REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Secretary of State for Health** **2. Care Quality Commission**
1	**CORONER** Christopher Dorries, senior coroner for the West district of South Yorkshire
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** On 28th August 2013 I commenced an investigation into the death of William Alfred Andrews (aged 77). The investigation has not yet concluded and the inquest has not yet been heard.
4	**CIRCUMSTANCES OF THE DEATH** Mr Andrews was a 77 year old man who was admitted to a hospital in Sheffield on the 11th July 2013 in heart failure. On the 21st August 2013 he underwent cardiac surgery. I set out below an extract from the Trust's Sudden Untoward Incident Report, it has been agreed that I might use this in making a Regulation 28 report. Whilst the inquest is yet to be held it is clear that the facts set out in the report are broadly unchallenged. *The procedure was technically challenging because of dense pericardial adhesions resulting from previous surgery. Repair of the tricuspid valve was abandoned as it was considered too risky. The aorta was opened in an unusually high position because of the difficulty experienced in gaining access. During the surgery, removal of an aortic valve may result in some particles of calcified tissue falling into the left ventricle. It is normal practice to wash out the ventricle in order to remove the debris. The surgeon routinely used a bulb syringe to perform the manoeuvre. The scrub practitioner filled two bulb syringes with saline, because she was aware that it was the surgeon's routine practice to perform two washouts in quick succession.* *On being asked for a syringe to wash out the ventricle, the scrub practitioner handed one to the surgeon. She placed the second on the surgical drapes on the operating table near the patient's feet. This was in anticipation of the surgeon asking for it, but in a place where she assumed it could not be reached easily. Because the syringe had a tendency to leak she replaced the cap which was supplied with the syringe, as she did not want to compromise the integrity of the drapes. At the time when a second washout was required, the scrub practitioner was not able to respond immediately as she was undertaking another task. On turning back to the operating field, she realised that the second syringe had already been*

	used. The surgeon is of the opinion that he asked for and was passed the bulb syringe, as it is not his normal practice to take instruments without requesting them. However, none of the other staff standing at the table can remember this. The bulb syringe was out of place, which may have led the surgeon to assume it was ready to use. Nobody scrubbed at the table or observing the procedure noticed that the syringe was capped. The cap is made of clear plastic, which is identical in appearance to the syringe. *On using the second syringe, the cap was dislodged into the left ventricle where it could not be seen beyond the aortic valve. The scrub practitioner did not enquire as to what had happened to the bulb syringe cap. The cap then remained unnoticed in the left ventricle and the operation continued as normal. Because her shift had ended, the scrub practitioner was relieved at approximately 1700 by SB. As per protocol swabs and instruments checks were completed at that time and deemed correct. SB was unaware of any issue regarding the syringe cap and it is her routine practice to discard all unnecessary extraneous items.* *Following surgery the patient made poor progress overnight in the Cardiothoracic Intensive Care Unit (CICU). A Transthoracic Echocardiograph (TTE) was performed at 0605 (22/8/13) which showed poor cardiac function. He suffered a circulatory arrest around 0715 and again at around 0800. The patient then had Trans Oesophageal Echocardiograph (TOE), which suggested a foreign body, followed by another loss of cardiac output at around 1300. A further TOE demonstrated a foreign body within the ventricle, which was tentatively identified as a bulb syringe cap. The patient then had another circulatory arrest at around 1.30pm and was returned to theatre where a second operation, to remove the syringe cap, was performed. The patient was put on femoro-femoral bypass and the object removed via left anterior thoracotomy and ventriculotomy. The patient returned to CICU in an extremely poor conditions and receiving maximum organ support. His condition deteriorated over the next few days and he died on the 24th August 2013.*
5	**CORONER'S CONCERNS** During the course of the investigation my inquiries 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) If a simple precaution was taken in ensuring that the tip of a bulb syringe or similar was a different colour to the rest of the equipment then it is difficult to see how a surgeon could use a syringe with the tip still in place by error. As the attached photograph shows there is no significant difference between the syringe with the tip on or off. (2) There is a further concern in respect of other information which is contained with the Trust's SUI report as follows; *It is perhaps of some relevance that in 2001-2 a number of instances of items of anaesthetic airway equipment being blocked with extraneous pieces of plastic and causing harm to patients were the subject of a national police investigation (Operation Orcadian). The police findings were examined by an Expert Group, which published a series of recommendations in 2004. Their conclusion was that there was no criminal intent but that the incidents had happened as a matter of chance. Strategies to reduce the chances of these events recurring were*

	recommended. Recommendation 1 states "The MHRA should recommend to manufacturers and the relevant Standards Committees that …. detachable caps (eg. On intravenous cannulae and giving sets) be manufactured in brightly coloured material, preferably red, to aid visibility". No action appears to have been taken in consequence of this. (3) The SUI report goes on to indicate that none of the team undertaking the operation were aware that the bulb syringe came supplied with a cap. The previous brand used by the Trust was not supplied with a syringe cap. The current bulb syringes in use obviously do have a cap but this is normally removed by the scrub practitioner before the syringe is supplied to the operating surgeon. Thus there has been little opportunity for surgeons to appreciate that syringes now have caps. This underlines the importance of ensuring that such devices are manufactured with a brightly coloured cap, if one is to be used at all. (4) There appears to be no standard procedure for checking for syringe caps (where used) at the end of the operation, such as there is with swabs. The evidence available to me suggests that items such as syringe caps are just discarded by the scrub practitioner without being retained for counting. Of course, the fact that some syringes are apparently manufactured with a cap and others without complicates the situation but is not actually a bar to counting the number of caps present at the outset of the operation.
6	**ACTION SHOULD BE TAKEN** In my opinion urgent 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 3rd March 2014. I 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 (through their solicitors) • The Trust (through their solicitors) I have also sent a copy to: • [redacted] • National Patients Safety Director NHS England • Medicines and Healthcare Regulatory Agency • NHS England (South Yorks and North Notts) and • The manufacturers 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 at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	**17th December 2013** **Christopher Dorries – Senior Coroner**
