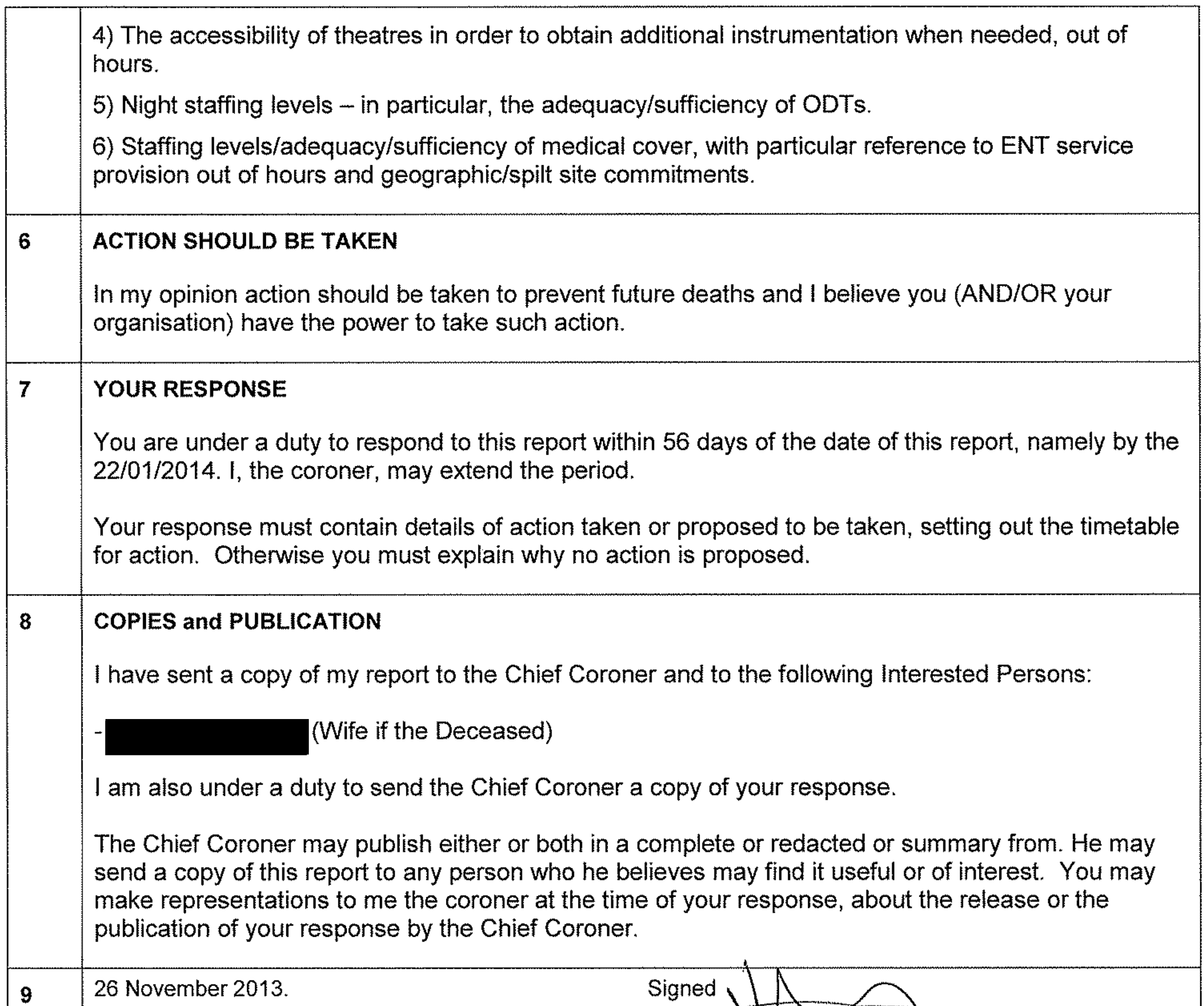
REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. Chief Executive, Pennine Acute Hospitals NHS Trust
1	**CORONER** I am Lisa Hashmi, Assistant Coroner for the coroner area of Manchester North
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroner's and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013
3	**INVESTIGATION and INQUEST** On 29/07/2013 I commenced an investigation into the death of Barry James LEWIS, then aged 68 Years. The investigation was concluded at the end of the inquest on 26/11/2013. The conclusion of the inquest was narrative – that '…Mr Lewis died as a result of the complications that ensued following an anaphylactic reaction of unknown origin. Difficulty was encountered in medically securing his airway. He went into respiratory then cardiac arrest. He died at 3:25 on the 24th July 2013…' The medical cause of death being: 1a) Consistent with anaphylaxis 2) Ischaemic Heart Disease due to Coronary Artery Atherosclerosis; Adhesive Pericarditis.
4	**CIRCUMSTANCES OF DEATH** Mr Lewis had been suffering from various types of physical health problems, including related weight management issues (clinical obesity). In the early hours of the 24th July 2013, he called for his wife's help as he was feeling unwell. He believed that he had had an allergic reaction and despite having taken oral steroids (prescribed to the deceased for another medical condition) his symptoms persisted. He had some time previously had an allergic reaction which had settled uneventfully. [redacted] took her husband to hospital whereupon a diagnosis of anaphylaxis was made. Appropriate emergency medical management was initiated however, the doctors were concerned about safe maintenance of Mr Lewis' airway (his tongue and face were swollen and he was having difficulty speaking). The medical team (initially consisting of ER Consultant and Anaesthesiologists) decided that it would be in the patient's best interests for his airway to be pro-actively medically managed. Preparatory steps were therefore taken. Whilst poorly, Mr Lewis' condition was deemed to be relatively stable at this point. It was the medical view that an Ear, Nose and Throat (ENT) doctor should be in attendance so that in the event that conventional intubation proved unsuccessful, surgical management could be initiated immediately. The overall viewpoint was that it would be an ENT doctor who had the necessary skills and expertise to surgically manage the airway in such circumstances. The 1st on call for ENT (a Senior House Officer - SHO) was based at the hospital caring for Mr Lewis, however it was held that such a junior Dr would not/did not have had sufficient clinical experienced to carry out surgical management. The hospital at which the deceased was being cared for was the only hospital within the Trust

	providing on call/emergency cover/theatre availability for ENT services. The only theatre at this hospital actively providing services out of hours was the ENT theatre. As such, there was only one Operating Department Technician (ODT) providing night cover. The 2nd on call ENT Dr (a middle/staff grade) was therefore called to attend Mr Lewis. At the material time, the 2nd on call was covering 3 hospitals, all in separate towns but within the same acute Trust. When contacted, he drove from one hospital to the other. Upon reaching the car park, the staff grade Dr received a call regarding a very ill patient at the hospital that he had just left. Advice was sought with regard to that patient's treatment and whether the Dr could return forthwith. The Dr established that the patient in question had been stabilised sufficiently and he therefore decided to make his way into the hospital in order to attend to Mr Lewis first. He headed up to theatre as he had been told that this was where intubation was to take place. En route, he met the SHO. They subsequently made their way to Accident and Emergency. Just prior to their arrival, the deceased's condition had rapidly deteriorated. He went into respiratory and then cardiac arrest. Cardio-pulmonary resuscitation/advanced life support (ALS) was carried out. The anaesthetic team struggled to secure the patient's airway by conventional intubation methods (3 different ways were attempted). This was due to the patient's weight problems (neck size/structure) and the swelling caused by the anaphylactic reaction. When ENT arrived, attempts were made to insert a surgical airway (tracheostomy/crycothyrotomy). However the ENT Dr experienced difficulties, over and above the patient's idiosyncrasies, in that: i) the standard pre-packed airway surgical sets available within the ER contained only smaller sized surgical instrumentation. Whilst there were routinely two packs of each of the four types of sets held, they only contained one size of instrument, smaller in size. In Mr Lewis' case, this meant that the skin retractor was too small and ineffective. ii) Similarly, the scalpel within the pack was a 'disposable'. This presented difficulties in securing an incision of sufficient depth/size. iii) The ENT Dr felt that the content of the sets in the ER differed to those that he was used to. iv) There was no additional, single, separately packed, larger instrumentation available in the ER (e.g. larger skin retractors/reusable metal handled scalpels to which the correct size of blade could be attached). v) Whilst reusable scalpels were available in main theatres the only person with ready access and practical knowledge of location and availability (out of hours) was the ODT. However, he was proactively involved in the resuscitation process and therefore could not be dispatched. Clinical staff felt unable to gain access to theatres, that there was no night manager on site/available to call upon and that the only other option open to them might have been to call switchboard to see if a porter was available to assist regarding theatre access. The ENT Dr did eventually manage to secure a surgical airway by 'feeling' for the relevant anatomical point once some form of incision had been achieved. The patient was 'bagged' and ALS continued. Following a downtime of 50 minutes the decision was taken to withdraw treatment and Mr Lewis died at 03:25.
5	**<u>CORONER'S CONCERNS</u>** 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) The adequacy/availability of emergency airway surgical sets, containing instruments of different sizes, within the ER department. The 'one size fits all' approach raises patient safety issues. 2) The consistency of instrumental content within the packs and familiarity with the same. 3) The adequacy and availability of additional, individually packed surgical instrumentation within the ER, as 'back-up' to the standard sets (e.g. larger retractors, scalpels etc.)



	4) The accessibility of theatres in order to obtain additional instrumentation when needed, out of hours. 5) Night staffing levels – in particular, the adequacy/sufficiency of ODTs. 6) Staffing levels/adequacy/sufficiency of medical cover, with particular reference to ENT service provision out of hours and geographic/spilt site commitments.
6	**ACTION SHOULD BE TAKEN** In my opinion 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 the 22/01/2014. 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: - (Wife if the Deceased) 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 from. 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	26 November 2013. Signed