A R W Forrest LLM, FRCP, FRCPath
GMC Number: 1333523
Her Majesty's Senior Coroner for South Lincolnshire

REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

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

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. [redacted] **Director Pharmacovigilance, MHRA** 2. [redacted] **Director CCP, National Institute for Health and Care Excellence, 10 Spring Gardens, London, SW1A 2BU** 3. [redacted]**, Medical Director Lincolnshire Community Health Services, Bridge House, Unit 16, Sleaford, NG34 8GG**
1	**CORONER** I am ARW Forrest, Senior Coroner for the Coroner's area of South Lincolnshire.
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 31st March 2014 I commenced an investigation into the death of Lynn POYSER, age 56. The investigation concluded at the end of the inquest on 22nd July 2015. The conclusion of the inquest was ACCIDENT.
4	**CIRCUMSTANCES OF THE DEATH** **Lynn suffered from a number of problems including impaired kidney function, fatty liver disease, Type 2 Diabetes Mellitus, Fibromyalgia and heart failure. She was being prescribed 22 different medicines including Spironolactone when she attended her G.P. for a nurse led chronic illness check on 5th March 2014. Her blood pressure was noted to be 144/80. The registered nurse, not a prescriber, printed out a prescription for 2.5mg Lisinopril once daily for Lynn. She took this to the duty doctor in the practice who was not Lynn's regular G.P. After**

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	discussion the prescription was signed. It was received in a pharmacy adjacent to the practice on 8th March 2014 and once dispensed was collected by her husband. Arrangements were made for a "blood test", including serum potassium on 24th March 2014. On 22nd March 2014 she was admitted to hospital with a serum potassium of 9.7 mmol / L. Despite appropriate treatment she had a cardiac arrest from which she could not be resuscitated. Her vitreous humour at post mortem had a urea concentration of 41.8 mmol / L and a creatinine concentration of 421 mmol / L. **The cause of death was recorded as:** **1a Hyperkalaemic Cardiac Arrhythmia** **1b Acute on Chronic Renal Failure** **1c Co-prescription Spironolactone and Lisinopril**
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 will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows. – 1: Evidence was presented at the inquest to the effect that the interaction between Lisinopril and Spironolactone is well known, and that Lisinopril can precipitate deterioration in a patient's renal function. NICE published guidelines on initiation of Angiotensin converting enzyme inhibitor therapy indicates that patients should be reviewed one to two weeks after initiation of therapy and have their renal function and electrolyte status checked 10 – 14 days after initiation of ACEI therapy. This is re-iterated in LCHS guidance. The expert evidence at the inquest pointed out that, following a report of a trial in 1999 "The Randomised Aldactone Evaluation Study", there was an increase in the co-prescription of Spironolactone and Lisinopril in heart failure, immediately followed by an increase in hospital admissions and subsequent deaths associated with hyperkalaemia.

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	Those to whom I make this report may wish to consider whether or not the current guidance relating to the co-prescription of ACEI drugs, such as Lisinopril, and Spironolactone draws sufficient attention to the need for caution and the need to take a holistic view of the best interests of the patient.
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 **21st September 2015** . 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] – Husband 2. [redacted] – Son 3. [redacted] - Daughter I am also under a duty to send the Chief Coroner a copy of your response. 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	**23rd July 2015** **ARW Forrest.........[redacted]...............................** **H M Senior Coroner for South Lincolnshire**

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