REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. Department of Health 2. Chief Executive, British Society of Gastroenterology
1	**CORONER** I am Ms L Hashmi, HM Area Coroner for the Coroner area of Manchester North.
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroner's and Justice Act 2009 and Regulations 28 and 29 of the Coroners (Investigations) Regulations 2013
3	**INVESTIGATION and INQUEST** On the 9th March 2018 I commenced an investigation into the death of **Stephen Whitehead.** The investigation was concluded by way of inquest on the 25th June 2018. The medical cause of death was: 1a) Septicaemia 1b) Bacterial ascending cholangitis 1c) Common bile duct calculi and stent 2) - I recorded a narrative conclusion: 'Died as a result of complications arising from an indwelling biliary stent. The stent had unintentionally been left in situ for a prolonged period and the deceased lost to follow up. Neglect more than minimally contributed to his death.'
4	**CIRCUMSTANCES OF DEATH** In October 2015 the deceased was admitted to hospital. A diagnosis of acute obstructive jaundice was made. He underwent an ERCP with stent insertion. Plans were subsequently made for further surgery on the 24th December 2015 but deferred at the deceased's request. On the 15th February 2016, the deceased underwent a laparoscopic cholecystectomy. The operation and immediate post-operative period were uneventful. A further post-operative ERCP to remove the stent and a large gall stone was to be scheduled for 2 months' time. On the 4th March 2016 the deceased attended hospital, as an emergency admission, with biliary obstruction. Treatment was administered and plans made to discharge and to re-admit on an elective basis for further intervention. He was re-admitted on the 15th March 2016 for an ERCP and stent change, with a follow up ERCP to be scheduled 6 weeks thereafter. An on-line booking from was not competed in this regard, resulting in the deceased not being recalled. The stent remained in situ for almost 2 years.

	At the material time, the Hospital Trust had multiple booking processes for repeat ERCPs. On the 6th February 2018 the deceased was admitted to the Emergency Department (ED) with abdominal symptoms. There was delayed recognition of the signs of sepsis. This error did not more than minimally contribute to the deceased's demise. Intensive treatment was instigated and the deceased transferred to ITU. It was not possible to carry out a CT scan as he was too unstable. Despite best efforts, the deceased continued to deteriorate and died in hospital on the 8th February 2018.
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:- Whilst the local NHS Trust has taken (and continues to take) significant steps to improve patient safety with regard to biliary stent insertion/management, I am concerned about the wider implications, namely: 1. **The absence of a national 'safety-netting' system (stent registry)**, akin to that already established for ureteric stents (a web-based registry). There is no equivalent for biliary stents. Without a safety netting system, I am concerned that there is a real risk that patients will remain susceptible to what is medically recognised as the 'phenomenon of the forgotten biliary stent', resulting in future deaths. 2. **Definition of 'short-term' in clinical guidance** - during the course of the evidence I heard that National Guidelines on the management of common bile duct stones currently indicates that the short term use of endoscopic biliary stents followed by further ERCP (or surgery) is an established and safe management option. However, the guidelines do not provide an operational definition of 'short term'. It is therefore unclear as to what is 'safe' in terms of timeframe.
6	**ACTION SHOULD BE TAKEN** **In my opinion action should be taken to prevent future deaths and I believe each of you respectively 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 the 24th August 2018. 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 namely:- • The deceased's family • The NHS Trust • Bury/Rochdale/Oldham CCGs – this is for information only. The CCGs are NOT required to take any action. • NHS Improvement, Wellington House, 133-155 Waterloo Road, London, SE1 8UG • NHS England (London & Manchester)

	• Royal College of Physicians, 11 St Andrews Place, Regent's Park, London NW1 4LE • Royal College of Surgeons, 35-43 Lincoln's Inn Fields, London WC2A 3PE 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 from. 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: 28th June 2018 Signed: