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 Secretary of State for Health and Social Care, Mr S Javid**
1	**CORONER** I am Kate Ainge, Assistant 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 01 July 2021 I commenced an investigation into the death of Katie Julia WILKINS aged 14. The investigation concluded at the end of the inquest on 26 May 2022. The conclusion of the inquest was that: Katie was a 14 year old girl with a diagnosis of Acute Promyelocytic Leukaemia (APML) which is known to have an associated and serious coagulopathy. Management and the treatment of the APML must also include treatment and management of the associated coagulopathy, that being a critical and basic element of the treatment of the condition. Katie initially presented at Warrington Hospital for concerns around pain and soreness in her vaginal area. She was diagnosed with a suspected labial abscess. Katie had no medical history of note and was not sexually active, this being an unusual presentation. Katie presented to the hospital initially on the 1/7/20 and subsequently on 5 further and separate occasions on the 2/7/20, 7/7/20, 14/7/20 and 15/7/20 and on the 21/7/20, each time relating to the unresolved labial abscess, pain and with tachycardia, including latterly with spiking temperatures. Despite the presentation on the 14/7/20 being the 4th occasion in which she was noted to be tachycardic, that increasing severity in the abscess was noted and there was an identified need for surgery the following day, no clinical review was undertaken or pre-operative blood tests directed. Those investigations were a basic part of the medical attention and treatment Katie required at that time. On the 26/7/20 Katie collapsed at home and was presented again to Warrington Hospital, at this time blood tests were instigated. Katie had a suspected diagnosis of APML and once stabilised, was transferred to Alder Hey Children's Hospital where she received a formal diagnosis and treatment for the APML and also the associated coagulopathy. The associated coagulopathy poses a significant risk of bleeding in APML patients and as such Katie's treatment plan was complex and multifaceted and involved the use of fibrinogen concentrate amongst other blood products, with regular blood testing to monitor the blood levels. Katie suffered a drop in fibrinogen levels on the 28/7/20 at 10pm and further falling levels were noted in the early hours of 29/7/20. Katie's plan of treatment for her coagulopathy was for treatment with fibrinogen concentrate when her levels fell below 1. Despite her initial falling levels from 28/7/20, the fibrinogen concentrate was not administered in accordance with treatment plan once the blood results were known. Further on the 29/7/20 at around 9:30am Katie was urgently prescribed further fibrinogen concentrate to be given immediately. Also on or around 9:30am, she also complained of a mild headache which was more likely than not evidence of the commencement of a intracerebral haemorrhage when taken with her low fibrinogen levels. Despite fibrinogen concentrate having been part of Katie's treatment plan when fibrinogen levels fell below 1, and the same being advised for immediate administration at 9:30am that day, that being a basic part of the medical

	treatment Katie required to manage her condition, it was not administered and Katie suffered a catastrophic intracerebral haemorrhage. Katie was taken urgently for a decompressive craniectomy surgery with evacuation of the intracerebral haemorrhage. Despite the surgery on the 29 July 2020 Katie did not recover. Having been assessed and undergoing an MRI scan, Katie was found to have no brain activity and deemed brain stem dead, she was subsequently extubated and passed away on the 31/7/20.
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: The inquest has highlighted an ongoing concern that Oncology Consultants will continue to be the lead Consultants for care of APML patients at Alder Hey Trust. The most significant risk of death in such patients is due to the risk of serious bleeding due to the associated and significant coagulopathy. Coagulopathy management should be led by a Haematologist to prevent future deaths due to this issue, that was recognised by a Consultant Haematologist who gave evidence to the inquest as a expert witness and as supported by a leading Haematologist at the Trust. There is nationally a shortage of Haematologists which leaves Alder Hey Trust without resources available to them to address this matter of concern or to recruit.
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 July 21, 2022. 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 [redacted] I have also sent it to **Alder Hey Childrens NHS Foundation Trust** 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: 26 May 2022**  **Kate AINGE** **Assistant Coroner for** **Liverpool and Wirral**