Regulation 28: REPORT TO PREVENT FUTURE DEATHS

NOTE: This form is to be used **after** an inquest.

	REGULATION 28 REPORT TO PREVENT DEATHS **THIS REPORT IS BEING SENT TO:** **1 NHS England & NHS Improvement (PFDs)**
1	**CORONER** I am Anita BHARDWAJ, Area Coroner for the coroner area of Liverpool and Wirral
2	**CORONER'S LEGAL POWERS** 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.
3	**INVESTIGATION and INQUEST** On 16 June 2022 I commenced an investigation into the death of Susan Elizabeth SKILLEN aged 61. The investigation concluded at the end of the inquest on 16 November 2022. The conclusion of the inquest was that: Susan Skillen was a 61 year old lady who had a number of co-morbidities including interstitial lung disease and a history of rheumatoid arthritis, for which she was prescribed methotrexate and leflunomide. Susan had recently been on holiday to Turkey where she developed pain to her upper back with large area skin redness and peeling skin. Her skin was treated, there appeared to be no signs of infection but as a precautionary measure, antibiotics were prescribed. On 26 May 2022 Susan was admitted to Arrowe Park Hospital after being found on the bedroom floor at her home address. She said she had slipped from the bed and found it very hard to stand but she was noted to have reduced consciousness. Susan was found to have low blood pressure and hypoglycaemia, with laboratory investigations showing severe neutropenia (low neutrophils - a type of white blood cell that fights infection). Despite medical treatment, she continued to deteriorate and died later the same day, 26 May 2022. The post mortem examination found Susan died as a result of neutropenic sepsis. As mentioned, Susan had a history of rheumatoid arthritis, for which she was prescribed methotrexate and leflunomide; these suppress the inflammatory response triggered by disease. Neutropenia and neutropenic sepsis are recognised but rare complications of these drugs. No other source of infection was seen either at post mortem examination or following histological assessment, however, it is more likely than not this area of skin loss over her back was the most likely source of infection. Phototoxicity is a condition that looks and feels like severe sunburn. It is a type of photosensitivity that occurs when a chemical (often a drug ingested or topically applied) combines with the UV light leading to skin damage in the region of sun exposure. Methotrexate has been associated with phototoxicity and from the evidence it is more likely than not the phototoxicity has likely contributed to the development of the area of skin loss over the back. Overall, it is more likely than not Susan died as a result of the inadvertent extremely rare consequences/side effects of the combined effects of sun exposure and medication to treat rheumatoid arthritis.
4	**CIRCUMSTANCES OF THE DEATH**
5	**CORONER'S CONCERNS**

	During the course of the investigation my inquiries 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. The **MATTERS OF CONCERN** are as follows: (brief summary of matters of concern) Phototoxicity is an extremely rare side effect of methotrexate but does not appear in literature given to patients. The hospital were requested to complete the Yellow Card system but it was unclear if the literature for patients needed to be reviewed depending upon how many other patients had suffered this side effect.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you (and/or your organisation) have the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by January 11, 2023. I, the coroner, may extend the period. 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.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons I have also sent it to **Arrowe Park Hospital LEGAL SERVICES** who may find it useful or of interest. I am also under a duty to send a copy of your response to the Chief Coroner and all interested persons who in my opinion should receive it. I may also send a copy of your response to any person who I believe may find it useful or of interest. 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 your response about the release or the publication of your response by the Chief Coroner.
9	**Dated: 16/11/2022** **Anita BHARDWAJ** **Area Coroner for**