Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Mr Siddique
Coroner,
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Coroner's Court,
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MHRA

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22nd March 2021

Dear Mr Siddique,

INQUEST INTO THE DEATH OF MRS LYNN HADLEY

RESPONSE TO THE REGULATION 28 REPORT TO PREVENT FUTURE DEATHS

I write in response to your regulation 28 report dated 18th January 2021 and received 23rd January. In your report you asked the Medicines and Healthcare products Regulatory Agency (MHRA), Health and Safety Executive (HSE), West Midlands Ambulance Service and the Care Quality Commission (CQC) to consider reviewing and issuing guidance for the operation and use of oxygen cylinders. This letter sets out the actions the MHRA has taken, and which we propose to take, in response to your concerns.

The issuing of guidance is not within the remit of the MHRA, however, we are able to provide a degree of leadership as the Agency which had primacy in the latter stages of the investigation of this incident.

As you know, issues around the storage, handling, setting up, operating and monitoring the use of oxygen, particularly with respect to oxygen cylinders, were reviewed and discussed in the MHRA report of 2nd October 2020, which was provided to assist you, Mrs Hadley's family and the other Interested Persons during the inquest.

The MHRA, as part of the multidisciplinary team who investigated this incident, which included the CQC the West Midlands Ambulance Service, the West Midlands Fire and Rescue Service, the HSE and the manufacturer of the oxygen cylinder, Medical Gas Solutions, have determined there are a number of actions we can collectively undertake over time to raise awareness of the extremely rare phenomena of ignition within valve components of oxygen cylinders leading to a fire. Many of these actions were discussed in the aforementioned report. However, since the report was produced other actions have also been discussed and taken forward.

Following the inquest, and from our subsequent discussions, it remains clear, because of the widespread use of oxygen and oxygen cylinders and the very diverse people and organisations who undertake the administration of oxygen to those in need of it, messaging will not be straightforward. This is particularly

so because there are also other issues related to the use of oxygen, as well as those just associated with ignition and fire - some of which are also associated with serious patient harm and sometimes death - which will all require consideration in the future.

We believe the MHRA is best placed to take specific leadership action in relation to the risk of incidents which can lead to ignition and fire in the context of oxygen cylinders we will firstly engage with all the professional organisations who are the most likely to be involved in the administration of oxygen. Their members will be involved in the key stages of setting up of oxygen cylinders and accessory devices (required for the administration to a patient) and the monitoring of the progress of the patient when this has begun. It is hoped, in their professional leadership roles, they will be able to understand and shape the final messages needed to effect culture change amongst their membership, with our assistance where it is within our remit.

The organisations we have identified to date are below, but we appreciate others may be identified as we commence the process of engagement. They are (in no specific order):

Royal Colleges and Specialist Societies and Associations

- Royal College of Anaesthetists
- Association of Anaesthetists
- Royal College of Physicians (London and Edinburgh), especially acute medicine cardiology and renal medicine
- Royal College of Paediatrics and Child Health
- The Faculty of Intensive Care Medicine
- The Intensive Care Society
- Royal College of Emergency Medicine
- Royal College of Surgeons (England, Edinburgh, Glasgow)
- Royal College of Nursing
- National Midwifery Council

Healthcare Organisations

- NHS England and Improvement
- NHS Scotland
- NHS Wales
- NHS Northern Ireland
- Association of Independent Healthcare organisations
- Defence Medical Services

Emergency Services

- The Fire and Rescue Services
- The Ambulance Services Regional Trusts

Organisations for Future Engagement

- Independent Ambulance Services

- Mountain Rescue
- Hyperbaric Facilities
- Diving Organisations

We are taking this approach, because we are hoping this will reach a significant number of those involved with oxygen administration and it is based on 2 assumptions. The first is, in our experience, ignitions and fires which lead to patient harm have been invariably associated with the initial operation of an oxygen cylinder. These are circumstances where there is an initial treatment being administered or where a changeover of oxygen delivery is taking place (replacing a cylinder or swapping from either a pipeline or concentrator supply to a cylinder).

The second is where oxygen is being administered by a non-medical or nursing professional. In this situation there will be oversight from an appointed clinician or medical director for governance purposes. Therefore, the second assumption we are making is, if the medical professional has been engaged with, then this will hopefully lead to the appropriate dissemination of the messages to the operators, whose organisations we will be able to engage with directly in the future.

To facilitate this engagement, MHRA have already commenced a dialogue with the Association of Anaesthetists (with input to their Safety Committee). The matter has also been raised with the Safe Anaesthesia Liaison Group of the Royal College of Anaesthetists (RCoA) and the other organisations will follow.

For additional information the Association of Anaesthetists has facilitated a multiagency group of its own to produce guidance related to the prevention of incidents and the safe evacuation of critical care areas in the event of serious incidents, including fire. This follows the Bath intensive care oxygen fire. MHRA were represented on this group, which hopes to publish its completed guidance once ratified by the Councils of both the RCoA and the AA over the next few months.

We hope these actions, as detailed above, which will be undertaken as soon as we are able to, will reassure you the concerns you have identified are being properly addressed and we are doing all we can to ensure the relevant users are being informed.

Yours sincerely

Dr [redacted]
FRCA FFICM FFMLM
Senior Clinical Adviser - Devices
On Behalf of the CE MHRA