Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

[redacted]
www.cqc.org.uk

Senior Coroner, Mr Z Siddique
Black Country Coroner's Court
Jack Judge House
Halesowen Street
Oldbury
West Midlands
B69 2AJ

Via Email

12 March 2021

Care Quality Commission (CQC)

Dear Senior Coroner, Mr Zafar Siddique

REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

Thank you for your Regulation 28 prevention of future death report dated 18 January 2021 following the inquest into the death of Mrs Lynn Hadley whilst receiving care from West Midlands Ambulance Service (WMAS) paramedics.
The role of the CQC (Care Quality Commission) as an independent regulator is to register health and adult social care service providers in England and to check, through inspection and ongoing monitoring, that standards are being met. All GP practices in England must be registered with the CQC

The Care Quality Commission's (CQC) purpose is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve. Our role is to monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety and we publish what we find including performance ratings to help people choose care.

Within our role through our inspection of regulated health and social care services, we inspect and assess a range of aspects which relate to oxygen cylinders and medical gases including storage and staff training, where we find that there are breaches of regulation we take action to address this. It is worthy of note that we do not have powers to enter private citizens own homes in community settings and regulate where oxygen is self-administered.

Our powers to regulate are laid out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. A range of regulations are considered when assessing and inspecting the safe storage and use of oxygen and medical

gases. This is dependent on the whether any concerns identified affect, safe use, training or safety of equipment.

Background to the trust

West Midlands Ambulance Service University NHS Foundation Trust (WMAS) were last inspected in April 2019. They were rated outstanding overall. We have carried out monitoring of data and intelligence since their last inspection. Since the pandemic, we have monitored the service via virtual meetings, where they are considered to be functioning well with suitable systems and processes in place.

Events of 13 April 2020

On the 13 April 2020, paramedics attended Mrs Hadley's home address where during the administration of oxygen sparks from the neck of the oxygen cylinder caused a fire at Mrs Hadley's home. Sadly, Mrs Hadley passed away as she was unable to be moved away from the fire.

WMAS were transparent, in immediately alerting us to the incident. After initial meetings with the Health and Safety Executive (HSE) and the Medicines and Healthcare Products Regulatory Agency (MHRA) , it was decided that the CQC would lead on the investigation as Mrs Hadley was in receipt of care when the incident occurred. However, primacy for the investigation later transferred to MRHA when it was considered that the equipment was the main concern as opposed to the delivery of care.

The trust reacted swiftly to investigate and reviewed the circumstances of this rare and tragic event. The collaboration between several agencies allowed a coordinated response to mitigating the risk of reoccurrence, based on the knowledge gained from initial investigations.

As part of the multi-agency meetings which were held it was identified that there was a widespread and general lack of awareness across all users of compressed oxygen, for medical purposes, about the potential of adiabatic compression and particle impact/combustion syndrome. Guidance and training did not directly reference adiabatic pressure to alert users of oxygen of the risks.

Immediate actions taken by WMAS

Three safety alerts were published for all West Midlands Ambulance Service Clinical staff, this was to raise awareness and to address the concerns of general medical gas safety, cylinder safety and adiabatic compression.

We are also aware of an article in the trust's Weekly Briefing which was disseminated to all staff. In addition, all clinical staff have been asked to sign to confirm they have read and understood the contents of the safety notices.

Ongoing mitigation

- Improvements have been made to the mandated WMAS training programme for 2020/21 and beyond, which now includes a designated session on medical gas cylinder safety, including adiabatic compression and particle combustion syndrome.

- A 30-minute face to face training session was delivered to ALL WMAS clinical staff. The session was available to staff to view prior to attending the training session and the link for the session was provided in the weekly briefing article.

- The training and awareness updates have been inserted into the Associate Ambulance Practitioner course, graduate training, Patient Transport Services training, and will feature in the next mandated training manual.

- All NHS ambulance services within the UK, and relevant partners within the region have been sent the WMAS safety notices and training plans are being made available to all appropriate staff.

- Communications have taken place between regulators, providers, Police and fire service representatives to ensure that lessons learned from this tragic event can be shared appropriately across many services.

- CQC continue to communicate regularly with WMAS formally in monthly meetings, where staff training and incidents are discussed.

We are satisfied that WMAS took proactive and suitable actions following the death of Mrs Hadley to reduce the risk of a similar incident occurring and no enforcement action was taken against the trust.

We will continue to monitor the actions taken by WMAS to improve safety.

Following the inquest, the matters of concern raised within your report were as follows:

1. 'All agencies involved may wish to consider reviewing and issuing guidance for the operation and use of oxygen cylinders.

As a regulator it is unfortunately outside of the CQCs remit to issue or change formal guidance or policies around oxygen usage or safety. We are not clinical experts on oxygen cylinders or have access to the expertise which would be necessary in order to issue safety guidance. This role is more suited to the MHRA and HSE from whom I am aware separate responses will be sent to you.

2. 'I am particularly concerned about the use of oxygen cylinders in the community in general and would invite the HSE and CQC to consider issuing further guidance urgently'.

Some community services do come under the scope of regulation. Where this is the case we will have oversight of the storage and use of oxygen and medical gases as part of our regulatory function. Where we identify risks in the course of inspections relating to the use and storage of oxygen and medical gases we have enforcement powers available to us to enable us to hold providers to account.

As stated earlier the CQC do not have a remit to regulate the use of oxygen and medical gases in private households.

I trust this makes clear our position and the range of actions which have been taken in order to be satisfied that the risk has been reduced as far as possible.

Yours sincerely,

Chief Executive