation to the displays on ventilators used in operating theatres, anaesthetic rooms and intensive treatment units

The MHRA is the regulator for medical devices in the UK. The MHRA has reviewed your report and has noted that it does not suggest a device failure or widespread user error.

By way of background, the MHRA has explained that during anaesthesia, capnography is typically displayed in two places: the screen of the anaesthetic machine itself; and, the screen of the multiparameter monitor. The anaesthetic machine delivers oxygen, air and gaseous anaesthetic drugs to the patient and these can be delivered under the manual control of the anaesthetist or using various methods of mechanical ventilation. The screen of these devices typically displays the measurements of gasses inhaled and exhaled by

the patient. This can include capnography labelled '*end tidal CO2*' or '*ETCO2*'. The layout of this display is bespoke to the manufacturers design. However, this is usually consistent across that manufacturers range.

It should be noted that anaesthetic machines are very different from intensive care ventilators, which serve a different purpose. Therefore, the display of an anaesthetic machine is very different to that of a ventilator, though there are some similarities in the information that is given.

A multiparameter monitoring system is a medical device designed to monitor a number of different aspects of the patient's physiology. This can include oxygen saturation, non-invasive and invasive blood pressure, electrocardiogram (ECG) and inhaled and exhaled gasses. The information displayed and layout of the screen of these devices can be customised, within certain parameters, by the user according to their specific need. This is an important feature of this device as they are used in many settings throughout a hospital such as high-dependency and intensive care units. These devices can also be integrated into anaesthetic machines to provide the monitoring needed during anaesthesia.

ISO standard, *ISO 80601-2-13:2011 A2:2019*, states that it is not compulsory for an anaesthetic machine to have built in CO2 monitoring equipment. Therefore, it should not be assumed that this information will be displayed on the screen of the anaesthetic machine itself.

The standard dictates that if the anaesthetic machine does not contain built in CO2 monitoring, a statement to users informing them of the need to equip such a monitoring device to the machine before putting it into use should be placed in the devices instructions for use.

This highlights the importance of users familiarising themselves with the instructions and function of medical devices before attempting to use them.

If CO2 monitoring equipment is installed on the device, then the information displayed should be clearly labelled and easy to recognise.

End tidal capnography readings are distinctive and anaesthetists will be taught to recognise these as part of their training. The display and alarm settings for all gas readings for these devices should conform, or be equivalent to, *ISO 80601-2-55:2018*, which dictates the basic safety and essential performance of respiratory gas monitors.

The displays of the multiparameter monitors used during anaesthesia have to be customisable so they can accommodate the different types of monitoring devices, which may be required for different types of anaesthesia and surgery being undertaken. This is necessary because the needs of the patient vary according to the complexity of the surgery being undertaken. If there was standardisation, this would either remove this flexibility or require unnecessary monitoring parameters where they are not essential. This in turn would have unintended impacts on patient safety.

Any gas readings measured and displayed by this device should also conform, or be equivalent to, *ISO 80601-2-55:2018*. If an anaesthetic machine does not have built in CO2

monitoring, then the multiparameter monitor would be the most logical place to integrate this type of monitoring. This can be achieved by the addition of an attachable module.

The MHRA's document on *Managing Medical Devices*[1], contains guidance for first time users of a device. This includes confirming that the user has received adequate training on the use of the device, as well as the user ensuring they have read the manufacturers and any local instructions for use.

Training for anaesthetists and intensivists in complex anaesthesia for complicated surgical procedures, should include methods that enable anaesthetists and intensivists to check the patient's physical condition to verify the readings on any monitors. This would include actions such as observing the patient's chest to ensure equal rise and fall as well as auscultation of the lungs for air ingress. These actions, among others, if undertaken should provide adequate risk mitigation for any malfunctions or misinterpretation of CO2 monitoring, as well as ensuring that a patient was being ventilated.

The MHRA recognises the complexity of some device's instructions for use. The *Managing Medical Devices* document advises that NHS trusts can produce their own local instructions for use for devices and are encouraged to do so when multiple devices are used together in one system. However, it is advised that these instructions are checked with the manufacturer to ensure accuracy.

The *Managing Medical Devices* document also contains advice for NHS trusts on the purchasing of equipment and attempting to assure, where possible, that there is uniformity to the equipment purchased to avoid user confusion.

Anaesthetists should know the importance of being entirely familiar with the monitoring they use within their own institution, and if they are unfamiliar, should not start an episode of patient care until they are, or receive the appropriate help.

All monitors have alarms and setting them should be routine practice for any clinician using monitoring devices. This should be done in accordance with The Association of Anaesthetists specialty guidance[2].

Conclusion

I hope this response is helpful and provides the necessary information to address your concerns.

It is essential that the Milton Keynes University Hospital NHS Foundation Trust takes the action necessary to ensure the safety of its patients and the quality of the care it provides, and I am aware that it has provided detail to you on the actions it has taken as a result of Mrs Logsdail's sad death.

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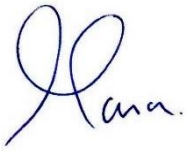
[1] Safeguarding public health (publishing.service.gov.uk)

[2] Recommendations for standards of monitoring during anaesthesia and recovery 2021 (anaesthetists.org)

My officials have brought your report to the attention of the Care Quality Commission (CQC), the independent regulator for care quality, and I am advised that the CQC has sought and received assurances from the Trust on the actions it has taken following Mrs Logsdail's death.

Finally, I am aware that the Trust referred this incident to the Healthcare Safety Investigations Branch (HSIB) to consider if it met its criteria for national investigation. I am informed that HSIB determined that this was not suitable for investigation. However, the information is helpful to HSIB's intelligence monitoring processes and can be used to inform any future work that might take place in this area.

Thank you for bringing your concerns to my attention.



MARIA CAULFIELD MP
PARLIAMENTARY UNDER SECRETARY OF STATE FOR PRIMARY CARE