Regulation 28: Prevention of Future Deaths report

Rubana PATHAN (died 21.11.15)

	THIS REPORT IS BEING SENT TO: **1. [redacted]** **Medical Director** **Homerton University Hospital NHS Trust** **Homerton Row** **London E9 6SR** **2. [redacted]** **Medical Director** **Johnson & Johnson Medical Devices** **Pinewood Campus** **Nine Mile Ride** **Wokingham** **Berkshire** **RG40 3EW**
1	**CORONER** I am: Coroner ME Hassell Senior Coroner Inner North London St Pancras Coroner's Court Camley Street London N1C 4PP
2	**CORONER'S LEGAL POWERS** I make this report under the Coroners and Justice Act 2009, paragraph 7, Schedule 5, and The Coroners (Investigations) Regulations 2013, regulations 28 and 29.
3	**INVESTIGATION and INQUEST** On 25 November 2015, one of my assistant coroners, Richard Britain, commenced an investigation into the death of Rubana Pathan, aged 40 years. The investigation concluded at the end of the inquest earlier today. I made a determination as follows.

	Rubana Pathan died as a consequence of a rare but recognised complication of medical treatment, being a staphylococcal aureus infection of her breast implant wound. (Breast reconstruction following a mastectomy undertaken to treat breast cancer.)
4	**CIRCUMSTANCES OF THE DEATH** Ms Pathan was admitted to Homerton University Hospital on Thursday, 5 November 2015 and was immediately recognised to be potentially very unwell. Her breast reconstruction wound later grew staphylococcus aureus, she was found to be positive for the TSST-1 gene, and was diagnosed with toxic shock syndrome. I recorded a medical cause of death of: 1a toxic shock syndrome 1b staphylococcus aureus infection 1c infected breast implant wound
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. Although Ms Pathan's MENTOR breast implant was suspected as being the cause of her sepsis and was removed on the evening of Saturday, 7 November 2015, her surgeon told me at inquest that she still did not believe this to be the cause, because she found no pus or localised redness. However, one of the treating microbiologists undertook a literature search after Ms Pathan's death and discovered that the toxin found to be responsible for her illness can supress signs of local inflammation such as the production of pus. Although this is a rare occurrence, it seems to me that the information could usefully be disseminated among those likely to be caring for patients who may be at risk of developing sepsis, both by the hospital and by the implant manufacturer.
6	**ACTION SHOULD BE TAKEN**

	In my opinion, action should be taken to prevent future deaths and I believe that 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 23 May 2016. 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 following. • HHJ Peter Thornton QC, the Chief Coroner of England & Wales • Professor Dame Sally Davies, Chief Medical Officer for England • Medicines and Healthcare Products Regulatory Agency • [redacted] husband of Rubana Pathan • [redacted] surgeon, Homerton University Hospital • [redacted], microbiologist, Homerton University Hospital 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, the Senior Coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	**DATE** **SIGNED BY SENIOR CORONER** 18.03.16