REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

IN THE MATTER OF THE INQUEST TOUCHING THE DEATH OF

JOHN ALFRED ROBERTS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. [redacted] Chief Executive Officer, Royal Cornwall Hospital Trust (RCHT)** **2. [redacted], Chief Executive Officer, National Institute for Clinical Excellence (NICE)**
1	**CORONER** I am Guy Davies, His Majesty's Assistant Coroner for Cornwall & the Isles of Scilly.
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. [HYPERLINKS]
3	**INVESTIGATION and INQUEST** On 22 July 2021 I commenced an investigation into the death of John Alfred Roberts. The investigation concluded at the end of the inquest on 14 April 2023. The conclusion of the inquest was as follows Medical cause of death **1a Peritonitis** **1B Perforated sigmoid colon (inoperable)** **1c Diverticular disease** **II Diabetes mellitus type 2, chronic kidney disease, myasthenia gravis and coronary artery disease** The four questions - who, when, where and how – were answered as follows … **JOHN ALFRED ROBERTS died on 26 June 2021 at High Barn St. Buryan Penzance Cornwall from a perforated sigmoid colon due to diverticular disease, contributed to by multiple co-morbidities.**

	My conclusion as to the death was a narrative conclusion **John died from recognized complications of necessary medical treatment, namely steroid therapy for myasthenia gravis, contributed to by multiple co-morbidities.**
4	**CIRCUMSTANCES OF THE DEATH** John was a 78-years-old gentleman with a past medical history of • diabetes (type 2) diagnosed 1999 • chronic kidney disease, from 2012 • diverticular disease from 2012 • raised BMI, at times over 30, • myasthenia gravis (MG), symptoms identified from around April 2020, John was prescribed steroids from December 2020 for MG, escalating to the highest recommended dose of 100mg prednisolone, taken every other day. John received this high dose from 21 February 2021 until his death on 26 June 2021. That is with the exception of a period between 7 and 13 June 2021 following an inadvertent reduction in dosage to 25mg whilst an in-patient at RCHT. John was discharged on 15 June 2021 after this dosage error. I found that John was medically fit at the time of discharge and that the dosage error did not contribute to his cause of death. John was re-admitted on 22 June with a history of vomiting and retching for 2 days before admission; I found on the evidence that this was the likely period when John suffered his perforated sigmoid colon. This was deemed inoperable. John did not respond to antibiotics and was discharged home on 25 June 2021 for palliative care. John died peacefully at home on 26 June 2021. I found on the evidence of the histopathologist [redacted], that steroid therapy was contributory to John's cause of death, alongside John's other conditions. I found on the evidence that it was not possible to distinguish between the multiple conditions contributing to, and causative of, the perforated bowel. [redacted] stated in evidence as follows: *…steroid therapy increases the risks of gastrointestinal complications including ulceration and perforation of the stomach, duodenum and the colon and these are recognised complications documented in the literature. The mechanism is unclear but steroids are thought to impair the mucosal barrier which enables bacteria to penetrate. Steroid induced colonic perforation is more likely to occur in patients with diverticular disease and the deceased was noted at autopsy to suffer from diverticular disease. It is speculated that in diverticular disease there is a localised concentration of bacteria. Also, if the patient is treated by high dose steroids, the signs and symptoms of gastrointestinal and colonic complications may be masked by the anti-inflammatory effects of the drugs. This may potentially lead to delays in identification of the drug induced complications, so potentially resulting in the patient presenting with advanced complications such as viscus perforation.*
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) **Royal Cornwall Hospital (RCHT)** • The concern is the inadvertent reduction of steroid dosage and the arrangements made in relation to the administration of medication dosages and the policies regarding dosage errors, and the application of those policies. • The Court heard that the dosage of 100mg prednisolone was inadvertently reduced to 25mg from 7 to 13 June. The full dose of 100mg was given either side of that period, on 5 and 15 June 2021. No explanation was offered for this reduction other than it being an inadvertent mistake. • RCHT Consultants accepted that the dosage error was a serious mistake. Furthermore, this mistake was not drawn to the patient John's attention or to the attention of the GP via the discharge summary, which made no reference to the dosage error. It was unclear whether treating physicians or discharging physicians were aware of the dosage error. **(2) The National Institute for Clinical Excellence (NICE)** • The concern is regarding the accuracy and rigour of the British National Formulary (BNF) guidance on Prednisolone, published by NICE, The National Institute for Clinical Excellence • BNF provides Key information on the selection, prescribing, dispensing and administration of medicines. The BNF aims to provide prescribers, pharmacists, and other healthcare professionals with sound up-to-date information about the use of medicines. • Evidence was taken at Inquest from a consultant neurologist that recent literature suggests an association between steroids (such as prednisolone) and the risk of bowel perforation in those with diverticular disease. This is not reflected in the BNF guidance regarding prednisolone. • In relation to a number of sections in the Prednisolone guidance it was found as follows • The '***Important safety information'*** section does not refer to the risk of perforation from using corticosteroids for those with diverticular disease • The '***Contra-indications For all corticosteroids (systemic)'*** section does not refer to need for caution in using corticosteroids for those with diverticular disease, albeit it does refer to caution in using with patients with diabetes mellitus and diverticulitis • The ***'Side effects'*** section makes no reference to bowel perforation as a risk, albeit it does make reference to peptic ulceration.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you and 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 20 June 2023. 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: the family, RCHT Consultant Neurologist [redacted], and GP [redacted]. 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	**25 April 2023** **Guy Davies**