

Mr Tom Osborne
HM Senior Coroner
HM Coroner's Office
Civic Offices
1 Saxon Gate East
Central Milton Keynes
MK9 3EJ

By email: [REDACTED]

12 July 2022

Dear Mr Osborne

I am writing to formally respond to the Regulation 28 report to prevent future deaths you made following the conclusion of the inquest into the death of Sangeerth Girirathan on 6 May 2022.

You also wrote to me on 19 May 2022 on two matters raised during this inquest, but which did not form part of the Regulation 28 report; namely the disclosure of notes in a paginated and indexed format; and the storage of data on monitoring units in the hospital, particularly the ICU. I will address these matters within this letter.

Regulation 28 Report

The Regulation 28 report reads as follows: *During the inquest it became apparent that in the ICU the alarms that are operating on the monitors had been disengaged. This resulted in the staff not being alerted when the patient's saturations fell below an acceptable level and he went into cardiac arrest. My understanding is that if a patient is being monitored at all then it is essential that the alarms remain operational. I believe that all staff should be reminded of the need for the alarms to be active so that future deaths in similar circumstances do not arise*

Response

There is no national guidance regarding frequency of observations on ICU and patients vary from those who are acutely unwell to those who are well and waiting for a ward bed and on occasions direct discharge home. Observations (frequency and type) are decided by ongoing dynamic risk assessments from the nurse looking after the patient with input from the medical team as required.

Alarm fatigue is a recognised detrimental consequence of intensive, continuous monitoring. As part of the wider learning from this incident, the importance of proportionate and appropriate use of alarms and alarm limits will be emphasised to all critical care staff. A reference is included at **Appendix 1**.

All registered nurses and consultant intensivists have been communicated to regarding the recommendations contained within the Regulation 28 report. The communication has reiterated that nursing staff must position themselves to have visibility of the monitor and when monitoring is deemed appropriate, the audible alarms set should reflect and augment the parameters monitored. If monitoring - intermittent or continuous but more important for the continuous - is deemed necessary then the alarms will not be disabled but parameters - highs and lows - may be altered to alert us a different points for different patients to avoid 'overuse' of the audible alarms.

The senior nursing team and consultant intensivists are doing point prevalence surveys to support and education staff as to safe and effective monitoring.

The ability to store data on monitoring devices following an incident that may have caused harm

Response

The ICU has a monitoring system provided by Spacelabs. There are several options to retain information/data from this monitoring system. Some of these options are longer term and require input from IT and all methods have risks associated with them that might result in failure to capture the appropriate data.

In the short term, all registered nurses, medical trainees, and consultant intensivists have been informed that in clinical situations where death may have been prevented or an incident may have resulted in serious harm, that the monitor should be quarantined and data preserved. As an interim solution, monitor data should be transferred into the monitor modules, uploaded into a Spacelabs transport monitor and preserved until the clinical engineering team has access to that monitor to download the data. The patient should not be unlinked from the monitor (i.e. 'discharged' or disassociated from the monitor) unless absolutely necessary (in the case of the monitor being required urgently for another patient). Registered nurses have received refresher training and have been competency assessed to ensure they can transfer data as above.

In the medium term, with training there is also an opportunity to draw across additional observations that have not yet been saved to eCare. In a situation where harm or death has occurred and the patient has not been discharged from the monitor, additional time points

can be added to assessments that will pull through observations at that time point. The downside to this will be that observations will not be corroborated in real time and some readings may be artefactual if monitoring is not correctly attached at the time (dampened arterial line trace, sats probe that is incorrectly positioned etc) leading to inaccurate data.

In the longer term, Spacelabs Intesys Clinical Suite held in the central station should be able to store 72 hours of data for a patient who has been on a monitor in ICU (or elsewhere in the hospital) and has since been discharged from that monitor. 72 hours of data can be accessed from the moment a patient is discharged. However, the amount of data available reduces over that time frame as it's not designed as a data repository. A business case is being produced to draw up a contract between Spacelabs and IT to further consider this option.

An action plan detailing ongoing work is included at **Appendix 2**.

Pagination and Indexing of Notes for Court Disclosure

Response

There is a meeting between your team and the MKUH Director of Corporate Affairs, [REDACTED] and Head of Clinical Governance and Risk, Tina Worth, on 19 July to discuss potential options and agree next steps to ensure disclosures to the Court are made appropriately, coherently and accessibly.

I trust that this response is satisfactory and as always, please do contact me if you would like any further information or assurance on any of the areas above.

Yours sincerely,

[REDACTED]

Chief Executive Officer

Appendix 1 Reference: Patient Monitoring Alarms in an Intensive Care Unit: Observational Study With Do-It-Yourself Instructions

Monitoring Editor: [REDACTED]

Reviewed by [REDACTED]

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Abstract

Background

As one of the most essential technical components of the intensive care unit (ICU), continuous monitoring of patients' vital parameters has significantly improved patient safety by alerting staff through an alarm when a parameter deviates from the normal range. However, the vast number of alarms regularly overwhelms staff and may induce alarm fatigue, a condition recently exacerbated by COVID-19 and potentially endangering patients.

Objective

This study focused on providing a complete and repeatable analysis of the alarm data of an ICU's patient monitoring system. We aimed to develop do-it-yourself (DIY) instructions for technically versed ICU staff to analyze their monitoring data themselves, which is an essential element for developing efficient and effective alarm optimization strategies.

Methods

This observational study was conducted using alarm log data extracted from the patient monitoring system of a 21-bed surgical ICU in 2019. DIY instructions were iteratively developed in informal interdisciplinary team meetings. The data analysis was grounded in a framework consisting of 5 dimensions, each with specific metrics: alarm load (eg, alarms per bed per day, alarm flood conditions, alarm per device and per criticality), avoidable alarms, (eg, the number of technical alarms), responsiveness and alarm handling (eg alarm duration), sensing (eg, usage of the alarm pause function), and exposure (eg, alarms per room type). Results were visualized using the R package ggplot2 to provide detailed insights into the ICU's alarm situation.

Results

We developed 6 DIY instructions that should be followed iteratively step by step. Alarm load metrics should be (re)defined before alarm log data are collected and analyzed. Intuitive

visualizations of the alarm metrics should be created next and presented to staff in order to help identify patterns in the alarm data for designing and implementing effective alarm management interventions. We provide the script we used for the data preparation and an R-Markdown file to create comprehensive alarm reports. The alarm load in the respective ICU was quantified by 152.5 (SD 42.2) alarms per bed per day on average and alarm flood conditions with, on average, 69.55 (SD 31.12) per day that both occurred mostly in the morning shifts. Most alarms were issued by the ventilator, invasive blood pressure device, and electrocardiogram (ie, high and low blood pressure, high respiratory rate, low heart rate). The exposure to alarms per bed per day was higher in single rooms (26%, mean 172.9/137.2 alarms per day per bed).

Conclusions

Analyzing ICU alarm log data provides valuable insights into the current alarm situation. Our results call for alarm management interventions that effectively reduce the number of alarms in order to ensure patient safety and ICU staff's work satisfaction. We hope our DIY instructions encourage others to follow suit in analyzing and publishing their ICU alarm data.

Appendix 2: Action Plan

Improvement Objectives	Actions Taken	Start date	Additional Support required	Review Schedule	Outcome
To communicate to all staff the need to store data on monitoring devices following any incident that might have caused harm	Email all RNs Email all Consultant Intensivists	05/05/22	Consultant Intensivists to communicate to medical trainees	27/06/22 To evaluate at Intensive Care senior nursing, medical and AHP group	
All RNs to receive training and be assessed as competent on transferring data from monitor to module	Senior nursing team provided one to one training and competency assessment to all staff	08/05/22	Band 7s to facilitate process	27/06/22 To evaluate at Intensive Care senior nursing, medical and AHP group	All RNs to receive training and be assessed as competent on transferring data from monitor to module
Engage with Spacelabs to discuss effective data capture process	Advanced Nurse Practitioner (ANP) Intensive care to communicate with Spacelabs representative	18/05/22		25/05/22 Communication received from Spacelabs	The data capture process is complex but potentially is not robust in present format for clinical staff to manage 24/7. There is potential for alternative individual monitor solutions and/or central monitoring solutions which require further investigation.
Face to face meeting to review ICU Spacelabs central monitoring system capabilities	ANP to communicate with Spacelabs to arrange meeting	08/06/22		16/06/22 Face to face meeting arranged between Spacelabs and ICU ANP	
Engage with Spacelabs, IT and Clinical Engineering to define and agree a process to effectively data capture from	ANP- Intensive Care emailed representatives from all specialist departments and company to proceed to a	25/05/22	Add to medical equipment training for Spacelabs monitoring when confirmed.	21/06/22 Planned meeting with key representatives from identified departments	Business case pre-approved and priority funding agreed to ensure IT & Spacelabs can update the

Improvement Objectives	Actions Taken	Start date	Additional Support required	Review Schedule	Outcome
Spacelabs monitoring 24/7 in the event of a clinical incident	meeting for resolution			Confirmation of contracts signed and work commenced will be provided ASAP.	Spacelabs Intesys Clinical Suite (ICS) held in the central station to store 72hrs of any patient data who has been on a monitor in ICU or elsewhere in the trust and has since been discharged from that monitor. 72hrs of data can be accessed from the moment a pt is discharged. However, the amount of data available reduces over that time frame as it's not designed as a data repository.
All RNs to receive training and be assessed as competent on transferring data from monitor to module	Senior nursing team provided one to one, small group training ongoing training.	21/06/22	Add to medical equipment training for Spacelabs monitoring	Ongoing	In a situation where harm or death has occurred and the patient has not been discharged from the monitor then additional time points can be added to assessments that will pull through observations at that time point. Observations will not be corroborated in real time and some readings may be artifactual if

Improvement Objectives	Actions Taken	Start date	Additional Support required	Review Schedule	Outcome
					monitoring is not correctly attached at the time (dampened arterial line trace, sats probe that is incorrectly positioned etc) leading to inaccurate data.
Ensure that nursing staff must position themselves to have visibility of the monitor and when monitoring is deemed appropriate, audible alarms set should reflect and augment the parameters monitored.	Matron has communicated this to all RNs	26/04/22	Band 7s have communicated this message via the 'safety huddle' which is communicated at every nursing hand over.	09/06/22 Evaluated, minuted and reiterated at senior nurses meeting	Continue to reiterate the message to all staff, face to face, safety huddle, role modelling and direct support to ensure compliance.
Ensure that if monitoring is deemed appropriate, audible alarms set should reflect and augment the parameters monitored.	Band 7 has communicated to Consultant Intensivist Leads, Band 7 & 8 RNs to support this process and ensure that this is being followed when attending patients and during ward rounds.	16/05/22		27/06/22 To evaluate at Intensive Care senior nursing, medical and AHP group	