



Department  
of Health

POC5 856041

From Dr Dan Poulter MP  
Parliamentary Under Secretary of State for Health

Richmond House  
79 Whitehall  
London  
SW1A 2NS

Tel: 020 7210 4850

Mr A Walsh  
Area Coroner  
Coroner's Office  
First Floor  
Paderborn House  
Howell Croft North  
Bolton  
BL1 1QY

10 JUN 2014

*Dear Mr Walsh,*

Thank you for your letter following the inquest into the death of Paul Michael Ashton. In your report you conclude that the medical cause of death was myocardial ischaemia, transplant associated coronary artery disease, heart transplant for cardiomyopathy and anaesthesia for knee arthroscopy. The conclusion of the inquest was that Mr Ashton died as a consequence of a recognised complication of anaesthesia. This followed a background of post-transplant coronary artery disease arising from necessary anti-rejection medication following heart surgery.

When Mr Ashton was 14 months old he had had an orthotropic cardiac transplant at Harefield Hospital, Middlesex and had follow up appointments there with the paediatric cardiology department until 2003. Following this surgery he was prescribed medication to reduce the risk of rejection of the transplanted organ.

In 1998 he was diagnosed with Non-Hodgkin's Lymphoma and was treated with chemotherapy. During his lifetime, he also had an appendectomy, a laparoscopic cholecystectomy and knee arthroscopy all performed with general anaesthetic. The knee arthroscopy was performed about three years before his death.

In 2003 his care was transferred to the cardiac transplant department at Wythenshawe Hospital, Manchester where he had follow up appointments until his death.

In 2013 he was referred to a surgeon at Salford Royal Hospital for a further knee arthroscopy and had a pre-op assessment. Both the anaesthetist and surgeon were aware of his full medical history including the cardiac transplant. The procedure was carried out on 6<sup>th</sup> January 2014 under general anaesthetic.

Neither the anaesthetist nor consultant at Salford Royal Hospital had consulted the cardiac transplant team at Wythenshawe hospital who were still monitoring Mr Ashton for his cardiac transplant. There was no protocol or guideline at Salford Royal Hospital regarding perioperative management of heart transplanted patients due to undergo non-cardiac surgery. In addition, it was not known that there is a high incidence of diseased arteries in heart transplanted patients who have survived more than 25 years after cardiac transplant. During the operation Mr Ashton had a cardiac arrest. Although he was given cardiac pulmonary resuscitation with adrenaline and shock treatment, he failed to respond and died.

You raise the following matters of concern:

- Salford Royal Hospital did not have a protocol or guideline on the perioperative management of heart transplanted patients undergoing non-cardiac surgery. Although the Trust is now developing such guidelines (available 14<sup>th</sup> May), it was evident that protocols and guidelines do not exist at many other hospitals in the UK. You are concerned about the absence of such guidelines nationally and you suggest the type of information you would like to see included in guidance to be available in all hospitals.
- The deceased became bradycardic prior to cardiac arrest and isoprenaline (a direct beta agonist and most effective agent for heart transplanted patients) was not available at Salford Royal Hospital for use in resuscitation. You state that this drug is no longer available in the UK although it was available until 10 years ago. You consider that there is no medical reason for its removal from the UK market, and note that the drug is available from non-domestic supplies and international sources and is available at Wythenshaw Hospital. You ask that the source of supply and the important use of Isoprenaline for resuscitation of heart transplanted patients be brought to the attention of all hospitals and health professionals in the UK.

Officials have consulted colleagues in NHS England about your concern that guidelines on the perioperative management of heart transplanted patients undergoing non-cardiac surgery should be available in all hospitals.

NHS England has advised us that the International Society for Heart and Lung Transplantation (ISHLT) has published guidelines for the care of heart transplant recipients. Section 12 of these guidelines gives specific advice about non-cardiac surgical procedures carried out in hospitals away from the transplant centre. This includes the importance of a discussion with the centre, and a specific set of recommendations for anaesthesia.

Heart transplant centres in England do ask patients to inform them when patients are having any medical or surgical procedure, and advise that the relevant medical staff should contact the transplant centre. The transplant centre is then able to send advice based on the ISHLT guidelines. However, it is not possible to ensure beyond doubt using this method that heart transplant centres are made aware of every procedure on every heart transplant patient.

NHS England is therefore considering a strategy that would empower patients to insist that the responsible medical staff take appropriate advice from the expert centre. Patients do not always feel able to voice their needs and concerns, as this tragic case may illustrate. The problem is not simple and NHS England intend to consider in more detail what the obstacles are to empowering patients in this way, and what can be done to make the process effective.

NHS England is also aware that the problem goes wider than heart transplant patients, though fatal outcomes are mercifully rare. NHS England will therefore task its Rare Disease Advisory Group to prepare recommendations, within six months, for practical steps to make improvements.

NHS England will also ensure, immediately, through Area Medical Directors, that all hospitals are made aware of the ISHLT guidelines for heart transplant patients.

NHS England also believes that it is likely that isoprenaline is used by all cardiac surgical centres, both adult and paediatric, and that it is also available in private hospitals performing cardiac surgery. It is therefore unlikely to be stocked by hospitals that do not perform cardiac surgery or tertiary cardiology. Good communication between the cardiac centre and the hospital operating on the heart transplant patient should enable supplies to be made available to cover specific procedures in high risk patients.

However, the Department of Health is aware that there have been problems with the availability of isoprenaline and I can confirm that as a result of the current problems, the Department of Health asked the NHS UK Medicines Information service (UKMI) to produce a "Shortage Memo" which summarises the situation and advises on alternatives. This was sent out to hospitals and uploaded to the UKMI website, at the following address, on 24<sup>th</sup> April 2014:

<http://www.medicinesresources.nhs.uk/en/Communities/NHS/SPS-E-and-SE-England/Medicines-Information/Discontinuation-Supply-Shortage-Memos/Shortage-of-isoprenaline-injection/>

The memo is also attached at **Annex A** for your information.

I hope that this response is helpful and I am grateful to you for bringing the circumstances of Mr Ashton's death to my attention.

With Best Wishes,

A handwritten signature in black ink, appearing to read 'Dan Poulter', written in a cursive style.

**DR DAN POULTER**