VERONICA HAMILTON-DEELEY, LL.B.
Her Majesty's Senior Coroner
for the City of Brighton & Hove

THE CORONER'S OFFICE
WOODVALE, LEWES ROAD
BRIGHTON
BN2 3QB

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Assistant Coroners
CATHARINE PALMER LL.B (HONS)
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## CORONERS SOCIETY OF ENGLAND AND WALES

### ANNEX A

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

*NOTE: This form is to be used **after** an inquest.*

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| | **REGULATION 28 REPORT TO PREVENT FUTURE DEATHS**<br><br>**THIS REPORT IS BEING SENT TO:**<br><br>**1. Matthew Kershaw Chief Executive, Brighton & Sussex University Hospitals, Royal Sussex County Hospital, Eastern Road, Brighton.**<br>**2. National Patient Safety Agency, 4-8 Maple Street, London**<br>**3. National Research Ethics Service, National Patient Safety Agency, 4-8 Maple Street, London.** |
| 1 | **CORONER**<br><br>I am Veronica HAMILTON-DEELEY, Senior Coroner, for the City of Brighton and Hove |
| 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 13th February 2014 I commenced an investigation into the death of John Henry ADAMS. The investigation concluded at the end of the inquest on 11th June 2014. The conclusion of the inquest was a narrative conclusion:- **John Henry ADAMS** died as a result of multiple complications of appropriate cardiac intervention in circumstances where, just prior to the procedure, he was recruited to a cardiac trial. |
| 4 | **CIRCUMSTANCES OF THE DEATH**<br>[redacted]<br>My concerns really relate to the Trial to which he was recruited on the day of the PCI, the 30th January 2014. |
| 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. |

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| | The **MATTERS OF CONCERN** are as follows. –<br><br>**THE CARDIAC TRIAL**<br><br>(1) It seems that the Trial was in very early stages at the Brighton Hospital and that Mr. Adams may have been the fourth patient to have been recruited.<br>(2) Was it appropriate that he should have been recruited within an hour or so prior to his procedure commencing?<br>(3) Did this give him time to read the several page booklet which was provided to him and to absorb the information and give informed consent?<br>(4) Is it appropriate for a visiting Cardiologist, only present at the Hospital for a few hours every fortnight to be the "operator" to take part in this trial?<br>(5) Given that the Consultant Cardiologist in Mr. Adams' case does only visit Brighton once a fortnight for a few hours, and this was his first patient on the Trial, was he himself appropriately informed?<br>In evidence I was told that he was already late for a Clinic when he left the Hospital, believing that Mr. Adams was fine, and that involvement in the trial meant that the procedure took longer than normal - possibly about half an hour longer.<br>Does that sort of pressure result in the best outcome?<br>(6) The Hospital notes for Mr. Adams admission on the 30th do not mention the view (apparently formed within an hour or so of surgery), that it was the pacing wires; which was the extra requirement of the Trial; which caused the cardiac tamponade.<br>Why not? Why was this information effectively concealed?<br>(7) The hospital notes in Brighton, the letter of referral to Kings College Hospital and the report to the Coroner all give the impression, because of the wording used, that what had happened at the PCI was that the diagonal artery had dissected and this is what is believed to have caused the pericardial effusion and tamponade.<br>The Consultant Cardiologist is the only person to have used the expression "dissection" to describe the damage to the diagonal artery which occurred during the PCI.<br>Should more care be taken on terminology? In this case it seems to have lead to a great deal of confusion.<br>(8) One of the organisers of the Trial has written in Mr. Adams' notes that he has been notified of what has happened to Mr. Adams but he makes no mention of what is believed to have occurred as a result of the Trial. Why not?<br>Why was the Trial not mentioned to Kings College Hospital in the Referral letter dated the 1st February 2014?<br>(9) Finally; surely the death of a patient while on a Trial is a matter of major concern to the Trial itself and yet no-one contacted the Coroner, either the original Coroner in South London or me, Coroner for Brighton and Hove when I took over jurisdiction pursuant to Section 2 of the Coroner's and Justice Act, to let us know that this man had been on a Trial.<br>If I had known that, and in particular if I had been able to tell [redacted] of that fact, she would have been able to ascertain precisely where the bleeding/haemorrhage originated and there would have been good clear helpful information for those managing the Trial and of course future patients who might have benefited from it. |
| 6 | **ACTION SHOULD BE TAKEN**<br><br>In my opinion action should be taken to prevent future deaths and I believe you AND your organisation have the power to take such action. |

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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 26th August 2014. I, Veronica Hamilton-Deeley, the senior 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<br><br>1. [redacted]<br>2. [redacted] Medico-legal Manager, Brighton & Sussex University Hospitals,<br>3. Secretary of State for Health, Department of Health<br>4. Sir David Nicholson/Simon Stevens – Chief Executive NHS England<br>5. Chief Executive, National Patient Safety Agency, NHS Commissioning Board Authority, 4-8 Maple Street, London.<br><br>I have also sent it to:-<br><br>1. [redacted] Director for Clinical Quality and Primary Care, Lanchester House, Trafalgar Place, Brighton<br>2. [redacted] Director of Public Health, Lanchester House, Trafalgr Place, Brighton<br><br>Who may find it useful or of interest.<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 | **Date: 1st July 2014** **SIGNED BY:** V Hamilton-Deeley<br><br>**Senior Coroner Brighton and Hove** |
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