	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Chief Executive, Royal Surrey County Hospital** **2. Chief Executive, Frimley Park Hospital NHS Trust** **3. MHRA** **4. Intensive care society** **5. Faculty of Intensive care of Royal College of Anaesthetists**
1	**CORONER** **I am Karen HENDERSON, assistant coroner for the coroner area of Surrey**
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 5th December 2013 I commenced an investigation into the death of Maria De Oliveria Alva LOPES, 31 years of. The investigation concluded at the end of the inquest on 26th June 2014. The medical cause of death given was: 1a. Multiorgan failure 1b. Rhabdomyolysis 1c. Propofol related infusion syndrome 1d. Complications of urosepsis 2. My narrative conclusion was: **Mrs Lopes has died from a rare reaction to propofol that has been used to support ventilation in order to aid her recovery from the consequences of septic shock, that has been caused by a delay in the recognition of urosepsis and a failure to receive timely medical treatment**
4	**CIRCUMSTANCES OF THE DEATH** Mrs Lopes presented to A&E on the 1st September 2012 with a short history of sudden onset of pain suggestive of renal colic. She had an IVU and was found to have a stone in her left ureter with associated hydronephrosis. She was admitted and seen the following day for the first time on the routine ward round undertaken by the on call urology registrar. Signs of Systemic Inflammatory Response syndrome (SIRS) were present at the time of the ward round but were not recognised as such and the management plan put in place was therefore inadequate. Mrs Lopes developed increasing signs of sepsis and despite documentation in the form of arterial blood gases and blood results demonstrating sepsis (raised CRP and lactate with hypoxaemia) and review by the critical outreach nurse and continuously raised Early Warning Scores its severity was not recognised or appropriately escalated and opportunities were lost to treat the sepsis in a timely fashion. Referral and transfer to the Intensive care unit was not properly expedited and resulted in a further delay in treatment. Mrs Lopes required intubation and ventilation and inotropic support for septic shock and multiorgan failure. Her sepsis was resolving after treatment with antibiotics and a nephrostomy but recovery was slow requiring prolonged ventilation using propofol for sedation. Mrs Lopes began to deteriorate on 7th September, 6 days after admission to ICU, with increasing oxygen requirements and pyrexia

	which was thought to be septic in origin. Despite intensive investigation no source of sepsis was found. She continued to deteriorate throughout 8th September developing myoglobinuria, a rising creatine kinase and hyperkalaemia from rhabdomyolysis. Supportive management of the hyperkalaemia was not successful and she became too haemodynamically unstable for haemofiltration and despite other supportive measures, she died on 9th September 2012. I heard expert evidence from two experts who both agreed the ultimate cause of death was propofol related infusion syndrome causing rhabdomyolysis and associated sequelae and this was a consequence of a slow recovery and weaning from ventilation as a result of the severe sepsis. The amount of propofol given was likely to be in excess of the recommended dose (both in length of time used and amount given) with control primarily undertaken by the nursing team.
5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise for concern. In my opinion there is a risk that future death 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. The consultant urologist's on call arrangements covering three hospitals at the weekend has no provision for consultant ward rounds, in contravention of suggested national guidelines 2. A general lack of knowledge or implementation of published 'on call' national guidelines 3. The overall supervision of out of hours urology trainees within the current system 4. The review of emergency admissions by urology (not on day of admission, once daily) 5. The recognition and treatment of sepsis as per national guidelines 6. The assessment and size of the renal stone and hydronephrosis, and undue reliance on blood tests taken on admission (18 hours previously) to assess Mrs Lopes's condition 7. The lack of active management to expedite physician's review and to facilitate admission to ITU 8. Failure to recognise and therefore escalate concerns of sepsis by critical care outreach team 9. Failure to act on or escalate elevated Early Warning Scores as per hospital protocol 10. Lack of clarity to the length, volume and dose of propofol infusion to be given in ITU 11. Lack of medical supervision and control of the use of propofol in ITU (no protocol in place) 12. Consideration for the use of daily Creatine Kinase levels when propofol infusions are given 13. Lack of understanding and acceptance Propofol related infusion syndrome (PRIS) is an accepted albeit rare, complication of the use of prolonged propofol for sedation in Intensive Care Units 14. Lack of understanding that PRIS may have an atypical presentation in adults and should always be a consideration when propofol is used for a protracted period of time 15. Lack of national understanding and acceptance of the amount of propofol that can be given and the importance of creating and adhering to guidelines or protocols for its use and to implement continual assessment to look for the complications of PRIS (serial CK levels)
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you and your organisation, Royal Surrey County Hospital and other organisations: Frimley Park Hospital, Basingstoke General Hospital, Royal College of Anaesthetists (Intensive care division), Association of Anaesthetists of Great Britain and Ireland (AAGBI), Intensive care Society and the MHRA 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, I, the coroner, may extend this 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] who may find it useful or of interest. 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: 11-July-2014** **SIGNED: K Henderson**