

26/11/2018

Dear Mr Woolley,

**Re: Regulation 28 Coroner's Report HARVEY**

Thank you for your Regulation 28 letter of 25th September 2018, following the inquest into the death of Deidre Harvey. I was sorry to hear of her death in such sad circumstances and wish to extend my condolences to her family.

In order to avoid confusion given multiple persons addressed, I will be responding only to the issue directed at me. However please note that NHS Improvement works closely with our counterparts in Wales to share information to improve the safety of patients and quality of care, including in the area of management of ligature points, and my patient safety team has also supported other persons and bodies addressed in your letter in their responses to you.

You have raised the issue that there may be other patients with conditions requiring Hydroxychloroquine, who may be at risk of toxic levels of this drug in their system, and that new guidance for healthcare professionals may be required in relation to monitoring of this medication. You directed this concern jointly to me and the CEO of the Medicine and Healthcare products Regulatory Agency (MHRA), who we have worked closely with on this issue. You kindly granted us an extension of our reply until 3<sup>rd</sup> December 2018 to allow more time to explore this issue.

The issue of monitoring for toxicity that you raised is primarily in the remit of the MHRA, and they will provide the substantive reply to you on this issue. We have supported their work through undertaking a search of the National Reporting and Learning System. This did not identify any additional cases where systematic toxicity from Hydroxychloroquine had been identified, but did reinforce the importance of annual eye screening for patients on long-term Hydroxychloroquine, as set out in current guidance from the British Society for Rheumatology and British health Professionals in Rheumatology 'Guideline for the prescription and monitoring of non-biologic disease-modifying anti rheumatic drugs (see <https://cks.nice.org.uk/dmards#!scenario:8>)

We stand ready to support the MHRA in ensuring any future changes to monitoring reach all appropriate healthcare professionals and patients, including through our shared national network of Medication Safety Officers.

Thank you for giving us this opportunity to work with our partners to identify any action needed to prevent future deaths.

Yours sincerely,



MBBS, FRCS

National Director of Patient Safety

NHS Improvement