REGULATION 28 REPORT TO PREVENT FUTURE DEATHS

THIS REPORT IS BEING SENT TO:

1. NORTH WEST ANGLIA NHS FOUNDATION TRUST
2. CAMBRIDGESHIRE & PETERBOROUGH CLINICAL COMMISSIONING GROUP
3. DEPARTMENT FOR HEALTH & SOCIAL CARE

1.	**CORONER** I am Miss Lorna Skinner QC, Assistant Coroner for the coroner area of Cambridgeshire and Peterborough.
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. Coroners and Justice Act 2009 (legislation.gov.uk) The Coroners (Investigations) Regulations 2013 (legislation.gov.uk)
3.	**INVESTIGATION and INQUEST** On 21 May 2020 I commenced an investigation into the death of Ethel Ann Beaumont, who died on 11 May 2020 aged 69 years. The investigation concluded at the end of the inquest on Thursday 29 April 2021. The conclusion of the inquest was: **Medical Cause of Death** – 1a liver failure 1b nitrofurantoin induced liver injury 1c colorectal fistula 2 atrial fibrillation, chronic obstructive pulmonary disease **Conclusion** – From liver injury caused by taking nitrofurantoin as prescribed from 28 February 2020 onwards.
4.	**CIRCUMSTANCES OF THE DEATH** At the time of her death, Ethel Beaumont had been scheduled for a subtotal colectomy. On 28 February 2020 her GP had prescribed nitrofurantoin 100mg twice daily for 7 days following advice from the registrar at Hinchingbrooke Hospital. On Consultant review in flexible cystoscopy clinic on 6 March 2020, Ethel was asked to continue the nitrofurantoin for a further two months, but advised not to take it for more than three. Accordingly, a prescription for 100mg once daily for 28 days was issued. Ethel attended clinic on 17 March 2020, agreed to go ahead with surgery and blood tests were taken on that day. The

	results were reported the following day – showing a raised alanine aminotransferase, or ALT level, of 134. The "normal" range is between 5 and 33. The potential effects of nitrofurantoin on liver function were not appreciated. It was anticipated that further liver function tests would be taken at a pre-operative assessment on 6 April 2020. When Ethel attended for her pre-operative assessment her eyes were yellow and she reported having been jaundiced for the last two days. Blood tests were taken and within 2 hours of returning home, Ethel was recalled to Hinchingbrooke hospital and admitted with suspected drug induced liver injury. She was transferred to Addenbrooke's for liver biopsies on 13 April and from there admitted to the Arthur Rank Hospice in Shelford on 7 May, where she died on 11 May 2020. The pathologist, Dr [redacted], concluded in his report that Ethel's drug induced liver injury was caused by the nitrofurantoin she had been taking, and was a rare but known adverse effect of long-term0 nitrofurantoin therapy. In order to assist me to investigate Ethel's death, I heard expert evidence, including from Dr [redacted] a consultant hepatologist. As a result of the evidence I heard from Dr [redacted], and in particular her careful synthesis of various studies, I accepted that drug induced liver injury secondary to nitrofurantoin is an extremely rare event – the risk of severe hepatoxicity remains at probably less than 1 per 3000 patients to whom it is prescribed. I also accepted that it is not predictable, so no testing pre-treatment could have identified that Ethel was at increased risk for this complication. I also accepted that there was no failure by Ethel's medical practitioners to appropriately monitor her nitrofurantoin as she was on it for such a short period, and the plan for surgery would likely result in her being able to stop taking it. I did, however, conclude that the abnormal blood test result, which had shown a significantly raised ALT, should have been followed up in a timely manner, and that a repeat should have been ordered with 7 days of 17 March. Had this been done, it would, on the balance of probabilities, have more than minimally reduced the chance of death occurring.
5.	**CORONER'S CONCERNS** 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. **The MATTERS OF CONCERN ARE** that there is a lack of clarity between hospital and primary care as to which of them should be responsible for monitoring where a GP is prescribing an antibiotic on the request of the hospital that a patient is attending regularly for review. I am concerned that these pathways

	should be clarified and that there remains a risk of future death at present.
6.	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you 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 05 January 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: (1) [redacted] (2) Dr [redacted] 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 other 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.
9.	 09 November 2021