County Durham and Darlington NHS
NHS Foundation Trust

Executive Corridor
Darlington Memorial Hospital
Hollyhurst Road
Darlington, DL3 6HX
e-mail: [redacted]

Your Ref: [redacted]
Our Ref: [redacted]

16th September 2016

Crispin A Oliver M.A.
HM Assistant Coroner
H.M Coroners Office
PO Box 282
Bishop Auckland
Co Durham
DL14 4FY

Dear Mr Oliver

I am writing in response to the Regulation 28 letter issued on 1 August 2016. The content of the Regulation 28 letter has been given due consideration and an action plan put in place to reduce any risk of future harm from a similar incident to patients in our care.

Mr Matthews was a gentleman who died from an infective exacerbation of chronic obstructive pulmonary disease on 19 February 2016. A concern was raised regarding equipment failure potentially contributing to the cause of death. An oxygen flowmeter had suffered a crack and was defective.

I have discussed the Regulation 28 with the Head of Clinical Engineering for the Trust and he has provided further clarity as follows:

> *The Flowmeter found to be damaged was still in use by the ward staff. However the flowmeter still delivered Oxygen but at an undefined rate due to the small crack in the plastic outer tube of the flowmeter body. Under pressure of the supply gas (nominal 4 bar, O_2) it is reasonable to assume the gas escaping to atmosphere via the crack was variable and hence related to the flow setting on the device caused by any back pressure level. Noise associated with the damage/leaking of O2 gas would most likely be evident to the user when operating the device but again probably related to the flow setting on the device itself.*
>
> *The actual crack damage would not get worse due to increased flow as such, but rather the gas 'lost' to atmosphere would increase by escaping through the crack in the outer tube.*

with you all the way

Overall maximum pressure within the flowmeter is limited to the supply gas pressure from the wall outlet (nominal 4 bar = 60PSI approx.).

Equipment suspected of damage should not be used. It should be removed from use, reported and a replacement device, in good condition, substituted. This is part of national and Trust policy. This issue is clearly documented in issued guidance from MHRA/DoH.

The O_2 flowmeter device in question is a very simple device with one mechanical moving part (on/off flow knob). Everything else is sealed by design and in normal conditions the flow indicator is proportional to the gas flow being set with the flow knob by the clinical user. Oxygen is a drug and administered accordingly.

In good condition these devices last for many years and are unlikely to fail due to natural component degradation. They require no planned technical intervention other than basic in-use functional checks by users. Damage is rectified by technical repair or replacement once the device is reported as defective. Replacement would normally be planned 'as required' by the users as a small value item (typically £60-£90), or following major damage that renders a repair uneconomical. All these devices work in the same way from the control knob action (anti-clockwise for 'ON' and flow increase versus clockwise for decreased flow and 'OFF')

Following review of this incident I can confirm that the damage report was not confined to within the Trust and I apologise that this information was not fully shared with you at the time. The incident was reported to the Adverse Incident Centre at MHRA and they asked the manufacturer to investigate our report of damage. The manufacturer responded to our report and MHRA responded to the Trust on 25 May 2016, and stated that they found the manufacturer response acceptable and that they had closed the incident, as follows:

MHRA Ref: [redacted]
Your Ref: [redacted]

Thank you for your report in connection with the following:
Device: Flowmeter, Manufacturer: Oxylitre Ltd

We asked the manufacturer to investigate your report. Their response is as follows:

"We found that there was a crack in the outer tube of one of the twin flowmeters. When plugged into a gas source with the control knob turned off, the bobbin (which indicates flow) is positioned at the top of the inner tube. When turned on the flowmeter would still supply the maximum flow rate. The customer indicated they noticed the crack when turning off the flowmeter, so regardless of the crack the flowmeter was continuing to supply oxygen. The crack in the top of flowmeter outer tube (approximately 30mm in length) was likely to have occurred by an impact. As soon as the unit is plugged into an Oxygen Terminal it would have been immediately obvious that it was leaking through the crack due to the very audible sound. Therefore we do not understand how clinical staff would deliberately use a defective unit. However, it is

possible that the damage occurred whilst in use, but as indicated the device would still deliver Oxygen. Note Oxygen tube fitting is missing from the base of the other flowmeter.

The returned unit is 15 years old. We could replace the cracked outer tube as a repair, but we do not support items that are over 10 years old and would normally offer a service exchange device. This has been indicated to the person who reported the incident as of 25.4.16. There is no other particular action Oxylitre can take since there is no design fault or any other problem with this model of device.

We have no idea how this item could be associated with the death of a patient. As indicated, it would still supply Oxygen to a patient regardless of the damage found. Also as indicated we cannot understand how an obviously faulty device would be used in a clinical environment to administer Oxygen to a patient. We can only conclude that because there is a link; however tentative, to a patient's death an adverse incident was raised regardless if there was zero contribution due to the damaged item."

We (MHRA) have reviewed the manufacturer's conclusions and consider them acceptable so we won't investigate any further.

You raised concerns that none of the information provided by the Trust has addressed the audible indication of damage to the device, and the fact that it was not detected by that means. A medical devices newsletter was circulated in April which outlined that the MHRA (2015) advises routine maintenance ensuring that the device continues to function correctly. It may include regular inspection and care, as recommended in the manufacturer's user information or Trust policy.

Tasks may include:

- Checking that devices work correctly before use
- Regular cleaning
- Specific daily, weekly checks
- Noting when a device has stopped working properly or when obvious damage has occurred, and then discontinuing use
- Contacting the relevant servicing organisation

Also included in the message was a reference to audible evidence of a gas leak from the device; '*when this type of damage occurs, staff may hear a hissing sound of the gas escaping when in use and see visible damage*'.

Medical Devices
Newsletter Issue 20 /

I have ensured that this issue has been raised at the Senior Nurse Leadership Group and all Care Group Governance Meetings within the organisation. All Associate Directors of Nursing have discussed this with clinical staff in all departments to reinforce the importance of checking oxygen flowmeters which includes any detection of audible hissing indicating a leaking of gas from the device.

Actions

1. All oxygen flowmeters across the Trust have been checked by the Clinical Engineering Department and any faults logged and reported to Department Managers

All Equipment Controllers/Department Managers to perform a full weekly check of all their flowmeters and report any damage to their local Clinical Engineering departments. A checklist has been devised by the Medical Devices Nurse and will be discussed at the next meeting of the National Association of Medical and Educational Trainers (NANDET) (*next meeting 21/09/16*) before being utilised across the organisation.

Medical Gas
Flowmeter checklist d

I hope the response addresses the concerns raised and provides assurance of the processes that have been put in place to prevent recurrence of this issue

Yours Sincerely

Sue Jacques
CHIEF EXECUTIVE

with you all the way