
From: [I/S] NHS ENGLAND – X24) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=941B714CDB1348168693DC704F0514EF-SARAH.JENNI]
Sent: 1/19/2024 1:25:36 PM
To: [I/S]
CC:
Subject: FW: official sensitive NHSE PS to MHRA FYI Oxehealth

Please note this email contains official sensitive and personal information

Forwarding FYI as per [I/S] out of office. Thank you

[I/S] | Patient Safety Clinical Lead - Medical Devices
NHS England
M [I/S] | E [I/S]

From: [I/S] (NHS ENGLAND – X24)
Sent: Friday, January 19, 2024 1:22 PM
To: [I/S]
[I/S]
Subject: official sensitive NHSE PS to MHRA FYI Oxehealth

Please note this email contains official sensitive and personal information

Dear MHRA Vigilance

This is also directed to [I/S] and Nathan Moore who we engaged with in 2021/2022

Please see the information below relating to an incident received through the LFPSE which we would like to make you aware of.

We are sharing this patient safety concern with you purely for information, as it involves a medical device that we have previously raised concerns with. The manufacturer is aware of the patient's death and is apparently preparing a download of captured data to see if there was any delay in alarm activation. There are a number of unknowns from the report however we felt following previous concerns with this device to share it with you. Feedback on whether you have received this as a Yellow Card report is useful, but we do not intend to pursue this further unless you have insight that may be relevant to our remit.

Incident description: *On the 11pm care round Patient A was found unresponsive laid on her front by staff member A, her alarm was not working. Ward staff were alerted by their alarms at 23:07. Patient A had ligatured with X6 socks these were removed by ligature cutters. Cyanosis was evident, staff member B immediately checked for a pulse and called for the red bag and physical observation machine was brought round to her bedroom. Staff were unable to find a pulse, on call medic was present on the ward and called for CPR to be commenced. staff member B asked staff member C to call an ambulance at 23:08. CPR chest compressions were rotated by staff member D, on call medic and staff member A and staff member E. Defibrillator pads were placed on patient A however there was no shock advised. Staff continued CPR, Staff member B took over ambulance call and stayed on the phone until Ambulance crew arrived. Ambulance crew arrived approximately 5 minutes later and as they entered a shock was advised by the defibrillator. staff member A and D were present with the paramedics throughout who then took over compressions. Paramedics reported gaining a pulse back however pupils were dilated. patient was then transported to ICU at JCUH at approximately 00:00. In addition to the above further investigations have taken place as part of an early learning review. We have reviewed CCTV, documentation, and Oxehealth systems as part of this. The following timeline has been put together using the CCTV:*

- 22:00 - Patient is in her bedroom and CARE round completed. Evidence of engagement can be seen from the CCTV
- 22:58 - A HCA and a Medic pass the bedroom to support another patient in a bedroom nearby

- 23:04:07 - CARE round completed by a HCA who enters the room and then shortly leaves to gain assistance from other staff.
- 23:05:26 - Medic and staff attend bedroom
- 23:06:55 - Red bag is on scene and one staff seen leaving area (to phone ambulance)
- 23:08:43 - DNC arrives from ward next door to support
- 23:18:43 - Paramedics arrive
- 23:19:30 - Further paramedics arrive
- 23:54 - Patient leaves the ward with paramedics

A meeting was held with the Oxehealth Team to review Oxevision footage. Although the picture is heavily pixilated the following can be seen:

- 22:16 - Patient A sat up in bed
- 22:19 - Patient A on floor next to bed
- 22:19 - Patient A moving around on the floor
- 22:24 - Sits up and appears to retrieve something from the bed
- 22:26 - Appears to be putting something around her neck 22:29 - Face down on the floor next to bed. No further movement noted 23:04 - Staff enter the bedroom

The oxehealth activity report has also been provided. From this we are able to establish that the patient moves from "in bed" to "in the room" around the time the patient moves to the floor. However there appears to be no alert until 23:00.

Incident source: LFPSE reported **death**

Date shared: 19.01.2024

Device type: Oxehealth/Oxevision system

Incident date: 12th January 2024

Organisation: Tees, Esk and Wear Valleys NHS Foundation Trust

Please note I am not the reporter of this incident, and this is simply sharing as part of agreed data sharing between our organisations. Should you require any greater insight to this incident, you may need to consider contacting the organisation or manufacturer directly.

Kind regards

[I/S]

Patient Safety Lead for Medical Devices
NHS England

M [I/S] | E [I/S]

[I/S]

w: www.england.nhs.uk Follow us [@ptsafetyNHS](https://twitter.com/ptsafetyNHS)

I work 'compressed hours' and am out of office every other Friday.