

| | | | | |
|---|--|--|--|---|
| <p>REGULATION 28 REPORT TO PREVENT FUTURE DEATHS</p> <p>THIS REPORT IS BEING SENT TO:</p> <ol style="list-style-type: none"> 1. [REDACTED] Patient Safety Lead, County Durham and Darlington NHS Foundation Trust, Darlington Memorial Hospital, Hollyhurst Road, Darlington, DL3 6HX 2. [REDACTED] Medicines and Healthcare Products Regulatory Agency | <p>CORONER</p> <p>I am Crispin A Oliver, Assistant Coroner, for the coroner area of County Durham and Darlington.</p> | <p>CORONER'S LEGAL POWERS</p> <p>I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013. (see attached sheet)</p> | <p>3</p> <p>INVESTIGATION and INQUEST</p> <p>On 1st March 2016 I commenced an investigation into the death of Leslie Matthews, born 6th May 1938. The investigation concluded at the end of the inquest on 20th July 2016. The conclusion of the inquest was that Mr Matthews had died from an infective Exacerbation of Chronic Obstructive pulmonary Disease on 19th February 2016 at University Hospital of North Durham. Having been a coal miner for 40 years he suffered from Pneumococcal pneumonia which was probably the predominant cause of the COPD and that his death was as a result of an Industrial Disease.</p> | <p>4</p> <p>CIRCUMSTANCES OF THE DEATH</p> <p>The original referral to the Coroner had been because Mr Matthews had been a Miner (coal face cutter) and further that there was a concern regarding equipment failure potentially contributing to the cause of death. An oxygen flow meter had suffered a crack and was defective. I authorised a forensic post mortem autopsy which concluded that in the particular circumstances of Mr Matthews' death "it is most likely that any contribution from the reduced oxygen supply has not been significant". This notwithstanding my investigation included evidence from the manufacturer of the flow meter which stated that even with the defect in the form of a crack in the outer tube of one of the twin flow meters it would still deliver oxygen and that further, as soon as it is plugged in to an oxygen terminal it would have been obvious that it was leaking through the crack due to the very audible sound. This was confirmed in a report provided by the NHS Trust by the Clinical Engineering Team Leader which stated that on commencement of their testing that it was clearly audible that there was a gas leak from the flow meter as this could be heard in the form of a "hissing". Also it was visible that there was a crack in the outer casing of the flow meter, at the top. The Clinical Engineering Team Leader's report went on, however, to say that the damage got worse under increased pressure of gas and that whilst it did deliver oxygen it was dependent on how far the crack had developed at the time and the exact setting of the flow meter in response to the crack. The Clinical Engineering Team Leader went on to state that the flow meter had sustained damage in use, almost certainly impact damage. This had never been reported to clinical engineering. Clinical engineering had then conducted an audit on the O2 delivery flow meters on the particular ward on which Mr Matthews had died, being the respiratory ward, and it was found that a further two flow meters were damaged but still available for use. They were twin flow meters with damage to one side with the continued use being in relation to the undamaged side. The author of the Root Cause Analysis report said that the damage to the flow meter in Mr Matthews' case had been at the back of the meter and was therefore not visible and that it had only become apparent when it had been difficult to switch it off. The other flow meters on the ward, she confirmed, had not</p> |
|---|--|--|--|---|

| | |
|---|----------------------------------|
| <p>been identified as broken prior to the engineering audit conducted pursuant to this incident. No explanation was discovered or provided during the course of the investigation with regard to precisely how the flow meters had been damaged.</p> | <p>CORONER'S CONCERNS</p> |
| <p>During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you.</p> <p>The MATTERS OF CONCERN are as follows. –</p> <p>(1) Undetected, damaged and defective flow meters were available to be used on the respiratory ward. Since the inquest concluded I have been provided by the NHS Trust with details of how the incident has been taken to Medical Devices Group Meetings on 11th March 2016 and 18th May 2016, and to Safety Committee on 31st May 2016. Checks have been conducted in Hospitals and Departments across the Trust. User checks are to be made routine. Older devices are to be replaced. Standardisation is "agreed going forward". Details of the incident have been proliferated across the Trust in quarterly staff news bulletins. An updated report from the Clinical Team Leader addressed the concern that flow meters are routinely in service for 15 plus years. However there remain the following concerns.</p> <p>(2) Notwithstanding the contention of the manufacturer that the oxygen was still being delivered by the defective flow meter in Mr Matthews' case, the conclusion of the Clinical Engineering Team Leader was that the damage got worse under pressure. The extent to which oxygen would be delivered was dependent on how far the crack had developed at the time it was being used, and the exact setting of the flow meter in response to the crack. Therefore notwithstanding the assertions of the manufacturer, it is available to conclude that this provides a potential life threatening danger and risk to patient safety. It is a concern that the manufacturer asserts that the device would be safe, in contradiction to the best evidence from the user.</p> <p>(3) While there is a brief reference in the 31st May 2016 Safety Committee minutes to "procurement to contact the suppliers to audit", the proliferation of information about this incident and the concerns it raises appears to be confined within this Trust. I am concerned that it should be proliferated further than that and in greater detail, not least because of the matters referred to in (2) above.</p> <p>(4) The Clinical Engineer Team Leader and the manufacturer concur that the damage to the flow meter in Mr Matthews' case was detectable from the outset of it being used because of a hissing sound. This had not been detected by nursing or medical staff and it was the evidence of the author of the Root Cause Analysis investigation report that the defect only became detectable to nursing staff from the moment at which the attempt was made to switch it off. None of the information supplied by the NHS Trust since the Inquest has addressed the audible indication of damage to the device, and the fact that it was not detected by that means. For instance the "Key Message" for July in the Trust Medical Devices Newsletter does not mention it in the list of pre-use checks. Also in the "Lessons Learned" Bulletin Q4 supplied to me by the Trust it simply admonishes staff to "ensure that the oxygen flow meters are working correctly if any cracks are identified on any apparatus can they be taken out of use" and "please check equipment for any damage prior to and during use to ensure equipment is working correctly". It does not state precisely how to check the equipment, or refer to hissing.</p> | <p>5</p> |
| <p>ACTION SHOULD BE TAKEN</p> <p>In my opinion action should be taken to prevent future deaths and I believe you and your organisation have the power to take such action.</p> | <p>6</p> |
| <p>YOUR RESPONSE</p> <p>You are under a duty to respond to this report within 56 days of the date of this report.</p> | <p>7</p> |

| | | |
|--|--|-----------------|
| <p>namely by Tuesday 20th September 2016. I, the coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.</p> | <p>8</p> <p>COPIES and PUBLICATION</p> <p>I have sent a copy of my report to the Chief Coroner and to the following interested Persons, Mr I Matthews.</p> <p>I am also under a duty to send the Chief Coroner a copy of your response.</p> <p>The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.</p> | <p>9</p> |
| <p>[DATE] 26/7/16</p> <p>[SIGNED BY CORONER] C.A. DAW</p> | | |