REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

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

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1.** Mr Jeremy Hunt MP, Secretary of State for Health **2.** Dr Ian Hudson, Chief Executive, Medicines & Healthcare Products Regulatory Agency (MHRA)
1	**CORONER** I am Alan Peter Walsh, Area Coroner for the Coroner Area of Manchester West
2	**CORONER'S LEGAL POWERS** 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** On 7th January 2014 I commenced an investigation into the death of Paul Michael Ashton, 27 years, born 26th March 1986. The investigation concluded at the end of the inquest on 1st April 2014. The medical cause of death was 1a) Myocardial Ischaemia, 1b) Transplant-Associated Coronary Artery Disease, 1c) Heart Transplant for Cardiomyopathy 2) Anaesthesia for Knee Arthroscopy. The conclusion of the Inquest was Paul Michael Ashton died as a consequence of a recognised complication of anaesthesia on a background of post-transplant coronary artery disease arising from necessary anti-rejection medication following heart transplant surgery.
4	**CIRCUMSTANCES OF THE DEATH** 1) Paul Michael Ashton died at the Salford Royal Hospital, Eccles Old Road, Salford on the 6th January 2014. 2) On the 25th May 1987 the deceased, who was 14 months old at the time, underwent orthotropic cardiac transplant at Harefield Hospital, Middlesex after a diagnosis of Dilated Cardiomyopathy and subsequently he had follow up appointments at Harefield Hospital with the Paediatric Cardiology Department until 2003 when his care was transferred to the Cardiac Transplant Department at Wythenshawe Hospital, Wythenshawe, Manchester where he continued to have follow up appointments until the date of his death. Following the transplant surgery in 1987 the deceased was prescribed medication to reduce the

risk of rejection of the transplanted organ.

3) In 1998 the deceased was diagnosed with Non-Hodgkin's Lymphoma which was treated with chemotherapy. The deceased also had an appendectomy, a laparoscopic cholecystectomy and a knee arthroscopy which were all performed with general anaesthetics and both the procedures and the anaesthetics were uneventful. The knee arthroscopy was performed approximately 3 years before the deceased's death.

4) On the 5th November 2013 the deceased was referred to [redacted] [redacted] who is a Consultant Orthopaedic Surgeon at the Salford Royal Hospital in Salford, with a loose body, being a small piece of bone in his right knee which was giving him mechanical symptoms and required surgical treatment by way of a right knee arthroscopy.

   The deceased had a pre-operative assessment and both the anaesthetist and [redacted] were aware of the deceased's full medical history including the cardiac transplant.

   The deceased consented to the procedure, namely a right knee arthroscopy, and the procedure was listed for the 6th February 2014 with a general anaesthetic.

5) At no time prior to the procedure did the Anaesthetist nor [redacted] consult with the cardiac transplant team at Wythenshawe Hospital who were continuing to monitor the deceased with regard to his cardiac transplant and there was no protocol or guideline at the Salford Royal Hospital relating to the perioperative management of heart-transplanted patients due to undergo or undergoing non-cardiac surgery. It was also not known that there is a high incidence of allograft vasculopathy, meaning the patients coronary arteries are in a diseased state, in heart transplanted patients particularly in patients with long term survival after cardiac transplant beyond 25 years, which is rare. The deceased had survived beyond 25 years from the date of his cardic transplant.

6) The deceased was admitted to the Salford Royal Hospital on the 6th January 2014 for the right knee arthroscopy as a day patient and the anaesthetic was commenced at 13.39 hours on that date. The deceased was transferred into the operating theatre at 13.58 hours and the procedure was commenced. During the procedure at 14.17 hours the deceased had a cardiac arrest and cardiac pulmonary resuscitation was commenced. The deceased was given cardiac pulmonary resuscitation with Adrenaline and shock treatment but in spite of the return of a weak pulse, the deceased failed to respond and his death was certified at 15.55 hours.

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:

(1) During the inquest evidence was heard that

i. The Salford Royal Hospital did not have a protocol or a guideline on the perioperative management of heart transplanted patients undergoing non-cardiac surgery. The Salford Royal Hospital Foundation Trust is now developing Trust wide guidelines for the management of heart transplanted patients undergoing non cardiac surgery and the guidelines should be available and operational in May 2014. However information was given at the inquest that protocols and guidelines do not exist at many other hospitals in the United Kingdom.

ii. A Consultant Cardiologist from the cardiac transplant team at Wythenshawe Hospital, Wythenshawe, Manchester confirmed that a member of the team is available 24 hours a day, 7 days a week for the referral of any patient or for guidance in relation to the treatment of heart transplanted patients. The cardiac transplant team at Wythenshawe Hospital would be available to discuss the perioperative management of heart transplanted patients undergoing non cardiac surgery and information has now been given to the Salford Royal Hospital by a cardiac anaesthetist from the Wythenshawe Hospital that the placement of an arterial line might have helped to detect abnormalities earlier during the course of the procedure although it is unclear whether this would have made a difference in relation to the death of the deceased. However the placement of an arterial line may have alerted the anaesthetist earlier of any impending deterioration of the patient's condition.

iii. The deceased became bradycardic in the short period prior to the cardiac arrest and Isoprenaline, which is a direct beta agonist, was not available at the Salford Royal Hospital for use in the course of the resuscitation attempts. Isoprenaline is the most effective anti-bradycardic agent in heart transplanted patients but the evidence at the Inquest was that Isoprenaline is no longer available in the United Kingdom. The evidence was that Isoprenaline was available in the United Kingdom up to approximately 10 years ago and there appears to be no medical reason for its removal from the United Kingdom market. It is understood that it is simply not cost effective for the pharmaceutical companies to make the medication available in the United Kingdom.

   Evidence was given that Isoprenaline is available from non domestic supplies and international sources. It was understood that supplies of Isoprenaline are available at the Wythenshawe Hospital, Manchester obtained from an international source.

The use of Isoprenaline for heart transplanted patients does not increase the resistance of the blood vessels around the body which means that the heart does not have to pump against increased resistance thereby benefitting any attempts at resuscitation particularly in relation to heart transplanted patients.

Salford Royal Hospital has now obtained stocks of Isoprenaline which is available in operating theatres together with laminated cards detailing how to prepare and administer the drug.

iv. The main root cause of the cardiac arrest suffered by the deceased and his subsequent failure to respond to all the resuscitative measures was identified as his past medical history of heart transplant more than 25 years ago. It has become clear that the predominant cause of death once the first 5 years after heart transplantation has passed is cardiac allograft vasculopathy, which is a form of coronary artery disease that is not amenable to surgical treatment such as angioplasty, stenting or even bypass graft surgery. Symptoms of myocardial ischaemia that occurs as a consequence of coronary artery narrowing e.g. chest pain, are frequently absent due to the denervated state of the transplanted heart.

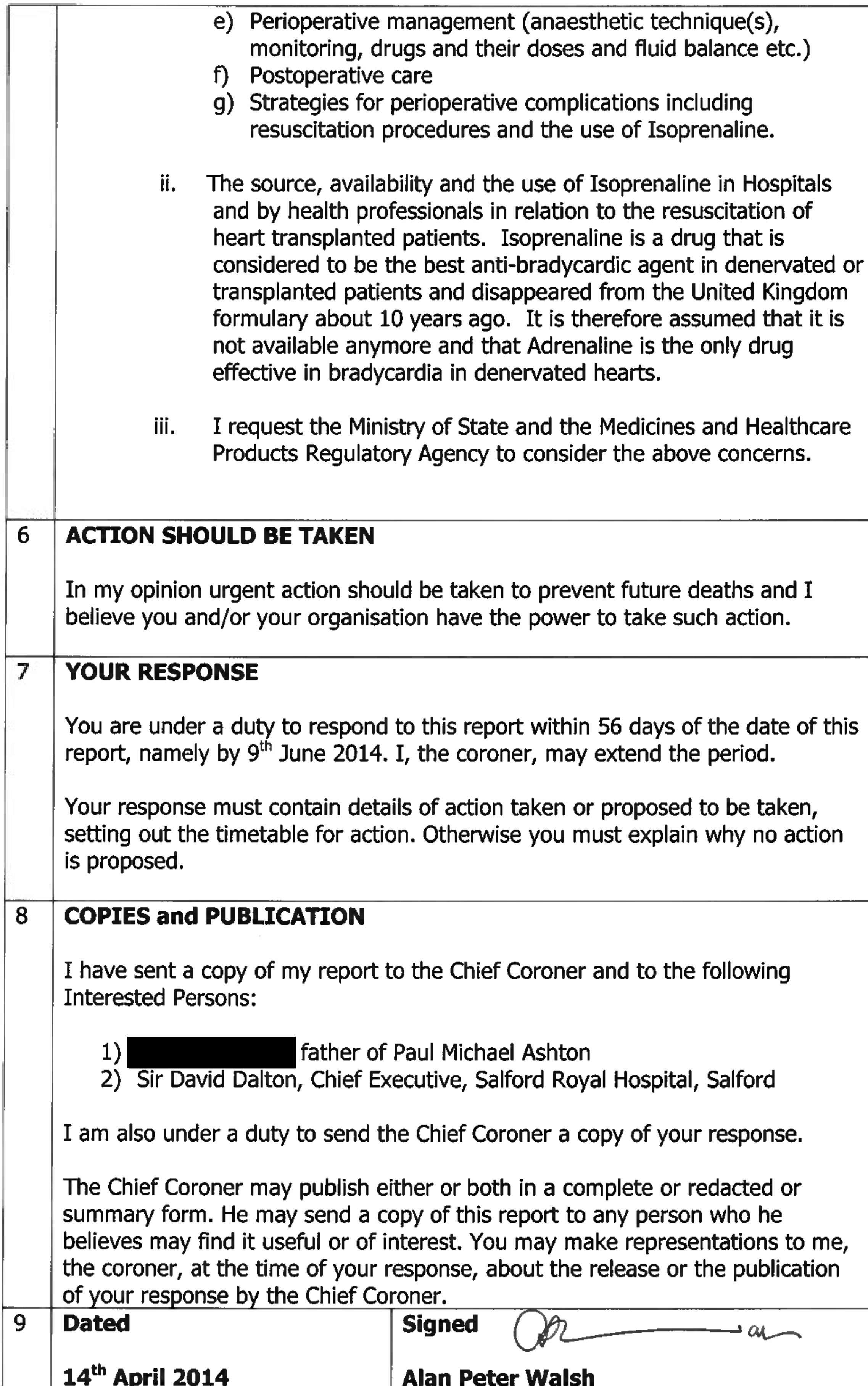
The knowledge of conditions special to heart transplanted patients is with Cardiac Consultants in cardiac transplant teams at regional centres around the United Kingdom who should be consulted to give guidance regarding the perioperative management of heart transplanted patients undergoing non cardiac surgery and such guidance could be embodied in protocols and guidelines at each hospital in the United Kingdom.

v. The supply of Isoprenaline is not available in the United Kingdom and the source of the supply and the importance of the use of Isoprenaline in the resuscitation of heart transplanted patients should be brought to the attention of all hospitals and health professionals in the United Kingdom.

(2) I have concerns with regard to the following:-

i. The absence of protocols and guidelines in Hospitals dealing with the perioperative management of heart transplanted patients due to undergo or undergoing non cardiac surgery. Such a protocol or guidelines could summarise issues that need to be considered when assessing and caring for a patient with a transplanted heart and the elements of such protocol or guidelines could include the following:

a) Pre-operative assessment
b) Liaising with the transplant unit the patient is under for follow up.
c) Guidance on risk
d) Benefit discussions with the patient and consent process



e) Perioperative management (anaesthetic technique(s), monitoring, drugs and their doses and fluid balance etc.)
f) Postoperative care
g) Strategies for perioperative complications including resuscitation procedures and the use of Isoprenaline.

ii. The source, availability and the use of Isoprenaline in Hospitals and by health professionals in relation to the resuscitation of heart transplanted patients. Isoprenaline is a drug that is considered to be the best anti-bradycardic agent in denervated or transplanted patients and disappeared from the United Kingdom formulary about 10 years ago. It is therefore assumed that it is not available anymore and that Adrenaline is the only drug effective in bradycardia in denervated hearts.

iii. I request the Ministry of State and the Medicines and Healthcare Products Regulatory Agency to consider the above concerns.

6 ACTION SHOULD BE TAKEN

In my opinion urgent action should be taken to prevent future deaths and I believe you and/or your organisation 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 9th June 2014. 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 Chief Coroner and to the following Interested Persons:

1) father of Paul Michael Ashton
2) Sir David Dalton, Chief Executive, Salford Royal Hospital, Salford

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 coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.

9	**Dated**	**Signed** [illegible]
	14th April 2014	**Alan Peter Walsh**