LUTON & DUNSTABLE UNIVERSITY HOSPITAL

CLINICAL EXCELLENCE, QUALITY & SAFETY

Lewsey Road Luton LU4 0DZ
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18th August 2017

**PRIVATE AND CONFIDENTIAL**
**ADDRESSEE ONLY**
HM Acting Senior Coroner Mr Ian Pears
Office of HM Coroner – Bedfordshire and Luton
C/O Mrs Kerry McIlroy (Coroner's Officer)
The Court House
Woburn Street
Ampthill
Bedfordshire MK45 2HX

Dear Mr Pears

**Regulation 28 Report to Prevent Future Deaths – Court Reference 39895 - 2016**

I write in my capacity as Acting Chief Executive of Luton and Dunstable University Hospital NHS Foundation Trust ("the Trust") to address the concerns raised in the Prevention of Future Deaths Report issued following the inquest into the death of Mr Patrick Woods.

The matters of concern raised in the Report were:

1) The alarms on the equipment and monitors seemed to play no part in managing risk for the Anaesthetists
2) The AAGBI Guidance is quite specific, but time and again the witnesses said their practice was in effect contrary to the guidance. It is unacceptable for such Guidance to be wilfully ignored
3) It was revealed that the factory setting for the Tiro for FiO2 was 18%. There seems to be agreement that this was not a safe setting, yet there were very few circumstances (mainly paediatrics) that the settings were changed.

The Trust has now considered the above concerns in detail and reviewed the action to be taken to prevent future deaths. On behalf of the Trust, I set out the response below and would like to reiterate our sincere apology and condolences to the family and friends of the late Mr Patrick Woods.

Alarms on anaesthetic equipment/factory settings

Every anaesthetic machine and monitor is configured with default alarms by the manufacturer prior to delivery of the machine to the Trust. As part of the commissioning of the machine, the settings of these default alarms are reviewed on behalf of the Trust by the Clinical Director for Anaesthetics to ensure they are fit for purpose. Since this incident, the default alarm settings have been discussed within the anaesthetic and operating department practitioners' forums, and the Trust has agreed a Trust default setting for each variable, which have been applied retrospectively to all machines currently in use from 21 July 2017, and will be applied prospectively to all future machines before they are deployed for clinical use.

These Trust defaults will be reviewed annually by the Clinical Director for Anaesthetics to ensure that they remain consistent with latest guidance, and provide safe alarm protection for all parameters.

The agreed default settings are as follows:

| | | |
|---|---|---|
| FiO2 | 30% - 100% | |
| ETCO2 | 3.0 – 7.0 kPa | |
| Respiratory rate | <8 breaths/min | |
| Pulse | 45 – 120 beats/min | |
| Blood Pressure | Systolic | 80 – 150 mmHg |
| | Mean | 60 – 125 mmHg |
| Oxygen Saturations | 94 – 100% | |

The default alarm settings have been agreed by the anaesthetists and operating department practitioners as providing acceptable safety for the majority of elective adult patients who are fit and well. We have highlighted this fact in our communication with anaesthetists and ODP's, and advised of the need to review alarm limits and set appropriate alarm limit values for all other cases.

Another point it is important to highlight is that the Tiro is manufactured and designed to display an "Oxygen Sensor Failure" message on the alerts screen if the FiO2 falls below 15%. This is only reasonable if it was considered impossible for a machine functioning correctly to deliver such a low level of oxygen, and that therefore such a reading must be due to a faulty sensor. What this case has demonstrated is that under the correct circumstances, this machine WILL deliver such an FiO2, and that for the machine to display such a message under these circumstances falsely leads the anaesthetist to believe that they should disregard the Low FiO2 alarm, because the machine is telling them that the sensor is not working.

Although the Trust is not able to take action in respect of manufacturing issues, the Trust considers that this is something which Drager should review and we would invite the coroner to consider the same when reviewing Drager's PFD responses. For example, had that message not been displayed in this case, it is quite possible that there would have been earlier investigation of the low FiO2 because the low FiO2 alarm would not have been disregarded, or the decision to switch to an alternative oxygen source and mechanism of ventilation might have been made earlier.

Implementation of AAGBI (Association of Anaesthetists of Great Britain and Ireland) Guidance

The AAGBI guidelines *"Recommendations for Standards of Monitoring During Anaesthesia and Recovery December 2015*[1]*"*, with the relevant sections highlighted, have been circulated to all anaesthetists and Operating Department Practitioner's by the Medical Director with an email[2] outlining the outcome of the inquest, and the concerns the Coroner raised.

Notices have been placed in each anaesthetic room to remind anaesthetists of the importance of ensuring they have received training on all pieces of equipment they are going to use, that they have checked the anaesthetic machine, and that they have reviewed the alarm settings. This TCA (Trained / Checked Machine / Alarms) methodology will become part of the routine practice of anaesthesia at the Luton & Dunstable Hospital, and will become part of the pre-operative huddle that occurs before the start of every list, including emergencies.

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[1] Recommendations for Standards of Monitoring during Anaesthesia and Recovery AAGBI December 2015 Available at http://www.aagbi.org/sites/default/files/Standards_of_monitoring_2015_0.pdf

[2] Email from Dr Robin White, Medical Director to all anaesthetists and ODP's sent 01/09/2017

It is important that I point out that to individually adjust all of the alarm settings on the patient monitor and the anaesthetic machine/ventilator takes approximately 10 minutes. For the majority of elective operating lists, it would be feasible to set appropriate defaults for the whole list at the start of the session, and this can be done alongside the operational checks that are carried out on each machine by the anaesthetist before use. However, the majority of machines will re-set to the default settings at the end of each case, requiring them to be re-set before each case in a list.

In an emergency setting, such as was the case of Mr Woods, the anaesthetist may be actively involved in treating the patient while transporting them to the theatre. As such, there will be scenarios where it may not be possible for an Operating Department Practitioner to be able to predict what alarm settings might be appropriate for such cases. Under such circumstances, the case may have to commence with the default alarm settings, and fine tuning of the alarm limits may need to take place during the case.

The Trust has written to AAGBI about this separately, to ensure that there is no conflict between the guidance and emergency situations, and if necessary to seek their assistance on ensuring there is a working practice within the Trust that adheres to the guidance.

Summary

The Trust believes that it has done all that it can reasonably be expected to do in addressing and raising awareness of the issues contained within the Prevention of Future Deaths Order, distributing and highlighting the current guidance available from the profession with respect to monitoring, and having put in place appropriate default alarm limits which enhance patient safety. The Trust will also take forward with AAGBI the application of the guidance in emergency situations.

The Trust would like to again re-iterate our sincere apologies and best wishes to the family and friends of the late Mr Patrick Woods, and to thank the Coroner for his careful and detailed examination of the facts.

If any further information is required by the Coroner, of if he would like to discuss the letter, please do not hesitate to contact my office on [redacted] or via email at [redacted]

Yours sincerely

**David Carter**
**Acting Chief Executive Officer**

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The matters of concern raised in the Report were:

1) The extent of the equipment portfolio held by the Hospital seemed to be unknown
2) Without the knowledge of the equipment held, no potentially dangerous equipment can be identified
3) Without the knowledge of that there is equipment that could potentially kill a patient, no risk assessment can be undertaken
4) Without a risk assessment, no action can be taken to prevent further injury to patients or fatalities

The Trust has now considered the above concerns in detail and reviewed the action to be taken to prevent future deaths. As acknowledged by the Coroner during the inquest itself, completing the actions in respect of these concerns is a time consuming task which requires substantial resources. However, on behalf of the Trust I set out below those measures which are already in place, and the action which will be taken by the Trust and the timescales for the same.

On behalf of the Trust I would like to reiterate our sincere apology and condolences to the family and friends of the late Mr Patrick Woods.

Action already taken

It is unfortunate that it was not made clear at the time of the inquest that the Trust does hold a register of all equipment and its location within the Trust.

A comprehensive log of equipment i.e. Manufacturer, model, serial no, device location (ward/department name), commissioning date & service requirement is already held by the Trust on an electronic database managed by the Clinical Engineering department. The database also keeps a record of the device history i.e. service, repair, and maintenance contract and field safety notice. In addition equipment is risk categorised into priority 1 to 5 based on the service requirement of devices. There is also a procedure in place for commissioning/disposing of devices on the database and a formal approval process is in place

for any device not already on the database and new to the trust. The department also keep a copy of agreed configuration related to specific devices and ward/department and ensure the device has the right dataset once it is serviced/ repaired

There is a Training need analysis (TNA) record for each location/ward held by the Trust on a database managed by the Clinical Devices Trainer.

The TNA analysis contains the list of equipment specific to the ward/department and the devices each clinician has been trained upon and alerts the expiry of competency. The TNA is distributed every other month to Ward Managers and Matrons for accuracy and follow up. The recording process is currently under review and the Trust is looking into an electronic database solution. The Clinical Devices Trainer along with the Clinical Educator offer a regular training session to Health Care Assistants (HCA), Registered Nurses (RN), Assistant Practitioners, and Student Nurses. The Clinical Devices Trainer arranges training for doctors as and when requested

In addition, at present, all incidents reported on the Trust's incident reporting system (Datix) involving faulty or any failure of equipment, are reviewed at each Medical Equipment Group meeting. The Medical Equipment Group meets every two months, and all events which have been reported through Datix pertaining to medical equipment are reviewed, regardless of what local action has already been taken. A decision is then made as to whether the event occurred as a result of user error, equipment malfunction or improper use. The results of this are then actioned by either our Clinical Devices Trainer (in the case of user error or improper use) or Clinical Engineering Manager (in the case of equipment malfunction). Because all events related to equipment are discussed at this one meeting, an overview is maintained in order to identify any themes or patterns which emerge. The group has the power to remove an item or type of equipment if necessary, and would communicate with the Medicines and Healthcare products Regulatory Agency ("MHRA") if necessary.

The Medical Equipment Group also review and act upon all "Medical Device Alerts" reported to the Trust by external agencies.

**Action to be undertaken**

The Trust has considered carefully what further action needs to be undertaken, and this is set out in the below table, with the timescales for completion of the same.

| Further action | Timescale |
|---|---|
| There is to be a review of each clinical area where an item of equipment is used, to ensure that the Trust has a complete and up to date "master" log of the equipment held. | The "sub-lists" to be sent to each area by the end of September 2017 |
| The current "sub-list" of equipment for each area (taken from the master log) will be distributed to the Clinical Director and Matron of each respective area, for them to review and cross-check with all equipment in that area. Any items in the clinical area which are not on the "sub-list" must be added.<br><br>The Trust's Head of Clinical Risk and Governance, supported by the Clinical Engineering Manager has | The Clinical Director / Matron of each area will be required to return the cross-checked and updated "sub-list" within two weeks of receipt of the "sub list" to the Chair of the Medical Equipment Group, with a copy also sent to the Head of Clinical Risk and Governance. |

| | |
|---|---|
| been tasked to create and distribute the "sub-lists" to each clinical area | |
| Once the updated "sub-lists" have been received by Chair of the Medical Equipment Group and the Head of Clinical Risk and Governance from each clinical area, Chair of the Medical Equipment Group must assimilate the information into the "master" log held by the Trust.<br><br>The "sub-lists" will also be kept for each clinical area. | The "master" log to be confirmed as updated and complete by the end of October 2017.<br><br>Each "sub-list" to be stored safely immediately upon completion and receipt. |
| From October 2017 the Trust will implement a new procedure whereby:<br>a) Any new equipment entered into the Trust will be reviewed and entered onto both the "master log" and the appropriate "sub-list" for the clinical area for where that item will be kept. The "master" and "sub-lists" will be maintained by the Medical Equipment Group, and the procurement team will cross-check the lists and provide an exception report to the Medical Equipment Group if any equipment has been bought and is not on the logs.<br>b) At regular intervals (every four months, i.e. at every other Medical Equipment Group meeting) both the "master" log and the "sub-lists" will be reviewed to ensure that they are accurate and up to date. The Clinical Director and Matron of each area which has a "sub-list" will be asked to confirm that the same is accurate in advance of the Medical Equipment Group meeting.<br><br>The Medical Equipment Group Committee will have overall responsibility for the "master" log and "sub lists". | Once the "master" log and "sub-lists" are completed as above, this new procedure will be in place.<br><br>At every Medical Equipment Group meeting (i.e. every two months) both the "master" log and "sub-lists" will be reviewed to ensure accuracy. |
| By the end of October 2017, a request will be sent to the Clinical Director and Matron of each clinical area which has a "sub list", who will then be responsible for undertaking a risk assessment of the identified equipment in their area and to review the unused functionality of said equipment / device. | The risk assessments must take place by the end of January 2018. |
| Risk assessments will thereafter be performed annually and reviewed at a specific Medical Equipment Group meeting for that purpose. The findings of the review will be reported to COB/COSQ | Ongoing from February 2018 |

Summary

The Trust believes that it has done all that it can reasonably be expected to do in addressing the issues contained within the Prevention of Future Deaths Order, to ensure that a complete and accurate portfolio of equipment is held at all times, and that appropriate risk assessments are undertaken.

If any further information is required by the Coroner, of if he would like to discuss the letter, please do not hesitate to contact my office on [redacted] or via email at [redacted]

The Trust would like to again re-iterate our sincere apologies and best wishes to the family and friends of the late Mr Patrick Woods, and to thank the Coroner for his careful and detailed examination of the facts.

Yours sincerely

**David Carter**
**Acting Chief Executive Officer**