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| | **REGULATION 28 REPORT TO PREVENT FUTURE DEATHS**<br><br>**THIS REPORT IS BEING SENT TO: M H R A** |
| 1 | **CORONER**<br><br>I am **Simon Jones Assistant Coroner** , for **Lancashire & Blackburn with Darwen** |
| 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.<br>http://www.legislation.gov.uk/ukpga/2009/25/schedule/5/paragraph/7<br>http://www.legislation.gov.uk/uksi/2013/1629/part/7/made |
| 3 | **INVESTIGATION and INQUEST**<br><br>On 6th November 2017 I commenced an investigation into the death of Margaret Elizabeth Clark aged 75. The investigation concluded at the end of the inquest on 6th February 2018. The conclusion of the inquest was that Margaret Elizabeth Clark died from a rare but recognised complication of surgery. |
| 4 | **CIRCUMSTANCES OF THE DEATH**<br>Margaret Elizabeth Clark suffered an oesophageal tear in the course of a transoesophageal echocardiogram ["TOE"] carried out at Blackpool Victoria Hospital on the 9th May 2017. She was transferred to Royal Preston Hospital, where the tear was repaired, but she died of sepsis which developed as a result of the tear, on the 12th August 2017. |
| 5 | **CORONER'S CONCERNS**<br><br>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.<br><br>The **MATTERS OF CONCERN** are as follows. –<br><br>I was told that in 2017 the types of probes used for TOEs were changed, to a design which required covering with a sheath. Using that sheath, three fatal oesophageal tears had occurred in the space of 5 months, involving in each case experienced anaesthetists who had conducted TOEs routinely for many years without event. [I was told that there had been one previous incident in the preceding 16 years]. The sheaths used – Ecolab Ultracover for TEE – were replaced at Blackpool Victoria Hospital with alternative [softer] sheaths – Probetection TOE/TEE Transducer Kit. Since the replacement sheaths have been used, there have been no incidents of tear. I was told that the Ecolab sheaths may still be used in other hospitals and Trusts. A Serious Incident Investigation Report expressed a concern that the tears may have resulted from the use of the Ecolab sheaths, which [it was felt] created more resistance on insertion than had been the case before their use.<br>(1) I believe you should review the use of the Ecolab sheaths and consider whether they should not be replaced in all hospitals and Trusts by the Probetection sheaths. |

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| 6 | **ACTION SHOULD BE TAKEN**<br><br>In my opinion action should be taken to prevent future deaths and I believe you have the power to take such action. |
| 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 **12th April 2018**. I, the coroner, may extend the period.<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 Valerie Clark [daughter of the deceased] and Blackpool Teaching Hospitals NHS Foundation Trust. I have also sent it to Alan Wilson [Senior Coroner for Blackpool] who may find it useful or of interest.<br><br>I am also 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 coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner. |
| 9 | Dated 10/02/2018<br><br>  <br>Signature<br>for **Lancashire & Blackburn with Darwen** |

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