## REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

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| | **REGULATION 28 REPORT TO PREVENT FUTURE DEATHS**<br><br>**THIS REPORT IS BEING SENT TO:**<br><br>**1. Chief Executive, Sandwell and West Birmingham Hospitals NHS Trust.**<br>**2. [REDACTED] Medical Centre, 199 Shady Lane, Birmingham, B44 9ER** |
| 1 | **CORONER**<br><br>I am Zafar Siddique, Senior Coroner, for the coroner area of the Black Country. |
| 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 the 5 June 2018, I commenced an investigation into the death of Mrs Sylvia Mitchell. The investigation concluded at the end of the inquest on 27 November 2018. The conclusion of the inquest was a narrative conclusion of:<br><br>Died after developing a rare but recognised complication of urosepsis after failures to adequately monitor and review a patient with a shelf pessary which had become impacted and resulted in a recto-vagino-vesical fistula. These failures to review more than minimally, negligibly or trivially contributed to the death and neglect as rider is added to this narrative conclusion.<br><br>The cause of death was:<br><br>1a Urosepsis<br>b Recto-Vagino-Vesical Fistula(impacted Gellhorn Pessary)<br>c<br>II Chronic Degenerative Mitral & Aortic Valvar Disease. Nephrolithiasia |
| 4 | **CIRCUMSTANCES OF THE DEATH**<br><br>i) Mrs Mitchell was a 90 year old woman with a previous medical history of osteoarthritis and also bladder prolapse. She was managed conservatively for the latter condition initially with a ring pessary between December 1999 and Aril 2008. During this period the pessary was regularly changed.<br><br>ii) From April 2008 onwards a new replacement Gelhorn pessary was issued. This was then reviewed in June but she failed to attend her appointment in September and did not then re-attend gynaecology services until 6 March 2013 when her GP referred her back.<br><br>iii) She then attended the outpatient clinic and an impacted shelf pessary was found. This required a surgical procedure under anaesthetic to be removed.<br><br>iv) She was then booked in for a pre-operative assessment but developed |

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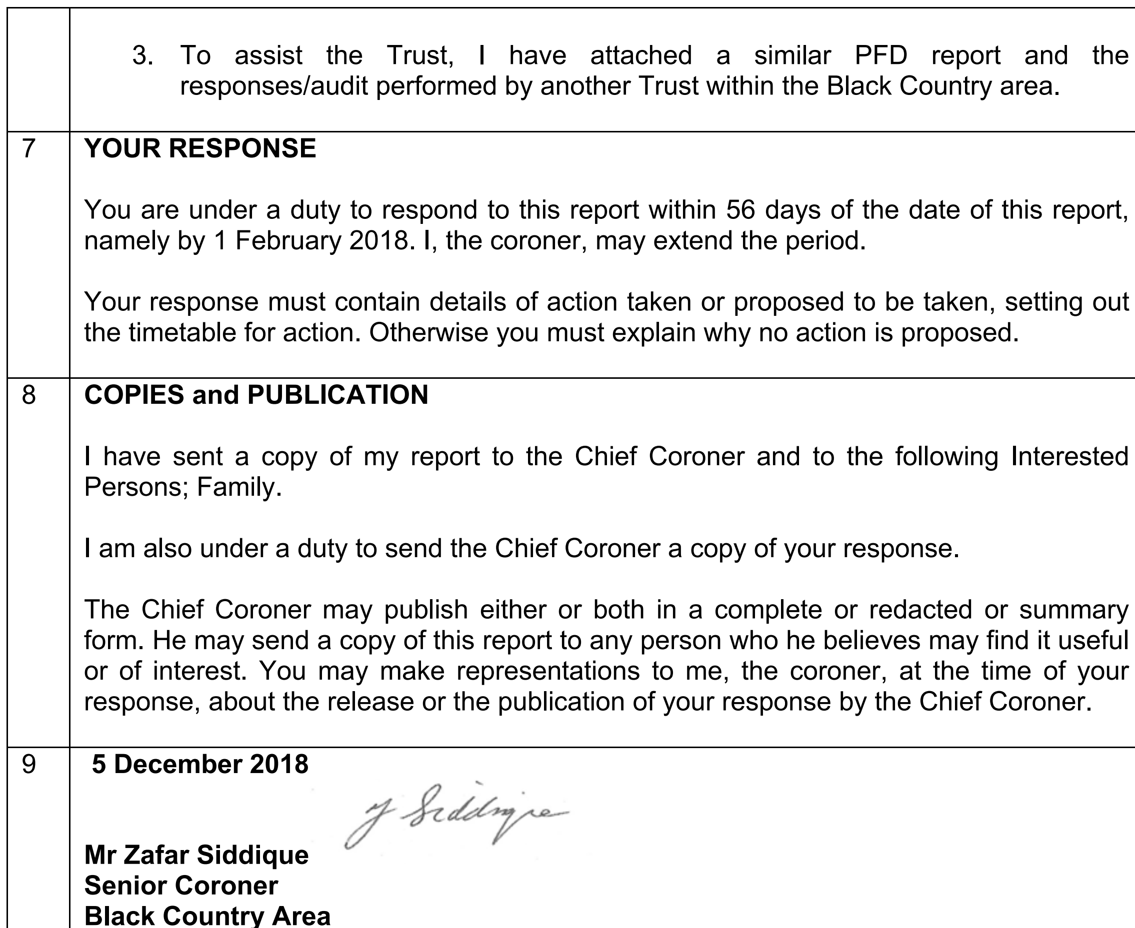
| | MRSA and the procedure postponed to January 2014. However she didn't attend this appointment due to illness. A further letter was sent by the Trust to her GP and to the patient to advise when she was fit to be seen again. The GP and patient don't have any record of this.<br><br>v) It wasn't until 1 August 2016 that a further appointment had been rescheduled. However, the patient cancelled this appointment.<br><br>vi) She had a number of Hospital admissions in 2017 including an admission on the 29 October 2017 when she was diagnosed with urosepsis. She recovered and was discharged in December. Her condition declined further and she was readmitted to Hospital on the 21 May 2018 and sadly she died on the 23 May 2018 at Good Hope Hospital. |
| 5 | **<u>CORONER'S CONCERNS</u>**<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>1. Evidence emerged during the inquest that there was inadequate communication between the Trust and GP advising Mrs Mitchell of the risks of not having the pessary removed urgently.<br><br>2. Specifically, the Pathologist gave evidence confirming that pessaries are typically used in the non-surgical management of severe pelvic organ prolapse, often in post-menopausal women with poorly oestrogenised, and easily traumatised vaginal mucosa. A pessary is a foreign object in constant contact with the vaginal epithelium, therefore, its use requires adequate follow-up to ensure proper fitting, routine cleansing and monitoring of the integrity of the vagina. Failure to observe these precautions heightens risk of infection, impaction/incarceration and ulceration, potentially with recto-vaginal and/or vesico-vaginal fistulation – the latter are very rare iatrogenic complications of pessary use with only approximately 8 cases reported in the world literature (Gordon GH et al. *J Clin Gynecol Obstet*. 2015; **4 (1):** 193-196), almost exclusively, however, associated with Gellhorn and shelf pattern prostheses, usually in the age range of 70 to 80 years, often allegedly contributed to by lapse of regular maintenance & hygiene procedures.<br><br>3. Due to the delays in removal of the pessary she died as a result of developing a fistula and urosepsis. |
| 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.<br><br>1. The Trust may wish to consider urgently reviewing the patients who maybe in a similar position and have failed to have any follow up review of the Gellhorn Pessary.<br><br>2. The GP Practice may wish to consider adding all patients to their list of patients with a pessary (either ring or Gellhorn) to ensure that adequate referral to gynaecology services occurs. |



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| | 3. To assist the Trust, I have attached a similar PFD report and the responses/audit performed by another Trust within the Black Country area. |
| 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 1 February 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; Family.<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 | **5 December 2018**<br><br>**Mr Zafar Siddique**<br>**Senior Coroner**<br>**Black Country Area** |