	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **Mr M Wilson, The Chief Executive, Surrey and Sussex NHS Trust, Trust Headquarters, East Surrey Hospital, Redhill, Surrey RH1 5RH**
1	**CORONER** I am Bridget Dolan, Assistant Coroner, for the Coroner area of West Sussex
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 19 March 2014 I concluded the inquest into the death of MRS KERRY JACOBS born 11June 1969 (aged 44 yrs), who died on 8 July 2013. I determined that Mrs Jacobs had died as a result of (1a) a pulmonary embolism arising from (1b) a deep vein thrombosis in the right calf and that her death was from a natural cause.
4	**CIRCUMSTANCES OF THE DEATH** 1. Mrs Jacobs suffered with progressive hearing loss and tests suggested that she probably had an auto-immune disorder putting her at risk of becoming deaf. Her treating Consultant ENT surgeon sought advice from a Consultant Otologist and a Consultant Oncologist, and it was determined that 'high dose' steroids (prednisolone) should be prescribed to her for a four week period, tapering off thereafter. The advice, as recorded in a typed note, was for a starting dose of 1mg/kg od. 2. The ENT consultant stated in evidence at the inquest that, in accordance with BNF guidelines, he considered that the maximum appropriate prednisolone dose was 60mg od. 3. However it was an ENT speciality doctor, rather than the ENT Consultant who next saw Mrs Jacobs in outpatients. He stated that he had discussed Mrs Jacobs' case with the consultant before the appointment. The specialty doctor prescribed 95mg prednisolone od. for four weeks, to then be reduced to 75 mg od. This dosage was based on his understanding that Mrs Jacobs' weight was 95kg. He stated that he had previously prescribed up to 60mg prednisolone and had never prescribed steroids at as high a dosage as 95mg od, however he knew of high dose steroids being given for a different disorder (myasthenia gravis) and he understood that he was following the consultants' recommendation. The speciality doctor did not recognise at the material time that he was prescribing outside BNF guidelines. 4. The ENT consultant stated in evidence that although a doctor can prescribe outside BNF guidelines if this is clinically indicated, he would not have prescribed steroids for Mrs Jacobs at this high level. However the ENT consultant was not copied into the relevant clinic letter and remained unaware that a dose of 95mg od. had been prescribed to his patient. 5. On 29 May 2013 Mrs Jacobs presented the prednisolone prescription at a pharmacy. The dispensing pharmacist noted the high dosage and declined to dispense the medication. The

pharmacist contacted the hospital to query the prescription. On 4 June 2013 the pharmacist was informed by a hospital secretary that the prescription dose was as intended. Therefore the prednisolone was then dispensed to Mrs Jacobs and taken as per the prescription.

6. The prescribing doctor had no recollection of being asked to confirm the prescription (although he stated usual procedure would be for the secretary to raise it with him). There was nothing within Mrs Jacobs' hospital records to indicate that a pharmacist had queried this prescription of steroids. I was informed that there is no policy or procedure within the Trust which requires such an inquiry by a pharmacist to be recorded.

7. The ENT consultant was unaware of the query by the pharmacist. He stated that if he had seen the clinic letter, or had the pharmacist contacted him, he would have reduced the prescribed dosage to 60mg.

8. On 30 June 2013 Mrs Jacobs developed pain in her right calf after a 2 hour car journey. She attended her GP the next day (1 July 2013) and was appropriately referred directly to Crawley Hospital for investigations for suspected deep vein thrombosis (DVT). Her right calf had a 2cm greater circumference than her left and her d-dimer level was above the normal range. An ultrasound examination was appropriately advised, however that examination did not reveal any thrombus. Mrs Jacobs understood the outcome of the tests was that she did not have DVT and she reported to her husband that an explanation offered to her for her continuing leg pain was that she may have suffered a muscle tear.

9. In the early hours of 8 July 2013 Mrs Jacobs suffered a fatal pulmonary embolism.

10. On post mortem examination a large thrombus was identified in Mrs Jacobs' right calf. A consultant physician advised, and I accepted, that it was probable that a clot had been present in the right calf on 1 July 2013. However the unanimous clinical evidence was that, in accordance with the standard procedure, only the proximal (upper) leg is examined on ultrasound sound and hence one would not expect that procedure to have identified a thrombus present in the lower leg.

11. Thrombo-embolism is one of the many potential side effects of steroids. The inquiry therefore considered whether the prescription of steroids had contributed to the death. The unanimous medical evidence was that thrombo-embolism is an extremely rare complication of steroids and that it was unlikely that the administration of 95mg prednisolone had caused or contributed to the DVT.

12. The Trust had conducted a Serious Untoward Incident (SUI) investigation following Mrs Jacobs' death and recommendations had been made regarding (i) improvements in the DVT pathway and protocols and (ii) changes to the information provided to patients and their GPs on discharge from the DVT assessment ward. These recommendations have already been acted upon and changes have been put place.

13. However the SUI investigation had not identified the overprescribing of steroids, nor were the SUI report authors aware that a pharmacist had queried the dosage and that this had been confirmed without reference back to the consultant in charge of the patient's care.

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) There was nothing within Mrs Jacobs' hospital records indicating any awareness that she had been prescribed steroid dose which was out with usual ENT practice and the BNF guidelines. Nor was the actual prescription issued confirmed with or reported to patient's consultant. The evidence was that there is no policy or procedure within the Trust which requires a doctor who prescribes a medication outside usual practice and/or BNF guidelines to note within the patient's clinical record that they have made the deliberate decision to do so and to record their grounds for so deciding.

	(2) There was no discussion between the pharmacist and either the prescribing doctor or the patient's consultant regarding the dosage when the query was raised by the pharmacist. I was informed by the consultant physician who conducted the SUI that, where a pharmacist queries the intended prescription of a drug, it is good practice for the clinician and pharmacist to discuss the matter and consider together the risks and benefits of the prescription. He stated that it "would clearly be of value" to have a protocol requiring such a discussion to take place, where practicable. The Trust has no such protocol. I consider that, although I did not find that Mrs Jacobs' death would have been prevented by correction of her prescription, there is a risk that future deaths may occur in similar circumstances and action should be taken to reduce the risk that the prescription of an unintentionally high dose of a drug is not identified and corrected.
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 16 May 2014. 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 of the deceased. 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	**DATE: 21/03/14** **SIGNED: Bridget Dolan, Assistant Coroner, West Sussex** pp Jenny Phillips