## REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

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| | **REGULATION 28 REPORT TO PREVENT FUTURE DEATHS**<br><br>**THIS REPORT IS BEING SENT TO:**<br><br>**Rt Hon Matt Hancock MP**<br>**Secretary of State**<br>**Department of Health and Social Care**<br>**39 Victoria Street**<br>**London**<br>**SW1H 0EU**<br><br>**Dr [redacted]**<br>**Interim Chief Executive**<br>**Medicines and Healthcare products Regulatory Agency**<br>**10 South Colonnade**<br>**London**<br>**E14 4PU** |
| 1 | **CORONER**<br><br>I am Nigel Parsley, Senior Coroner, for the coroner area of Suffolk. |
| 2 | **CORONER'S LEGAL POWERS**<br><br>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**<br><br>On 4th October 2018 I commenced an investigation into the death of **Susan Warby**<br><br>The investigation concluded at the end of the inquest on 7th September 2020. The conclusion of the inquest was that the death was the result of:-<br><br>**The progression of a naturally occurring illness, contributed to by unnecessary insulin treatment caused by erroneous blood test results. This, in combination with her other co-morbidities, reduced her physiological reserves to fight her naturally occurring illness.**<br><br>The medical cause of death was confirmed as:<br><br>**1a Multi-organ failure**<br>**1b Septicaemia**<br>**1c Disseminated aspergillus pneumonia**<br>**2 Perforated diverticular disease (operated 27th and 29th August 2018) with faecal peritonitis, insulin induced hypoglycaemia, pneumothorax, hypertension and hypothyroidism.** |
| 4 | Susan Warby was a 57-year-old lady admitted to the West Suffolk Hospital on the 26th July 2018.<br><br>Sue had been unwell from the 18th July 2018 and on the morning of 26th July 2018 suffered a collapse at home. She was admitted into hospital and was found to be suffering from a perforated bowel (diverticular perforation with faecal peritonitis). |

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| | Sue underwent emergency surgery and was transferred onto the Intensive Treatment Unit on the 27th July 2018. Whilst in the operating theatre, Sue had an arterial line fitted that required an intravenous fluid infusion to keep the line flushed.<br><br>The incorrect intravenous fluid (500mls of Dextrose at 4% with Sodium Chloride at 0.18%) was attached to this line and a number of checks that were required to be conducted failed to identify this. The incorrect intravenous fluid remained in place for approximately 36 hours before it was changed.<br><br>As a direct result, blood tests on samples drawn from the arterial line gave incorrect results. The incorrect results were exacerbated by the poor technique being used by staff to draw blood from the arterial line transducer set when they failed to fully account for the 'dead space', which needed to be fully removed to obtain an accurate result.<br><br>These erroneous blood results led to Sue being given doses of insulin medication over a two-day period that she did not need. The incorrect insulin doses caused Sue to suffer from bouts of extremely low blood sugar (hypoglycaemia) which caused her to develop a brain injury of uncertain severity.<br><br>Sue never fully regained consciousness, so the extent of that brain injury could not be meaningfully assessed.<br><br>Sue underwent a further surgery on the 29th July 2018 and returned to the ITU. Sue remained on the ITU where her abdominal surgery and condition settled but she developed a serious fungal chest infection.<br><br>Evidence heard that due to Sue's poor physiological reserve, caused by her bowel perforation, chest infection and sepsis, the additional insult of a degree of brain injury would have been a contributing factor leading up to her death.<br><br>Sue remained on the ITU at the West Suffolk Hospital until her tragic death on the 30th August 2018. |
| 5 | **CORONER'S CONCERNS**<br><br>During the course of the inquest the evidence revealed matters given rise to concern. In my opinion there is a risk that future deaths could occur unless action is taken. In the circumstances it is my statutory duty to report to you;<br><br>the **MATTERS OF CONCERN** as follows. –<br><br>1. During the evidence it was clear that packaging and visual identification aids available for intravenous fluids to be used in arterial line transducer sets were not sufficiently distinctive.<br><br>It was heard that following Mrs Warby's death that as far as possible the West Suffolk Hospital has asked its suppliers to change the labelling on the intravenous fluids it purchases. These were exhibited in court and even with the changes the manufacture was prepared to make, the packaging cannot be considered at all distinctive for fluids to be used in an arterial line. |

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| | In direct contrast, we saw that the tubing used on an arterial line transducer set has a solid red line running its length. This is to clearly indicate to staff that it is an arterial line and therefore must not be used for the administration of drugs or medicinal fluids.<br><br>I am therefore concerned that the packaging of the 0.9% Sodium Chloride intravenous fluid to be used with an arterial line is not also so clearly distinguished. It was heard in evidence that there is currently no 0.9% Sodium Chloride intravenous fluid available which is specifically and clearly labelled for arterial line use only.<br><br>It is important to note that the issue identified in this inquest regarding the use of incorrect intravenous fluid in an arterial line is not a new one. In 2008 the UK National Patient Safety Agency issued a Rapid Response report highlighting problems with infusions and sampling from arterial lines. In that 2008 report the UK National Patient Safety Agency had already identified 84 incidents where the wrong infusion was attached to an arterial line with two of those cases proving fatal.<br><br>It is understood that the 0.9% Sodium Chloride intravenous fluid has a number of medicinal uses other than just as a flushing fluid in an arterial line. However, the number of cases identified where the incorrect fluid is being used in arterial lines, clearly demonstrates the confusion and errors which occur when using generically labelled intravenous fluids with an arterial line transfusion set.<br><br>2. The court was told that the medical staff taking blood samples from the arterial line transducer sets were not using the correct technique to ensure erroneous blood samples were not taken.<br><br>The court heard that even if the incorrect intravenous fluid is fitted to an arterial line, a good technique used by staff (ensuring to fully account for the 'dead space' when drawing the blood sample) would prevent false readings being obtained.<br><br>As such, in Mrs Warby's case the error of the incorrect intravenous fluid being fitted to her arterial line was exacerbated by medical staff using an incorrect technique when drawing her blood samples.<br><br>The court was told that training in drawing blood from an arterial line is given as part of standard training for staff caring for patients with an arterial line in place. However, there were a number of erroneous samples taken in Mrs Warby's case, these samples being taken by a number of different staff.<br><br>As such, the West Suffolk Hospital has already implemented new training and operational regimes for its staff.<br><br>However, given the apparent prevalence of errors regarding the incorrect use of intravenous fluids and incorrect blood sampling techniques involving arterial lines, a review of training and operational regimes may be considered necessary on a wider basis. |
| 6 | **ACTION SHOULD BE TAKEN**<br><br>In my opinion action should be taken in order to prevent future deaths, and I believe you or your organisation have the power to take any such action you identify. |

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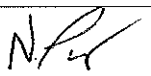
| 7 | **YOUR RESPONSE**<br><br>You are under a duty to respond to this report within 56 days of the date of this report, namely by 20th November 2020 I, the Senior Coroner, may extend the period if I consider it reasonable to do so.<br><br>Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed. |
| 8 | **COPIES and PUBLICATION**<br><br>I have sent a copy of my report to the Chief Coroner and to the following Interested Persons;-<br><br>1. Mrs Warby's family.<br>2. The West Suffolk Hospital, Bury St Edmunds.<br><br>I am under a duty to send the Chief Coroner a copy of your response.<br><br>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 Senior Coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner. |
| 9 | **25th September 2020** **Nigel Parsley**  |