REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Derby Hospitals NHS Foundation Trust** **2. Medicines and Healthcare Product Regulatory Agency** **3. National Patient Safety Agency** **4. NICE** **5. Patricia Mellor's family** **6. Chief Coroner**
1	**CORONER** I am, Jane Gillespie, Assistant Coroner, for the coroner area of Nottinghamshire.
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 29th January 2014 I commenced an investigation into the death of Patricia Ann Mellor, aged 63. The investigation concluded at the end of the inquest on 7th October 2014. The conclusion of the inquest was: On the 24th day of January 2014 Patricia Ann Mellor died as a result of aspiration pneumonia. This was a direct result of the hypoxic brain injury that she suffered following a cardiac arrest during surgery in 2004. The cardiac arrest during general anaesthesia was a consequence of a phenomenon known as acquired Long QT Syndrome, due to a combination of citalopram, nortriptyline and ranitidine therapies. This reaction could not have been predicted in 2004.
4	**CIRCUMSTANCES OF THE DEATH** On 30.03.04 Mrs Mellor underwent an arthroscopic examination of her left temporomandibular joint for chronic pain in this area. Mrs Mellor was subject to a thorough assessment by [redacted] Consultant Anaesthetist, on the morning of her surgery. [redacted] had some concerns regarding the placement of a breathing pipe necessary for the operation given Mrs Mellor's difficulty in opening her jaw and her significant reflux disease. She had also previously experienced severe post-anaesthetic nausea and vomiting and episodes of hypertension during general anaesthetic. [redacted] was confident that these risks could be managed and the general anaesthetic went ahead, in preparation for the operation which was to be performed by [redacted] Consultant Maxillofacial Surgeon. Very shortly into the operation, before any incision was made, Mrs Mellor became hypertensive, did not respond to the usual medications and went into cardiac arrest. Resuscitation was commenced and continued for 20 minutes before spontaneous circulation was re-established. When Mrs Mellor's was taken off sedation she was found to have a hypoxic brain injury. Since that time she has been severely disabled and fully dependent on others for her care and health needs. On 24th January 2014 she died as a result of aspiration pneumonia, 10 years after suffering her hypoxic brain injury. Following this event, a full investigation was carried out to try to establish the cause of her cardiac arrest. Anaphylactic shock, abnormal heart valve/s and abnormalities in the heart muscle were all excluded. It was concluded that Mrs Mellor had acquired Long QT Syndrome, from the combination of citalopram, nortriptyline and ranitidine therapies. It

	was considered that this caused a reaction to general anaesthesia, which in turn provoked the Long QT Syndrome, leading to cardiac arrest. Long QT syndrome (LQTS) is a disorder of the heart's electrical activity. The term "long QT" refers to an abnormal pattern seen on an electrocardiogram. It can cause sudden, uncontrollable, dangerous arrhythmias. This may be an inherited naturally occurring condition or it may be acquired. Acquired LQTS can be caused by certain medication/combinations of certain medications.
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. – [redacted] Consultant Anaesthetist has advised that in response to this incident, the Derby Hospitals NHS Trust undertook the following action; · All 12 lead ECG devices were programmed to print a "Long QTc" warning when detected · An educational programme on LQTS was delivered to all Anaesthetists working in the Trust · A protocol was developed to require a pre-operative ECG for all patients taking drugs listed on the expert database at "high" and "intermediate" risk levels of causing cardiac arrest – this overrides the advice in the NICE CG3 document · When a prolonged QTc is discovered; o The patient is questioned about cardiac arrest or sudden unexpected death in a young family member; if this is discovered, the patient is referred to a cardiologist to exclude Congenital LQTS o The patient has plasma electrolyte levels (specifically potassium, magnesium and calcium) measured irrespective of any contrary advice in the NICE CG3 guideline. Any abnormal low level is treated before surgery · The Anaesthetist for the relevant operating list is alerted to any abnormal QTc finding · A protocol was developed to; (1) guide the safe administration of general anaesthesia to patients with LQTS, and (2) guide the optimum management of cardiac arrest if this occurs under anaesthesia · Investment was provided for electronic pumps to allow the ready availability of TIVA [redacted] further advised that the likelihood of this event being due to a drug-related phenomenon was reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) using the "yellow card" scheme. There were further communications with the MHRA suggesting that; · The product information for inhalational anaesthetic agents should contain a

	warning on the potential risks of cardiac arrest when administered to patients with LQTS · The product information for other drugs such as $5HT_3$ anti-emetics should contain a warning on the potential risks of cardiac arrest when administered to patients with LQTS during inhalational anaesthesia · The particular issues with antidepressant agents and LQTS should be highlighted in the regular bulletins from the Agency Furthermore, [redacted] reported that recommendations be sent to NICE updating guideline CG3 to; · Instruct anaesthetists to consider drug-induced LQTS in their pre-operative assessment before following the recommendation not to perform a 12 lead ECG · Instruct anaesthetists to specifically examine the QTc interval in all pre-operative ECGs performed for any indication · To require a 12 lead ECG to be recorded and the QTC to be specifically examined in all patients receiving agents deemed to be of "high" and "intermediate" risk of inducing cardiac arrest in LQTS [redacted] advised that despite the above notifications and recommendations, no action has been taken by these agencies.
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. I require you to provide an explanation and reasons regarding; (i) the decision taken not to respond to the recommendations set out above (ii) whether this decision will be reviewed in light of this report (iii) if no action is to be taken in light of this report, the reasons for this (iv) if action is to be taken, what that action will be and the timescales for such
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 7th January 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 Derby Hospitals NHS Foundation Trust, Medicines and Healthcare Product Regulatory Agency, National Patient Safety Agency, NICE and Patricia Mellor's family 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 12th November 2014**	**Jane Gillespie, Assistant Coroner**