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Dr Karen Henderson
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18 October 2022

Dear Dr Henderson

Re: Regulation 28 Report to Prevent Future Deaths – Connor Samuel Timothy Wellsted who died on 17 May 2017.

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 15 May 2022 concerning the death of Connor Samuel Timothy Wellsted on 17 May 2017. In advance of responding to the specific concerns raised in your Report, I would like to express my deepest condolences to Connor's family and loved ones and I am very sorry to hear about the tragic circumstances of Connor's death. NHS England are keen to assure the family and the Coroner that the concerns raised about Connor's care have been listened to and reflected upon, in the hope that an incident such as this one never occurs again.

I am grateful for the further time granted to respond to your Report, and I apologise to the family for the delay, as I appreciate this will have been an incredibly difficult time for them.

Following the inquest, you raised concerns in your Report relating to the following issues:

1. The cot itself;
2. Monitoring of Connor during the night;
3. Probity and investigation by the Children's Trust, Tadworth; and
4. Senior management at the Children's Trust, Tadworth (including the lack of transparency and openness around the circumstances of Connor's death, which were not properly investigated or notified to the relevant statutory bodies).

As a consequence of the above, your Report raised that there was a need to introduce and develop robust clinical governance processes and systems, to reassure the public and supervisory statutory bodies that they will be informed of any future adverse events and that they will be investigated with openness, candour and transparency.

The role of NHS England (NHSE) regarding your Report has been to seek assurance that all relevant NHSE policy teams who are responsible for policy setting and

transformation in those areas (such as Specialised Commissioning and the Children and Young people Programme) were aware of this Report and the concerns raised. The team investigating and drafting this response have met with representatives from a variety of teams that cover this domain of healthcare. We have also ensured that they are aware of the new guidance on beds and cots 'Bed rails: Management and Safe Use .

Further, your Report has been shared with the NHSE Regulation 28 Working Group, who in turn have shared the Report with their regions through their mortality working groups, whose membership includes Integrated Care Systems (ICSs). ICSs are partnerships of organisations that come together to plan and deliver joined up health and care services, and to improve the lives of people who live and work in their area. ICSs are responsible for providers within their area and are able to check that they are adhering to guidance which could prevent future deaths.

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK. Beds, bedrails and cot sides are included in their remit. Patient Safety Incidents around the use of bedrails / cots and padded bedrails were reviewed by NHS Improvement in October 2017 and March 2018, in their Patient Safety Review and Response Report (see page 18). The report was shared with MHRA, Medical Device Safety Officers (MDSOs), and the National Association for Safety and Health in Care Services. As a result, MHRA were asked to consider the issue of padded bedrail bumpers/sides in their 'Bed rails: Management and Safe Use guidance. This guidance now contains a section on 'Inflatable bed sides and bumpers' (see section 6, case study 6). This section states that it is "important not to change the mattress or bed rails from the size or specification recommended by the manufacturer, to avoid creating entrapment gaps and instability". This aligns with The Children's Trust's response dated 8 July 2022, where they state that "The new beds have built in cot sides and padding, integral to the bed rather than separate bumpers".

In terms of investigation, the NHS England Patient Safety Incident Response Framework in July 2022. The Patient Safety Incident Response Framework (PSIRF) sets out the NHS's approach to developing and maintaining effective systems and processes for responding to patient safety incidents, for the purpose of learning and improving patient safety. The PSIRF is a contractual requirement under the NHS Standard Contract, and as such is mandatory for services provided under that contract and will include Providers such as The Children's Trust at Tadworth Court.

I note that you also sent your Report to the Chief Executive and Medical Director of the Children's Trust, Tadworth, and I have had sight of their response as referred to above. On 15 July 2022, representatives from the South East Region attended upon the Trust and carried out a comprehensive review of all of the points that you made in your Report. They concluded that there were no current quality concerns, however there was room for improvement. The outstanding actions for improvement will continue to be monitored by NHS England South East. I am assured that the Children's Trust, Tadworth, have addressed all of the concerns raised in your Report.

I would also like to provide further assurances on the national NHSE work taking place around the Reports to Prevent Future Deaths. All reports received are discussed by the Regulation 28 Working Group, comprising Regional Medical Directors and other clinical and quality colleagues from across the regions. This ensures that key learnings and insights around events, such as the sad death of Connor, are shared across the NHS at both a national and regional level and helps us to pay close attention to any emerging trends that may require further review and action.

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.

Yours sincerely,

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National Medical Director