NHS
Buckinghamshire, Oxfordshire and Berkshire West
Integrated Care Board

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[redacted]

Ms K Thorne
HM Coroners court
Reading Town Hall
Blagrave Street
Reading
RG1 1QH

12th October 2023

Dear Ms Thorne

Re: Regulation 28 Report to Prevent Future Deaths – Devon Drew Turner who died on 10 May 2022

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 18 August 2023 concerning the death of Devon Drew Turner who died on 10 May 2022. In advance of responding to the specific concerns raised in your Report, I would like to express my deep condolences to Devon's family and loved ones. Buckinghamshire Oxfordshire and Berkshire West ICB (BOB ICB) are keen to assure the family and the coroner that the concerns raised about Devon's care have been listened to and reflected upon.

I have liaised with our colleagues who represent system partners. On 13th May a Joint Agency Response meeting held with all stakeholders, I have assurance that actions were identified and completed with a copy of the minutes being sent to the coroner's office for consideration. Subsequently, on 8th June a Child Death Review meeting was convened with all partner organisations involved in Devon's care, and at the time of his death.

Although Berkshire Healthcare NHS Foundation Trust were not invited to participate in the inquest, nor cited in the Regulation 28 report, I have sought clarification from them as part of this reply, as they sit within the Buckinghamshire, Oxfordshire and Berkshire Integrated Care System and they supplied the equipment cited in the report to the parents of the deceased.

I have raised questions with Berkshire Healthcare NHS Foundation Trust directly regarding the provision of equipment, training, service, and maintenance process and I have enclosed their response at Appendix 1 for completeness.

The engineer from the manufacture of the SATS machine detailed their findings during the inquest of which is included within the Report. I have contacted the Medicines Healthcare Regulatory Authority (MHRA) by both telephone and follow-up email, I am cognisant that there are defined processes for direct escalations of concerns regarding pharmaceutical equipment. The organisation confirmed that they are aware of the incident from the Regulation 28 Report and are in receipt of the manufacturer's investigation into the Medtronic equipment (serial number MBH1920704). Which was examined by the manufacturer with the police present, and it was confirmed that no fault was found with the device. The alarm volume was set at its

maximum. The MHRA is continuing to work with the manufacturer to ensure this matter is fully investigated and action taken as needed.

Furthermore, the MHRA detail that the operator's manual for the device indicates it is intended for home use when used as an adjunct in patient assessment and is to be used in conjunction with monitoring for clinical signs and symptoms. There are several warnings in the operating manual regarding the alarms including for example ensuring the speaker is clear of any obstruction to prevent an inaudible alarm tone. Also, to keep patients under close surveillance when monitoring as it is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and the monitoring system can cause inaccurate measurement readings and not to rely entirely on the monitoring system's readings for patient assessment. The team confirmed that they are also in contact with the coroner's office to determine what response is required from the MHRA in relation to their findings and recommendations for actions. The MHRA keeps the safe and effective use of all medicines and medical devices under continuous review.

To conclude, I am satisfied that all organisations detailed within the Report, have responded proportionately. Additionally, that system partners have collectively examined the timeline of events with those directly involved supporting the family to care for Devon.

I would also like to provide further assurances taking place within BOB ICB around the Reports to Prevent Future Deaths. All reports received are summarised within the Learning from Deaths system Network Group. This ensures that key learnings and insights around preventable deaths are shared widely across our Health and Social Care organisations and helps us pay close attention to any emerging trends or themes that may require further review and action.

Your Regulation 28 Report asked the ICB to take action to identify what happened in relation to the reliability and ease of use of the SATS machines being used. The ICB and the MHRA have been involved in the oversight of the review of the machine and, following a review of the evidence presented at the inquest, the ICB feel that there is no further action needed in order to Prevent Future Deaths.

You also ask that the trusts, ICB, MHRA, NHSE and Medtronic investigate the events leading up to the death in relation to the loudness and reliability of the alarm on the Medtronic SATS machine. This has been undertaken as described above and the ICB, on behalf of all partners, feel that there is no further action to be taken in order to Prevent Future Deaths.

Thank you for bringing these important patient safety issues to my attention and please do not hesitate to contact me should you need any further information.

Your sincerely

[redacted]

[redacted]
Chief Nursing Officer

Appendix-Berkshire Healthcare NHS Foundation Trust response to direct questions:

In relation to the bedside saturation monitor given to the family on 22 April:

1) **Did the family receive training, in line with recognised Trust processes, to use the saturation monitor that was given to them on 22 April?**
The Community Children's Nurse [CCN] recorded in Devon's clinical record that she had explained to the parent how to use the handheld and bedside oxygen saturation monitors on the day she gave them the equipment. This was in line with Trust processes. At the first home visit by the CCN all medical equipment in use was reviewed, checked, and documented in Devon's clinical record. Berkshire Healthcare's 'Acknowledgement and terms of Equipment loan' document was completed and signed by the parent and the CCN at the next home visit on 27 April 2022.

2) **Did the family have a designated contact and/or contact number to use if they identified any issues with the saturation monitor?**
During the first home visit on 22 April 2022 the CCN explained the CCN service. She also discussed her role as named CCN in supporting Devon's care in the home. Parents are encouraged and advised to contact the CCN team with any queries or concerns they have about their child or their child's care and are given contact numbers for the team. There is evidence in the clinical record to show that the family contacted the CCN team when they needed advice around Devon's care, and also when they had concerns about the monitor being faulty on 25 April 2022.

3) **Please confirm the type and nature of the saturation monitor provided to the family on 22 April.**
The family were supplied with a tabletop (bedside) Nellcor PM 100N and a handheld Nellcor PM10N

4) **Please confirm whether the saturation monitor supplied to the family on 22 April was of a different type to that which had previously been used by the family.**
The saturation monitor was different to the monitor that had been used at University Hospitals Southampton [UHS].

   At the discharge planning meeting on 19 April 2022 Devon's Consultant/ Clinical Nurse Specialist team at UHS advised that Devon would require overnight and spot-check saturations as per his respiratory care plan. It was agreed that Devon would be discharged home with an oxygen saturation monitor from the ward at UHS and that this would be replaced with a Nellcor oxygen saturation monitor loaned to him by the CCN team whilst specific [Nellcor] equipment was being ordered for him. The agreement was that the parent would return the UHS equipment to the ward the following week when he returned for a scan.

5) **Was the saturation monitor supplied to the family by Berkshire Healthcare on 22 April checked and maintained in line with the Trust's maintenance specifications?**
All equipment supplied to Devon had been checked by the CCN before allocation, was within its service dates and had been serviced annually as per manufacturers guidelines.

6) **Have there been any other reports from families/users or staff of faults with the type of saturation monitor supplied to the family on 22 April? If so, what actions have been taken to investigate/rectify these?**
Nellcor is the only make of oxygen saturation monitor that the CCN service provide to families. The parents' report of a fault on 25 April regarding the machine supplied to them on 22 April is the only instance recorded of a fault of this kind with this type of equipment. All reported faults are listened to and acted upon by the team and equipment is sent for review and repair, and replacement equipment is issued. The team hold a pool of equipment to replace any items that need to be sent for repair or for annual maintenance. A clear record is kept of when oxygen saturation monitors have been brought in for

review and repair and also for annual planned preventative maintenance. The team always provide families with additional equipment in the home in case of equipment developing faults. Devon's family were provided with a bedside oxygen saturation monitor and a handheld portable saturation monitor.

In relation to the bedside saturation monitor given to the family on 25 April which remained in place on 10 May (i.e., at time of death):

1) **Did the family receive training, in line with recognised Trust processes, to use the saturation monitor provided to them on 25 April?**
   The Community Children's Nurse [CCN] recorded in Devon's clinical record on 25 April 2022 that the monitor had been replaced and that she had explained to the parent how to use the monitor. Berkshire Healthcare's 'Acknowledgement and terms of equipment loan' document was completed with details of equipment supplied and was signed by Devon's named CCN and the parent and uploaded to Devon's clinical record on 27 April 2022. This document includes an acknowledgement that the equipment is in good working order and that the parent understands instructions for use. It also asks users to immediately contact a member of Trust staff if the equipment is broken or damaged.

2) **Did the family have a designated contact and/or contact number to use if they identified any issues with the saturation monitor?**
   During the first home visit on 22 April 2022 Devon's named CCN explained the CCN service. She also discussed her role as named CCN in supporting Devon's care in the home. Parents are encouraged and advised to contact their CCN or the CCN team with any queries or concerns they have about their child or their child's care and are given contact numbers for the team. There is evidence in the clinical record to show that the family contacted the named CCN and other members of the CCN team when they needed advice around Devon's care, and also when they had concerns about the initial monitor being faulty on 25 April 2022 and the monitor was promptly replaced that day.

3) **Please confirm the type and nature of the saturation monitor provided to the family on 25 April.**
   The family were supplied with a tabletop (bedside) Nellcor PM 100N.

4) **Please confirm whether the saturation monitor supplied to the family on 25 April was of a different type to that which had previously been used by the family.**
   The saturation monitor supplied on 25 April 2022 was the same make and model as the monitor supplied on 22 April 2022.

5) **Was the saturation monitor supplied to the family by Berkshire Healthcare on 25 April checked and maintained in line with the Trust's maintenance specifications?**
   All Oxygen saturation monitors held by the Community Children's Nursing team have annual planned preventive maintenance in line with Berkshire Healthcare's HS020 Maintenance and repair of medical devices policy and procedure. The team keep an inventory of all medical devices and the dates when equipment needs to be recalled for scheduled maintenance. All equipment has a visual check before it is allocated, and it is checked to see if it is working correctly before it is set up in the patient's home or given to the patient.

   All equipment supplied to Devon had been checked by the CCN before allocation, all were within their service dates and had been serviced annually as per manufacturers guidelines.

6) **Have there been any other reports from families/users or staff of faults with the type of saturation monitor supplied to the family on 25 April? If so, what actions have been taken to investigate/rectify these?**

All reported faults in oxygen saturation monitors are acted upon by the team and equipment is sent for review and repair, and replacement equipment is issued. The team hold a pool of equipment to replace any items that need to be sent for repair or for annual maintenance. A clear record is kept of when oxygen saturation monitors have been brought in for review and repair and also for annual planned preventative maintenance. The team always provide families with additional equipment in the home in case of equipment developing faults. Devon's family were provided with a bedside oxygen saturation monitor and a handheld portable saturation monitor.