


## REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	<p><b>REGULATION 28 REPORT TO PREVENT FUTURE DEATHS</b></p> <p><b>THIS REPORT IS BEING SENT TO:</b></p> <ol style="list-style-type: none"><li><b>1. UK Health Security Agency</b></li><li><b>2. Department of Health and Social Care</b></li><li><b>3. NHS England</b></li></ol>
1	<p><b>CORONER</b></p> <p>I am Rebecca Sutton, assistant coroner, for the coroner area of County Durham and Darlington</p>
2	<p><b>CORONER'S LEGAL POWERS</b></p> <p>I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and Regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.</p>
3	<p><b>INVESTIGATION and INQUEST</b></p> <p>On 6 November 2023 an investigation into the death of Patricia Heather Lines, aged 77, was commenced. The investigation concluded at the end of the inquest before a jury on 22 October 2024. The medical cause of death was:</p> <p><i>I a Septicaemic Shock</i> <i>I b Necrotising Fasciitis, Right Shoulder</i> <i>I c Invasive Group A Streptococcus Pyogenes Infection</i></p> <p><i>II Type 2 Diabetes Mellitus; Ischaemic, Hypertensive and Valvular Heart Disease</i></p> <p>The conclusion of the jury was "Accident".</p>
4	<p><b>CIRCUMSTANCES OF THE DEATH</b></p> <p>The deceased underwent an intramuscular Vitamin B12 injection into her right shoulder on 17 October 2023. The following day she became unwell and was admitted to hospital. Blood tests revealed that the deceased was suffering with an Invasive Group A Streptococcus Infection. Despite receiving hospital treatment, the deceased's condition deteriorated and she died on the 23rd October 2023. The post mortem pathology evidence indicated that the most likely source of the Invasive Group A Streptococcus Infection was the intramuscular injection; it was likely that streptococcus bacteria was present on the skin of the shoulder at the time of the injection and it was introduced into the deeper tissues of the shoulder when the injection was administered.</p>
5	<p><b><u>CORONER'S CONCERNS</u></b></p>

	<p>During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths could occur unless action is taken. In the circumstances it is my statutory duty to report to you.</p> <p>The <b>MATTERS OF CONCERN</b> are as follows:</p> <p>The nurse who administered the injection gave evidence that she did not clean the skin prior to administering the injection. She did not do so because she was following both her training (she quoted from an NHS e-learning module on administering intramuscular injections) and national guidance in the form of a document titled “Immunisation Against Infectious Disease”, which is also referred to as “The Green Book”.</p> <p>Chapter 4 of “The Green Book” provides guidance on immunisation procedures. In relation to cleaning the skin the Green Book states as follows (at page 29):</p> <p><i>If the skin is clean, no further cleaning is necessary. Only visibly dirty skin needs to be washed with soap and water.</i></p> <p><i>It is not necessary to disinfect the skin. Studies have shown that cleaning the skin with isopropyl alcohol reduces the bacterial count, but there is evidence that disinfecting makes no difference to the incidence of bacterial complications of injections (Del Mar et al., 2001; Sutton et al., 1999).</i></p> <p>The evidence that I heard at the inquest included that alcohol wipes are relatively cheap and their use does not give rise to any significant risk. I note that the Green Book states that cleaning the skin with alcohol reduces the bacterial count. Common sense would seem to suggest that reducing the bacterial count would reduce the risk of bacteria being inadvertently introduced into the deeper tissues during an injection. Whilst it is noted that the Green Book also makes reference to there being evidence that disinfecting makes no difference to the incidence of bacterial complications, it is also noted that the literature quoted is now over 20 years old.</p>
6	<p><b>ACTION SHOULD BE TAKEN</b></p> <p>In my opinion action should be taken to prevent future deaths and I believe your organisation has the power to take such action.</p>
7	<p><b>YOUR RESPONSE</b></p> <p>You are under a duty to respond to this report within 56 days of the date of this report, namely by 20 December 2024. I, the coroner, may extend the period.</p> <p>Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.</p>
8	<p><b>COPIES and PUBLICATION</b></p> <p>I have sent a copy of my report to the Chief Coroner and to the following Interested Person, [REDACTED]. I have also sent it to the GP surgery where the injection was administered, who may find it useful or of interest.</p> <p>I am also under a duty to send the Chief Coroner a copy of your response.</p> <p>The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of</p>

	your response, about the release or the publication of your response by the Chief Coroner.
9	<b>24 October 2024</b>  <b>Rebecca Sutton HMAC County Durham and Darlington</b>