

Ms Rebecca Sutton

Assistant Coroner
County Durham and Darlington Coroner's Service
Crook Coroners Court
North Terrace
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DL15 9ES

National Medical Director

NHS England
Wellington House
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20th December 2024

Dear Coroner,

Re: Regulation 28 Report to Prevent Future Deaths – Patricia Heather Lines who died on 23 October 2023

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 24 October 2024 concerning the death of Patricia Heather Lines on 23 October 2023. In advance of responding to the specific concerns raised in your Report, I would like to express my deep condolences to Patricia's family and loved ones. NHS England are keen to assure the family and the Coroner that the concerns raised about Patricia's care have been listened to and reflected upon.

Your Report raises the concern that both an NHS e-learning module on administering intramuscular injections and Chapter 4 of "The Green Book" do not advise to wash, wipe or disinfect skin that already appears clean at the site of and prior to immunisation. You also raised that the relevant section of "The Green Book" is now over 20 years old.

My response to your Report has been informed by the Infection Prevention team here at NHS England. Our own [Infection Prevention and Control \(IPC\) guidance](#) aligns with 'The Green Book' (UKHSA guidance, published on 11 September 2013), which serves as the national standard for vaccination and immunisation by injection. As you have noted in your Report, [Chapter 4 of The Green Book](#) indicates that skin preparation is unnecessary if the skin is clean and not visibly dirty. It is the responsibility of the UK Health Security Agency (UKHSA) to confirm that 'The Green Book' remains current and to update it when required. In addition, local policies should inform practice in specific cases (e.g. immunocompromised patients). NHS England will review the contents of UKHSA's response once this has been received

As part of our review into this case, we have identified additional sources of published guidance, some of which provide conflicting advice on the practice of cleaning a patient's skin prior to immunisation. However, the maintenance and updating of such guidance falls outside of NHS England's remit. Some examples include:

- The Royal Marsden manual of Clinical and Cancer Nursing Procedures ([Medication: intramuscular injection - Royal Marsden Manual](#)), which states: "Clean the injection site with a swab saturated with isopropyl alcohol 70% for

30 seconds and allow to dry for 30 seconds. To reduce the number of pathogens introduced into the skin by the needle at the time of insertion and to prevent a stinging sensation if the alcohol is taken into the tissues upon needle entry.”

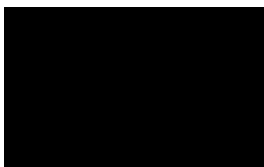
- [WHO guidelines](#) (2010, p.7) recommend skin cleaning before injections, although these are global standards and are not specific to the UK.

In Patricia’s case, it is entirely possible that this was an isolated incident, although it is difficult to comment on this without further information. The infection may have been due to factors such as commensal bacteria or external contamination, rather than a failure to clean the skin prior to injection. It is essential that healthcare practitioners administering intramuscular injections receive appropriate training to ensure they are proficient in best practices, including hand hygiene and infection prevention protocols.

I would also like to provide further assurances on the national NHS England 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 Patricia, 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,




National Medical Director