

Birmingham Children's Hospital

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28 May 2010

Private & Confidential

Ms Paula Stevenson
C/O 115 Newcastle Road
Kilkeel
County Down
Northern Ireland
BT34 4NJ

Dear Ms Stevenson

Re: Your daughter Hayley

Thank you for your letter dated 15 December 2009 and for your patience whilst we investigated the detailed concerns you had in relation to Hayley's treatment. I would like to take this opportunity to express my sincere condolences on the sad death of your daughter, Hayley.

The Trust takes all complaints very seriously and seeks to work with children, young people, carers and families to resolve concerns and identify how we can improve the quality of services in the future. For this reason, your concerns were investigated in line with our internal risk processes and treated as a Serious Untoward Incident (SUI).

Your complaint letter provided a lot of helpful details upon which the investigation was based. It was not possible to answer each of your questions individually and this is why the investigation team grouped your concerns into themes where some issues were covered by the SUI Investigation and the remainder within the complaint report. The enclosed reports identify the circumstances of your complaint and the details of each investigation.

I know that reading through these reports will be an extremely painful thing for you to do but I hope you will receive some assurance that we have taken each of your concerns seriously and thoroughly investigated the issues agreed with you.

The SUI report is very detailed and as such I will aim to briefly summarise the findings of the investigation. Once you have had time to read through the reports, you may decide that you would like to meet with members of the investigation team. If this is something that you would like us to arrange, please contact the Complaints Service on 0121 333 8419.

I cannot imagine how distressing Hayley's admission must have been for you and your family. Hayley was admitted to BCH in October last year for correction of her Fallots Tetralogy and to close the hole in her heart. Harley then had a prolonged stay on our Paediatric Intensive Care Unit (PICU) for a number of reasons before she was transferred to Ward 12 on 31 October 2009.

Our investigation has revealed several failings summarised below;

After being transferred to Ward 11, Hayley's oxygen requirements gradually increased and although they remained relatively low, the review team noted that an increasing need for oxygen 3 weeks after her surgery should have raised clinical concern.

On 9 November the medical team were worried about Hayley's oxygen requirements, and after her chest x-ray showed significant changes, the medical staff became concerned she had a chest infection. As you know, Hayley's lung had collapsed and she was being treated with physiotherapy and antibiotics to address any possible infection that may have caused this. It was the opinion of the review team that Hayley's collapsed lung was a significant factor in her death.

By the morning of the 10 November, Hayley was clinically in distress. The investigation has highlighted there was an incorrect perception amongst the cardiology doctors that a patient needed to demonstrate 5 criteria, detailed on page 11 of the report, in order to be considered for admission to PICU. This is not the case as patients are admitted for a range of critical conditions based on their overall condition.

Hayley began to clinically deteriorate on 9 November and although standard treatment was started, the cardiology team had failed to consider the respiratory problems Hayley had whilst on PICU and put these into context with her present problems.

There is no way to soften the conclusion of the investigation for you, but the review team concluded that Hayley should have been referred to PICU for a review on 10 November as there was sufficient grounds to request this, and had she received early ventilatory support, this may have prevented her death.

Several factors contributed to this failure, as outlined within the SUI Report, and it was not found by the Investigation Team to be attributable to any one specific event or individual. Indeed, I note that several of your concerns are related to Dr Ben Anderson, Cardiology Fellow. The review team considered the conduct and competence of Dr Anderson, taking into account his record and the opinions of senior colleagues who have worked closely with him. The Investigation team concluded that there were no concerns regarding Dr Anderson's clinical practice, indeed he was considered to be an outstanding doctor, both clinically and in the way that he communicates.

I know from previous contact with you that you did not want us to apologise to you unless we were admitting liability for Hayley's death. I am not able to provide you with an admission of that kind and whilst it feels entirely wrong that I cannot apologise for the failings identified in the report, I am respecting your request. I hope you feel that we have been thorough and honest in our investigations, although I fully realise this is little comfort to you at this time and my heart goes out to you.

Similarly, the recommendations within the report will have little meaning for you and your family, but it is important that we take any learning from our investigation and implement changes to ensure this cannot happen again.

We are committed to addressing any issues that patients, families or their carers raise and to this end, as previously mentioned, I would be grateful if you would contact us if you would like to arrange a meeting or if you feel that we can do more to address the issues that you have raised.

Once again, please accept my sincere condolences on your sad loss.

Yours sincerely

Sarah-Jane Marsh
Chief Executive Officer

NEXT STEPS

If you remain dissatisfied at the end of local resolution, you can put your complaint to the Parliamentary and Health Service Ombudsman. The Ombudsman can carry out independent investigations into complaints about poor treatment or service provided through the NHS in England. The Ombudsman's services are free.

If you have any questions about whether the Ombudsman may be able to help you, or about how to make a complaint, please contact their helpline on 0345 015 4033, email phso.enquireis@ombudsman.org.uk or fax 020 7217 4000. Further information about the Ombudsman is available at www.ombudsman.org.uk You can write to the Ombudsman at;

The Parliamentary and Health Service Ombudsman
Millbank Tower
Millbank
London
SW1P 4QP

Should you require any direct help or advice making your complaint you can contact your local Independent Complaints Advocacy Service (ICAS) office. These details can be found in the leaflet enclosed in your acknowledgement letter. If you need any assistance with these details, you can contact our Complaints Service on 0121 333 8419 or make use of the POHWER website: www.pohwer.net ICAS provides independent advocacy to people making complaints under the NHS complaints procedure.

You are also able to report any concerns to the Care Quality Commission (CQC), which is the independent regulator of health and adult social care in England. The CQC does not investigate individual complaints or concerns about NHS Trusts but is interested in hearing from people who use services about their views and experiences to help them monitor compliance with standards. If you would like to inform the CQC about any concerns you may have about Birmingham Children's Hospital, you can contact them by telephone on 03000 616 161 or make use of the CQC website: www.cqc.org.uk or you can write to the CQC at:-

Care Quality Commission
Finsbury Tower
103-1-5 Burnhill Row
London
EC1Y 8TG

If we do not hear from you within 28 days of receiving this letter, it will be assumed that you are satisfied with this response.

Root Cause Analysis Report
Full Report
(Investigation ref: 09/10:28)

1.0 Introduction

This report considers events prior to the patient's death to identify whether there were any reasonable actions that staff could have taken to avert this outcome.

1.1 Terms of reference

- 1.1.1 To investigate the death of the patient identifying contributory and root causes, with specific reference to:
 - 1.1.1.1 Bed space and ward allocation
 - 1.1.1.2 Isolation procedures
 - 1.1.1.3 Clinical monitoring systems
 - 1.1.1.4 The patient's clinical status
- 1.1.2 To review the events and clinical care provided at Birmingham Children's Hospital from 12th October 2009 onward leading up to the patient's death on 11th December 2009.
- 1.1.3 To identify what reasonable actions could have improved the care provided
- 1.1.4 To establish if any national standards or guidelines are relevant to the incident, and review their implementation.

1.2 The Investigating Team

- 1.2.1 Dr Phil Debenham, Consultant Paediatrician and Hospital at Night Lead (Chair)
- 1.2.2 Dr Adrian Plunkett, Consultant Intensivist
- 1.2.3 Heather Steele, Educational Practitioner, Education and Learning
- 1.2.4 Caron Eyre, Associate Director of Nursing
- 1.2.5 Helen Watson, Head of Nursing for Directorate 3
- 1.2.6 Bryony Winnall, Deputy Associate Service Director for Directorate 3
- 1.2.7 Judy Green, Non-Executive Director
- 1.2.8 Mr William Brawn, Consultant Cardiac Surgeon
- 1.2.9 Mr David Barron, Consultant Cardiac Surgeon and Clinical Lead for Cardiac Services
- 1.2.10 Nina Barbosa, Risk Manager (Facilitator)

1.3 Investigating methodology

The investigation was carried out using principals of root cause analysis by a multidisciplinary team within the terms of reference listed in section 1.1.

The investigation team made reference to the contributory factor checklist to ensure that a range of factors were considered.

The investigation was carried out in accordance with the NPSA's guidance on **level 2** investigations.

1.4 Incident classification

The incident classification is incident type '60; *Care monitoring and review – Delay or failure to monitor*' under the incident domain: '*Safe High Quality and Co-ordinated Care*'. The incident is graded as a SUI and is therefore subject to investigation using RCA. Using the Trust's risk matrix the incident would be graded as consequence 5 x likelihood 3.

2.0 Summary of Incident

This patient underwent a cardiac surgical procedure (repair of Fallot's Tetralogy and closure of Ventricular septal defect (VSD) on 14 October 2009.

Postoperatively the patient remained on the paediatric intensive care unit (PICU) until transfer to Ward 12 on 31st October 2009 and subsequently to Ward 11 on 3rd November 2009. The patient had a cardiac arrest on the 11th November 2009 at 0756. Despite full resuscitation measures, death was declared at 0815. The patient's carers raised concern that the Trust had failed to recognise clinical deterioration and failed to undertake appropriate clinical management.

3.0 Background to incident

This has been prepared from the clinical record, pathology and radiology databases and additional supporting information listed in section 4.0.

The patient was a female born on the 6th October 2008 with a complex form of Fallot's Tetralogy. This involved pulmonary atresia (PA) with VSD and unusual positioning of the heart with dextroposition. She also had small, narrowed pulmonary arteries and bilateral superior vena cavae that further complicated the condition. She had previously undergone palliative cardiac surgery in Ireland which involved a modified left BT shunt and PDA closure, in December 2008. Following this she was referred to BCH Cardiac Services team by the team in Belfast.

The patient was admitted on the 12th October 2009 to Ward 12 for repair of Fallot's Tetralogy and closure of VSD. She was then taken to theatre on the 14th October 2009. The operation successfully corrected the condition. Although the anaesthetic staff noted that the central venous catheter (CVC) cannulation was very difficult in the neck and there was evidence of dilated superficial veins in chest walls. The CVC was placed in the femoral vein. There was also some oozing (bleeding) in theatre immediately post-operatively, but this improved with blood, platelets and cryoprecipitate. The thromboelastogram (TEG) was reportedly normal.

PICU admission

The patient had a prolonged period on PICU, which is not unusual for a patient with this diagnosis. The patient had two failed attempts at weaning off ventilation. Left and right sided lung collapse / consolidation were identified on serial chest x rays. There were clinical indications of a lower respiratory tract infection (pneumonia). The patient was treated with a range of antibiotics. No causative organism was identified.

The cause of the bilateral lung collapse is unknown. Insertion of an endotracheal tube too deep could cause unilateral lung collapse, but does not cause bilateral lung collapse.

Chest x-ray at 03:37 hours on 19th October 2009 shows a small right basal pneumothorax and has resolved on repeat chest x-ray at 11:49 hours on 19th October 2009. This may be what was referred to as "lung perforation" in the carer's formal complaint. This is unlikely to have resulted from the intubation, due to the rapid resolution without intervention.

In view of the two failed episodes of ventilation weaning, diaphragm paralysis was considered. An ultrasound scan excluded this diagnosis.

Successful ventilation weaning was achieved by using a combination of BIPAP (a form of non-invasive ventilation) and CPAP.

The patient was also noted to have enlarged liver and abnormal liver function tests, secondary to higher pressure in the right side of the heart, which is common in pulmonary atresia. This normalised whilst on PICU.

After the patient was weaned off BIPAP and CPAP she was monitored for a further 36 hours prior to transfer to Ward 12.

Transfer to Ward 12

The patient was transferred to Ward 12 on the 31st October 2009 where she continued to require high dependency care, with a persistent oxygen requirement. She continued to have regular physiotherapy for several days, de-escalated following physiotherapist assessment to "physiotherapy review on request".

The patient was moved to Ward 11 on 2nd November 2009 (To allow the admission of another patient requiring a bed on Ward 12).

Transfer to Ward 11

The patient was transferred to Cubicle 1 on Ward 11 late afternoon of the 3rd November 2009.

The Patient's paediatric early warning scores (PEwS) ranged from 1-5, with frequency of observations ranging from 2-8 hourly from 3rd – 9th November 2009.

There was a trend of gradual increasing oxygen requirements since 7th November 2009.

The nursing staff perceived the patient to be one of the more stable on the ward until 10th November 2009.

The medical staff report concern about this patient from 9th November 2009. Chest x-ray was requested on the midday consultant ward round, with a formal radiology report available at 15:00 hours. The cardiology team reviewed the chest x-ray at 18:00 hours noted the deterioration in the lungs and planned to defer physiotherapy until 10th November 2009.

The patient's chest wound continued to be managed in accordance with instructions from the surgical team and a Mepolax dressing was used, which is left in place for 48 hours unless there is a lot of oozing.

At 02:00 hours on the 10th November 2009 nursing staff raised concern of clinical deterioration and escalated this to the duty cardiology senior house officer. This doctor reviewed the patient at 02:00 hours and 03:00 hours. Clinical assessment indicated marked respiratory distress. Repeat chest x-ray showed worsening consolidation and capillary blood gas was normal. The doctor telephoned the duty cardiology registrar to share her concerns of the patient's condition and whether a review by the PICU team or antibiotic therapy was appropriate. The cardiology registrar advised not for physiotherapy or PICU review unless further clinical deterioration and to await further discussion with the consultant in the morning.

At approximately 05:00 hours on the 10th November 2009, the duty cardiology registrar reviewed the patient and was of the opinion that whilst she was the sickest patient on the ward, a PICU review was not indicated because the capillary blood gas was normal and the patient's clinical status did not reach this doctors perceived threshold for discussion with PICU.

The on call physiotherapist was contacted at 07:30 hours on the 10th November 2009. She was already on route to work by train. Based on the information provided regarding the patient's clinical status, a decision was taken that on arrival at the hospital she would arrange for a physiotherapy review. On arrival at the hospital, the on call physiotherapist met the physiotherapist whom had the most experience with the patient and a decision was taken for the physiotherapist with the most knowledge of the patient to undertake the assessment. This occurred at 09:40 hours.

As approximately 10:00 hours on the 10th November, the cardiology registrar led ward round acknowledged the overnight clinical deterioration. Infection was considered a possible cause for the deterioration, and investigations to identify an infective source were requested. This included the request for respiratory viral detection (including H1N1 in light of the current pandemic) from nasopharyngeal secretions. It is Trust infection control policy that all patients undergoing testing for H1N1 are isolated until a negative result is received.

The patient remained in the same cubicle but with the door shut to comply with isolation practices.

The patient's mother expressed concerns regarding the isolation procedure to the nurse caring for the patient (Staff Nurse 4), whom relayed these concerns to the Ward Manager. The mother however did not wish to discuss these concerns with the Ward Manager at the time.

That night Cardiology Senior House Officer re-instated enteral feeds at 21:00 hours at maternal request. Initially 50 % enteral, 50 % intravenous with a plan to go to full enteral feds at 03:00 hours on the 11th November 2009.

The duty Cardiology Registrar on call for the night of the 10th November 2009 reports reviewing the patient overnight and was of the impression that the clinical status was stable with an infective aetiology most likely due to the pus in the chest wound and elevated inflammatory markers (Not documented in clinical record).

At 06:55 hours the patient was noted to be working slightly harder to breathe and the patient's nurse (Staff Nurse 1) requested a review by the Cardiology Senior House Officer. The doctor reviewed the patient at 07:10 hours due to worsening respiratory distress. Enteral feeds were reduced to 50 % and 50 % given intravenously.

At 07:30 hours the patient's mother alerted the team that patient was deteriorating further. The Cardiology Senior House Officer reviewed the patient and took a sample for a blood gas check on PICU. The results were concerning therefore she returned to Ward 11 with the duty Cardiology Registrar and the PICU Registrar. The PICU Registrar recognized the impending signs of respiratory arrest and that the patient would need ventilation and transfer to PICU, so commenced a rapid sequence induction and intubation. The patient had a cardiac arrest at 07:56 hours and the arrest call was put out, while the resuscitation commenced.

Resuscitation

The patient remained on bag ventilation via the ETT and CPR continued throughout this time except for pulse checks and very brief echocardiogram (to exclude pericardial effusion / tamponade). Intravenous access was limited and so intraosseous (IO) access was obtained twice in the tibia. The first needle only lasted a few seconds and therefore a second IO device was inserted. IO needles often do not last very long in young children but provide quick vascular access in an emergency and a route for resuscitation drugs and fluids. Subsequently an IV cannula was placed in the right femoral vein, through which resuscitation drugs (bicarbonate, adrenaline and calcium) could be administered.

The PICU medical team carrying out the resuscitation noted that the chest was very poorly compliant, requiring very high pressure with the bagging circuit when they were trying to get air into the lungs. This was suggestive of a severe recurrence of lung collapse. It was also noted that the patient's blood gases were not improving despite being ventilated. This indicated that the resuscitation measures were not succeeding and despite air flowing into the patient's lungs; it was not able to cross into the blood.

After 20 minutes, the cardiac rhythm had deteriorated from pulseless electrical activity (PEA) to asystole. This means that the heart went from having an electrical activity but not beating, to having no activity at all. An echocardiogram (ECHO) showed cardiac standstill despite correct resuscitation protocols being followed. The blood gas revealed a severe mixed acidosis and the chest compliance remained very poor. The patient was declared dead at 08.15.

4.0 Supporting Information

- 4.1 Timeline prepared for health records
- 4.2 Comments from Consultant Cardiac Surgeon
- 4.3 Comments from Consultant Paediatric Intensivist
- 4.4 Comments from Intensive Care Registrar
- 4.5 Comments from Consultant Cardiologist
- 4.6 Review of ultra sound imaging by Consultant Cardiologist
- 4.7 Review of Cardiology Registrar 1's competence
- 4.8 Comments Cardiology Registrar (1)
- 4.9 Comments Cardiology Registrar (2)
- 4.10 Comments Cardiology Registrar (3)
- 4.11 Notes from Meetings with Cardiology SHO (1); Cardiology SHO (2); Cardiology Registrar (4); and Cardiology Registrar (3)
- 4.12 Comments from Cardiac Liaison Nurse
- 4.13 Nursing Summary by the Ward Manager
- 4.14 Notes from Meeting with Ward Manager
- 4.15 Comments from Staff Nurse (1)
- 4.16 Comments from Staff Nurse (2)
- 4.17 Summary of conversation with Junior Sister (Infection Control link worker)
- 4.18 Comments from Staff Nurse (3)
- 4.19 Comments from Staff Nurse (4)
- 4.20 Comments from Stella Duncan
- 4.21 Comments from Clinical Support Worker
- 4.22 Summary of PEWS review
- 4.23 Comments from Principal Physiotherapist
- 4.24 Notes from meeting with Physiotherapist and Senior Physiotherapist
- 4.25 Radiology reports
- 4.26 The Normal Heart Diagram
- 4.27 Fallot's tetralogy heart diagram
- 4.28 Post Mortem
- 4.29 Isolation Policy

5.0 Specific Concerns Raised

- 5.1 To investigate the death of the patient identifying contributory and root causes, with specific reference to:

5.1.1 Bed space and ward allocation

Carer concerns were raised that the patient was not placed in the appropriate beds on Ward 11, and that the patient had been moved from Ward 12 to Ward 11. When a child is moved from PICU, they are routinely told that they will be receiving High Dependency Care on the Ward. Ward 12 has two beds (Bay 5) allocated as high dependency, which are opposite the nursing station. If these two beds are full and the ward receives a patient who needs high dependency care, they are put in Bay 7 where there are another four beds where patients can receive the same level of monitoring.

There are frequently bed shortages on Wards 11 and 12 due to the high workload therefore patients are sometimes moved to accommodate new elective admissions. Both wards are dedicated cardiac wards, although routinely Ward 11 is used for babies between 0-6 months and the older children are nursed in Ward 12. However, Ward 11 will sometimes be used for infants up to 18 months old. At the time of this incident, a bed was needed for an older child and therefore, as the youngest patient on Ward 12, it was proposed that the patient should be moved to Ward 11.

Movement between the wards to accommodate elective admissions is normal and is carried out as a dynamic process during normal working hours, with the bed state being formally assessed every morning. This assessment of bed allocation is led by the nursing staff in conjunction with the Nurse Manager or Head of Nursing, but there is also consultation with medical staff as necessary.

The patient and mother were offered one of the beds in the high dependency area with Ward 11. Beds in the high dependency area have room for a chair next to them for family members but do not have room for a parental bed. The patient's mother wanted to have a bed alongside her daughter, therefore it was not possible to accommodate the mother's wishes whilst nursing the patient in a high dependency bed, and this is the reason why the patient's transfer was delayed from Ward 12. Once the patient was weaned off milnirone due to her stable condition, she could safely be put in a non-high dependency bed. Had staff felt it was essential that the patient was in the high dependency area then they would have insisted, irrespective of mum's wish to have a bed alongside the patient, however in this instance it was assessed to be safe and it was not necessary for the patient to be in high dependency.

It was noted that the dependency of the other patients on the ward at the time could have impacted on the decision on where to place the patient. The dependency of other patients during this patient's admission on Wards 11 and 12 was high resulting in this patient being one of the more stable patients for much of her admission. It was also noted that if a patient requires high dependency care, then the nurse to patient ratio is altered for that patient and the nurse caring for them will only have one other patient to care for. This means that high dependency care can be provided in normal bed spaces. It was noted that as the patient deteriorated she was nursed more intensively, with the nurse spending the majority of her time with this patient on the 10/11/2009, providing a higher nurse patient ratio of one nurse to two patients.

It was noted by the review team that the patient's mother was not happy about the bed allocation. It was also noted that this concern was not escalated whilst the patient was on the wards. If this had been escalated to the Ward Manager, or the head of nursing, then they could have helped to explain the rationale for the move to the mother or her parents.

It was also noted that it is usual for parents to be anxious following discharge from PICU. This is especially the case when the patient had had an extended PICU admission. The review team questioned whether the method of providing high dependency care was explained adequately to the mother.

The review team considered whether the closeness of monitoring would have been an issue when considering distance from the nursing station. It was firstly noted that a patient receiving high dependency care would be having 1:2 nursing, even if they were not in a high dependency bed space. The patient's overall condition and the dependency of other patients would determine which cubicle the patient was admitted to. It was noted that closeness to the nurses station does not necessarily equate to closer monitoring.

There is a perception that patients closest to the nursing station are most closely monitored. The nursing station is not constantly manned as nurses are frequently moving around the ward whilst delivering care. When at the nurse's station they will tend to be carrying out specific tasks, although patient care would always be the priority.

5.1.2 Isolation procedures

The patient was noted to be deteriorating on the 09/11/2009 and this continued on the 10/11/2009. No case for this deterioration had been identified therefore the clinical team considered whether the patient may be suffering from H1N1. To rule this out samples were taken for testing and sent to microbiology. Trust policy states that a patient who is tested for H1N1 must be nursed in isolation until a negative result has been received.

The review team noted that the reason for testing the patient for H1N1 did not seem to be understood by the patient's mother and that the implications of this were not clearly understood.

The review team were advised that the main difference between nursing a patient in isolation was that the cubicle door would be shut and that staff would have to put on disposable protective clothing before entering the cubicle. It was noted that it is harder to hear the patient's monitors if the door is shut which is why, when a patient is put in isolation, the monitors are normally put outside the cubicle.

In this instance this was not always done because the patient's mother wished to be able to hear the monitors whilst with her daughter. Staff assessed that this would be acceptable because the patient's mother was always with the patient during the night and she could alert staff to any changes. When the patient's mother was not with her daughter, the monitor would be put outside the cubicle.

It was noted that the mother felt that this impacted on her daughter's care, because when she needed to summon help, she had to leave the cubicle. Confirmation has been received that there are emergency buzzers in all of the bed spaces on Ward 11, and that had the mother needed to summon help, she could have pulled the buzzer rather than leaving the cubicle. It is necessary to ensure that patients are aware of the system for summoning help when they are providing significant input into the nursing of the patient.

5.1.3 *Clinical monitoring systems*

The observation and monitoring policy recommends that a patient receiving oxygen should have hourly observations. This was not undertaken for this patient.

The PEWS score was not always calculated on the observation chart and occasionally not calculated correctly, even though appropriate observations had been performed. The review team also observed that the PEWS score can only be correctly calculated and interpreted when all 7 parameters, including blood pressure, have been documented.

The review team were also advised that concerns had been raised regarding the use of the monitors, with the patient's mother being concerned that the monitor was not working properly. It is believed that the member of the nursing team, who is reported to have informed the family that some of the new monitors were not working, was making reference to the fact that poor quality pulse oximetry can be multifactorial.

5.1.4 *The patient's clinical status*

The patient had a fairly standard post-operative course. Her chest remained open for some time after the procedure. On day 2 there was a slight deterioration with an increase in inotrope being administered. This meant that the patient would need longer to recover and therefore the chest closure was delayed. During her time on PICU she showed some signs of infection and had difficulty weaning from ventilation and had episodes of collapsed lung segments. The patient also developed a large liver and abnormal liver function around day 2-4, however this responded quickly.

It was also noted that the patient's ventricles were quite stiff which could be seen from the patient echocardiogram (ECHO). This was a good indication for the patient's long-term prognosis, although, it does mean a harder immediate post-operative course.

The level of support that the patient was on whilst on PICU was relatively low.

The review team considered the mother's comments regarding perforation of lungs. It was believed that the lung collapse was interpreted as being due to perforation. It was also noted that the patient had a small pneumothorax, which could have been, miscommunicated to the mother and subsequently, misinterpreted as a perforation of the lung. The pneumothorax resolved itself within 24 hours.

It was also noted that the patient's arterial line stopped working whilst on PICU. This compromised the patient's blood supply to the artery that the cannula is placed. The line stopped working due to a spasm in the right hand. This is not uncommon and was treated with some heparin and conservatively and resolved itself. Comments received by the patient's mother also indicate that she is concerned that we did not make use of a broviac line to maintain venous access for this patient. It was noted by the review team that a broviac line is only used for long term medication administration which was not needed for this patient.

The review team wondered whether an infection could have been responsible for the post-operative difficulties. It was however noted that this was investigated and no evidence for an infection was found at the time. The review team then questioned whether a weakness with the diaphragm could explain some of the symptoms. The patient's diaphragm was however noted to have been of normal strength.

The review team also considered the causes for the repeated consolidation/collapse of the patient's lungs. It was questioned whether the position of the heart (on the right side) could have contributed to this, or whether the patient had an underlying bronchomalasia. It was noted that there were no documented issues with her bronchial tract. A conclusion was not reached.

The patient was transferred to Ward 11 on the 6th November 2009 and the parents and grandparents say that they noted a decline in the patient from that point. The information provided by the clinical team indicates that the patient's observations were stable until the 9th November 2009.

The patient's oxygen requirements increased whilst on Ward 11 over a period of time from 0.3L/min to 0.5L/min and then to 0.75L/min although this remains a relatively low oxygen requirement. The review team noted that three weeks after surgery increasing oxygen requirement should have raised clinical concern.

On the 9th November 2009, the medical team were worried that the patient was now requiring 0.75L/min of oxygen via nasal prongs to maintain her oxygen saturations at 97-98%. On examination she was comfortable and mildly breathing faster and she had strong peripheral pulses. A chest x-ray was requested due to the known history of collapse of lung segments which showed documented significant consolidation of the left chest and volume loss on the right side. Blood results showed no evidence of infection with a CRP of 21 and a white cell count of 14.3. Subjectively the patient was felt to be worse than before by the doctors and there were increased concerns regarding a possible chest infection.

At 02.00 hours on 10th November, the nursing staff had specific concerns about a decrease in the patient's oxygen saturations to 91 %. Increased oxygen was delivered and the SHO contacted and a CXR and blood gas taken. At this point the method of oxygen delivery was changed from nasal prongs to allow 40-45 % oxygen to be administered via a head box, enabling oxygen requirement to be more accurately assessed.

The review team enquired whether the clinical teams were considering right heart failure. It was noted that at the time the teams thought that the right heart failure was being caused by the lung collapse.

The review team consider the lung collapse to be a major aetiology of the patient's death. It was noted that the patient's lungs were being treated by physiotherapy and antibiotics to try and address any underlying infection that could cause the consolidation and collapse. This is standard treatment for such concerns.

The review team noted that by the morning of the 10th November 2009, the patient was clinically in distress. There was a perception amongst the cardiology doctors that there were five criteria for admission to PICU of which one is a poor blood gas count. The others were reported to include: the patient looking unwell, increased oxygen requirements, increased work of breathing, worsening x-ray. This is not the case, patients are admitted with a range of other critical conditions based on the overall clinical context.

The cardiology registrar discounted admission to PICU because the patient did not meet all of five perceived criteria, even though they met the other four. It was also noted that the patient's chest x-ray showed worsening bilateral changes which would in itself be concerning.

The review team noted that even though the patient had deteriorated from the 9th November 2009, she was considered to be stable during the night of the 10th and 11th November 2009. It was noted that the patient had a slight increase in work of breathing, but this appeared to have remained stable.

The review team also noted that there was reference to CPAP made in the notes by the physiotherapist. Reports from the physiotherapist have confirmed that this was a note for consideration for the physiotherapy team, and that this was discounted following discussion with the senior physiotherapist.

When considering the events immediately pre-arrest, it was noted that the decision to intubate was the correct one given the severity of the respiratory distress. Although the cardiac arrest occurred immediately after administration of anaesthetic drugs, the clinical signs observed by the PICU registrar would suggest that cardiac arrest was inevitable. In such circumstances, the correct first course of action is to establish a definitive airway – i.e. intubate. The choice of ketamine and rocuronium as induction drugs is also entirely appropriate, as they are least likely to cause cardiac suppression (as compared with other anaesthetic agents).

The review team considered whether during the resuscitation intubation the oesophagus was reached and that's why the air would not go in. However, the placement of the ET tube was checked at the time.

The review team also noted that it was important to recognise the high-risk nature of cardiac post-operative patients. The relationship between PICU and the cardiac team needs to be improved. It was however noted that there are resource constraints, and that the increase in PIC consultants actually only allowed the number of PIC doctors to remain the same as before, but with an increase in seniority and experience. There has been an equal reduction in junior doctors in PIC.

6.0 RCA Outcome

6.1 Overall Impression

This patient began to objectively clinically deteriorate on the 9th November 2009. Treatment to address this deterioration was started by the clinical team based on their assessment of the patient. This treatment was in line with standard practice.

The cardiology medical team failed to put the clinical deterioration into context of the prior respiratory complications experiences by the patient on PICU.

The patient should have been referred to PICU for review on the 10th November 2009.

Early commencement of pressure support ventilation of this patient could have prevented the patient's death.

6.2 Contributory Factors

6.2.1 Patient Factors

The speed with which the patient deteriorated was unusual, and a significant factor in the outcome noted. The presence of the persistent chest wound infection, skewed the management towards chest infection more than lung collapse. It is possible that the patient's unusual anatomy impacted on the respiratory issues. Another factor that was related to the patient was that compared with most families seen in PIC and cardiac services, this family were generally more concerned about the patient at all stages of her admission.

6.2.2 Individual Factors:

The review team considered the evidence that had been provided regarding the competence of Dr Anderson, cardiology fellow as this had been specifically questioned by the mother. They also heard the opinions of other senior colleagues that had worked with this person. It was noted that not only were there no concerns regarding Dr Anderson's clinical practice, but that he was considered an outstanding doctor both clinically and in his communication. It was also noted that the person had few contacts with this patient and none were within the last days of her life.

It was also noted that specific concerns had been raised regarding one of the nursing staff's involvement in the isolation of the patient. It was noted that the member of nursing staff was following the correct procedure.

6.2.3 Task Factors:

The review team noted that there were no national standards or guidelines that were considered to be relevant to this patient's treatment. The Isolation Policy was followed. The Trust's Observation and Monitoring policy was not fully complied with regarding frequency of observations for patient.

The review team were concerned to hear that the perception of the junior doctors that PIC involvement was criteria driven, and that PIC review could not be triggered by senior house officers. This view was not held by the PIC team, who acknowledge that they have resource issues, but non-the-less would encourage early requests for PIC review.

6.2.4 Communication Factors

The review team noted that there were a number of communication issues with the family.

- These issues include the difficulty that the mother and grandparents had ensuring that their concerns were heard and inadequate feedback on what was being done about them
- The families understanding of the reasons for the bed moves and bed allocation including the implication of this
- The reasons for isolation and the implications of this
- The mechanism for summoning help when required, ie the emergency buzzer

6.2.5 Team and Social Factors

A number of team factors were identified. The most significant of these was considered to be the hierarchical nature of working within the clinical specialty. It was noted that all escalation of concerns was within the team, even when the concern had not been fully addressed. It was recognised that the nature of this specialty is highly complex, however, the review team concluded that earlier escalation to the PIC team was required in this case, and that all junior staff should have felt empowered to escalate their concerns to the PIC team.

The review team also noted that there is a difficulty with balancing continuity of care with a team based approach to providing treatment. The most consistency is found on weekends when there is one registrar responsible for the while weekend. During the normal working week a different registrar is on duty each day.

It was noted that the medical staff and nursing staff has differing perceptions of how unwell the patient was. The medical staff note that they began to become concerned about this patient on the 10th November 2009, and that they considered this patient to be one of the most concerning ones from this point. The nursing staff did however, not become that concerned until the following day.

6.2.6 Education and Training Factors

The Observation and Monitoring Policy recommends that if a child is receiving oxygen, then hourly recordings of respiratory rate, respiratory effort and pulse oximetry should be completed.

6.2.7 Equipment and Resource Factors

A number of resource factors were identified as significant in this case. The lack of bed capacity on the cardiac wards was noted to be an issue, as was the specific issue with high dependency capacity. It was however, noted that the patient was placed in appropriate beds based on her clinical need at the time, and that the movement to a high dependency bed would have been complicated by the concern regarding H1N1. Regardless of the patient's bed allocation, it is possible for nursing staff to provide high dependency care in a normal bed, which is what happened during the 10th and 11th November 2009.

It was also noted that the lack of PIC capacity is recognised by clinical teams and the perception of this impacts on the decision of when to refer a patient to PIC. It is considered that there needs to be high burden of evidence to justify PIC review. The PIC team have however, confirmed that they will review any patient where there are serious concerns. Had the PIC team been called about this patient they would have responded, the issue is that until approximately 0730 on the 11th November 2009, the clinical staff did not feel that they were able to refer to PIC based on the information they had available. It is therefore concluded that the issues with capacity did not affect this patient's treatment.

6.2.8 Working Conditions

No working condition factors were identified.

6.2.9 Organisational and Strategic Factors

The lack of capacity within PIC and Cardiac Services is an organisational issue which is being monitored closely and for which action plans are in place. This issue is, however, not one that we can quickly address and will require ongoing input.

6.3 Root cause of incident/conclusion

The root cause of the incident was a team factor. There was a culture of hierarchy in the teams, which meant that junior staff did not feel comfortable calling PICU for advice unless there was very strong evidence. It was noted that there were sufficient concerns to involve PIC on the 10th November 2009, and that had these concerns been raised to the PIC staff, the outcome may have been altered.

7.0 Areas of good practice noted

The review team did note a number of areas of good practice during the course of the investigation. These included;

- The care that was provided on PICU following the operation on the 14th October 2009
- The continued regular input of the physiotherapy team on Ward 12 until the patient had recovered to a more stable condition
- The staff nurse's immediate request for review by the medical staff on the morning of the 11th November 2009, and speed of response by the Senior House Officer and then by the PIC Registrar and the Cardiology Registrar.

8.0 Recommendations

8.1 Regarding clinical practice:

8.1.1 The review team noted the importance of early preliminary discussions with the intensive care team. An open door style policy must be pursued. It was noted that this was an aim of the intensive care team and that their increase in consultant numbers helped this. Although it was also noted that the overall numbers of PIC medical staff had remained the same, the review team did however note that the perception held by junior doctors was that a significant amount of evidence would be needed to justify involving the intensive care team. It is necessary to empower junior medical staff and nursing staff to summon support from the PIC team when they feel that this is justified. This should include the understanding that the criteria for justifying PIC input must be considered in the context of the patient's overall condition, so that staff feel comfortable escalating a patient to PIC whenever they have a concern.

8.1 It is however, recognised that cardiac patients pose an especially high clinical risk. One suggestion that was muted at the RCA was that there should be joint PIC and Cardiology Registrar handovers or ward rounds, potentially after Cardiac ward round on PICU or at the end of the night shift. The feasibility and benefit of this requires more exploration.

8.2 The review team reinforced the importance of considering the totality of a patient's symptoms and seeking assistance when a concern is identified.

8.3 The review team also considered whether the Trust needed to develop some form of a Rapid Response Team or Medical Emergency Team as an outreach service from PICU. This has worked well in a number of organisations. Some hospitals in the USA have even enabled parents to activate this service, which has been found to be valuable and not severely misused.

8.4 The review team also considered whether a referral model such as is used in Child Protection concerns should be used. With child protection concerns, any concern raised by any member of the team must be fully investigated and if considered not to be valid, then the reasoning for this must be carefully recorded in the patient's health records.

8.5 It was also noted that there is little surgical review in post-operative patients once they have been discharged from PICU, as the patients are then under the care of the cardiologists. The surgeon responsible for this patient was not advised that there were specific concerns with the patient's progression, and current practice does not automatically involve review by the surgical team. This must be addressed.

8.6 The review team also considered that there was inadequate awareness amongst the nursing staff of the requirement to increase the frequency of observations to hourly when a patient was receiving oxygen or when the amount of oxygen required was increased. Further training on observation and monitoring is required.

8.7 The review team then agreed that there should be an increase in simulation training, and possibly some training using the STEPS model of communication.

8.8 Regarding other practice

8.8.1 It was noted that there was no formal debrief for medical staff following the incident and that the debriefing session for nursing staff occurred some time after the incident. This is not an acceptable standard of support for our staff and this should be reviewed and a formalised process developed that is well understood by all staff.

9.0 Action Plan

Rec	Action	Lead	Due date	Evidence of completion
9.1	Highlight the outcomes of the investigation to the cardiac team (including junior medics and nursing staff) and encourage a discussion about how this cultural issue can be addressed in a sustainable manner.	D Barron	01/05/2010	Notes from meeting reflecting discussion
9.2	Reinforce this message at local induction sessions for junior doctors	All clinical leads	Ongoing	Confirmation that this issue will be incorporated into local inductions
9.3	Highlight the importance of involving PIC at an early stage when there are concerns, and ensuring that the whole of the patient's condition is considered at all times, at the junior doctors induction programme.	S Rao R Gupta	Ongoing	Slide from appropriate element of induction session
9.4	Consider the merit and feasibility of a joint Cardiac and PIC review of ward patients on a regular basis.	D Barron & F Reynolds	01/05/2010	Feedback to CRQAC through the Directorate Risk Report
9.5	Consider the merit and feasibility of a medical emergency team or rapid response team that is attached to PIC	F Reynolds	30/06/2010	Feedback to CRQAC through the Directorate Risk Report
9.6	Consider the merit and feasibility of a child protection model of responding to concerns raised by junior doctors within cardiac services	D Barron	31/05/2010	Feedback to CRQAC through the Directorate Risk Report
9.7	Consider how the surgical team can play a more routine part in the post-operative ward care	D Barron	20/05/2010	Feedback to CRQAC through the Directorate Risk Report

9.8	Highlight issues to the nursing staff with regards to observation and monitoring skills, the need to escalate frequency of observations in line with policy and the requirement to accurately calculate PEWS	H Watson	10/04/2010	Feedback to CRQAC through the Directorate Risk Report
9.9	Continue ward based nurse training in observation and monitoring skills and the use of PEWS	H Steele	Ongoing	Update reports on progress with training included in report to Education Committee
9.10	Introduce simulation training to embed observation and monitoring skills and the use of PEWS to the medical team in Cardiac Services	D Barron S Harris	31/05/2010	Update reports on progress with training included in report to Education Committee.
9.11	Review medical staff training across the Trust relating to observation and monitoring and the use of PEWS	R Gupta S Rao H Steele	30/06/2010	Update reports on progress with training included in report to Education Committee
9.12	Consider how to improve team communication by using a model such as STEPPS	CMO nomination		Report to CRQAC in September 2010
9.14	Discuss the timeliness, consistency and mechanism of providing support for staff involved in an incident and identify a robust plan for improving this	CRQAC		Report to CRQAC in August 2010

Timeline of events based on evidence collated for the Investigation

Date	Relevant Information
Pre-admission /Admission	
	Her first palliative operation was a left Blalock Taussig shunt with ligation of the ductus arteriosus by Mr Dennis Gladstone in Royal Belfast Hospital on 1st December 2008. She was then referred by Dr Frank Casey to Birmingham Children's Hospital for further management.
12/10/2009	The patient is admitted to Ward 12.
Operation	
14/10/2009	The patient was admitted to PICU post-operatively where her first post-operative day was normal and she was kept on a normal inotrope regime. The post-operative echocardiogram showed good systolic ventricular function, and satisfactory repair.
15/10/2009	Her adrenaline requirement increased the following day, which was suggestive that more time was required for recovery of the heart – therefore chest closure was postponed and diuretics were increased.
16/10/2009	<p>The patient stabilised the following day therefore her chest was closed and feeds restarted. Post-procedure echocardiogram showed good biventricular systolic function, with normal ventricular flow.</p> <p>The patient was noted to have thick secretions in her lungs on that day. This can suggest an infection, but this would be accompanied by other changes, such as blood test markets, and fever.</p>
17/10/2009	<p>The ventilation was weaned throughout the day with a plan to extubate. However, the patient deteriorated with desaturation, hypotension and fever. The ventilation and inotropic support were increased. These findings are suggestive that the patient was developing an infection – most likely in the lower respiratory tract. An infection in the lower respiratory tract is sometimes referred to as “pneumonia”. In view of possible infection, samples were taken for culture (to identify the cause of infection) – blood, urine and ETT secretions were cultured.</p> <p>The liver function tests (LFTs) were also noted to be deranged at this time and her liver was also enlarged on clinical examination. Echocardiography showed evidence of high right atrial pressure secondary to restrictive physiology of the right ventricle. High pressures on the right side of the heart are common in pulmonary atresia, and could explain enlargement of the liver, and derangement of the liver function tests. It is likely that the elevated pressure in the right side of the heart was due to the underlying cardiac condition. The abdomen was also noted to be distended, but abdominal x-ray did not reveal any pathology.</p>
18/10/2009	Despite the apparent deterioration on 17/10/2009, the patient rapidly improved on day 5 post-op, and adrenaline infusion was discontinued. The ventilation was weaned, and the patient was extubated at midnight (to CPAP). The decision to extubate was taken on the grounds of minimal requirement for ventilator support.
19/10/2009	<p>Unfortunately three hours later she required re-intubation for respiratory distress and hypoxaemia. The chest x-ray following intubation revealed bilateral collapse / consolidation. An x-ray was not taken just prior to reintubation, as the patient required emergency intubation on clinical grounds. It is likely that the consolidation / collapse revealed on the x-ray was present prior to reintubation, and reflected the reason intubation was required.</p> <p>It is not likely that the intubation itself caused such extensive bilateral collapse / consolidation.</p> <p>A bronchoalveolar lavage (BAL) was undertaken to look for respiratory infections, and broad-spectrum antibiotics were started (meropenem and vancomycin). Cultures from this specimen revealed no growth.</p>

20/10/2009	The patient did however improve the next day and showed a number of signs that her lungs had rapidly recovered. The patient's liver function tests still remained abnormal, but they were more normal than before. As the patient was overall getting better, the patient was extubated again at 15:30 on 20/10/09 – to CPAP.
21/10/2009	The patient unfortunately required reintubation 11 hours later for increased work of breathing and hypoxaemia. Again CXR and clinical findings were consistent with bilateral collapse and consolidation.
22/10/2009	The respiratory status rapidly improved again following re-ventilation. In view of the fact that the patient had demonstrated a tendency to recurrent lung collapse and consolidation, we made a plan to try to avoid this following the next extubation, by using BIPAP (a form of non-invasive ventilation which provides more pressure than CPAP). It anticipated that this may decrease the chance of lung collapse.
23/10/2009	The patient was extubated again at 08:00 on (day 10 post-op) to face-mask BIPAP. The plan was not to wean the non-invasive ventilation quickly.
24/10/2009 – 30/10/2009	Post-extubation from the 24/10/2009 – 30/10/2009 , there was evidence of a recurrence of the right upper lobe collapse / consolidation. However, the patient did not require re-intubation, and the non-invasive ventilation was continued and slowly weaned over the next week. The right upper lobe improved on serial chest x-rays. During this weaning phase, the LFTs normalised – a sign of liver recovery. The patient showed signs of distress, possibly due to opiate withdrawal. This is seen commonly in children who have required sedation for extended periods (i.e. more than one week). The patient's drug regime was changed to facilitate weaning and help return to a normal sleep cycle.
31/10/2009	HF was discharged from PICU day 18 post-op. At the time of discharge, she had not required non-invasive ventilation for about 36 hours. The chest x-ray appearances had improved. She continued to receive milrinone at 0.5mcg/kg/min. She was tolerating enteral feed, but had some diarrhoea and nappy rash. The sternal wound was requiring regular dressings and she remained on Flucloxacillin for this.
Ward 12 Admission	
31/10/2009	The problems on the Ward were a persistent low oxygen requirement and a superficial wound infection, which was treated with Flucloxacillin. Her inotropic support could be weaned on 2 November 2009. However the patient improved and physiotherapy was reduced to on request only.
01/11/2009	The patient was reviewed by Cardiology Registrar (1), Grandparents were present on this occasion.
02/11/2009	Hayley was transferred to Ward 11 in the late afternoon of November 2 nd . Normally she would have been transferred into HDU as she was on milrinone, however the patient's mother was very keen to be able to stay with her daughter throughout the night. This is not possible in the HDU areas as there is not enough space for a parental bed in the bed spaces. The patient was therefore weaned off milrinone on Ward 12 and then transferred to Ward 11 the following day when she was considered stable enough to go into Cubicle 1.
Ward 11 Admission	
03/11/2009	If possible we would have put her into a cubicle near the nurse's station, however the dependency of the patient's at this period of time was high and the Ward Manager reported that the patient appeared relatively well.
04/11/2009	The patient appeared to be stable. Staff continued to monitor her chest wound.
05/11/2009	
06/11/2009	

07/11/2009	<p>Cardiology Registrar (2) reviewed the patient and noted that the patient was in oxygen and being fed. All of her observations overnight (heart rate, resp. rae, temperature) were all stable. There was no indication of her being in any distress. Her examination was also unremarkable and no evidence of any problems could be found. She had had a blood gas done previously and that was acceptable, given that she was on oxygen. Her last set of blood results were also normal. It is noted that Granddad stated that the patient was doing alright and feeding. The nurses had no concerns about the patient. The patient was reviewed again in the afternoon during the afternoon walk around and mum was present. Again no concerns were expressed about the patient.</p>
08/11/2009	<p>The patient was reviewed by Cardiology Registrar (1) at 11:00 on the daily ward round with the Senior House Officer and Nursing Staff member. The patient's grandparents were again present; her mother was not present. He notes that;</p> <p>At this time the patient was stable in her condition</p> <ul style="list-style-type: none"> • She was known to have a wound infection; she had been reviewed by the surgical team and was being actively treated with antibiotic therapy (Flucloxacillin IV) • Her observations and clinical findings were similar to that which had been documented the day prior • She was in oxygen at 0.75L/min, which had not changed in the preceding 24 hours; her oxygen requirement had fluctuated during the week prior • Her respiratory had been stable around 40/min • Her heart rate was between 110-140/min and had been stable • She was afebrile (no temperature) • She had been gaining weight on a combination of oral and naso-gastric tube feeds • Her medications were unchanged • I discussed her condition with her grandparents in the absence of her mother <p>He also notes that he received no calls regarding this patient during the remainder of the night whilst he was on call.</p>
09/11/2009	<p>During the weekly Grand Round lead by the Cardiology Consultant, it was noted that the patient's breathing was a bit fast with a respiratory rate of 40 breaths per minute. She was receiving 0.75 l of oxygen via nasal prongs and was maintaining saturations of 97-98 %. On examination, she was comfortable but mildly tachypnoeic. She had good peripheral pulses and perfusion. Her tummy was soft and her liver was palpable to 1 cm. On auscultation, her chest was clear and there was overall good bilateral air entry. Her blood results at the time did not show evidence for an infection with a CRP of 21 and white cell count of 14.3.</p> <p>Her bloods and a chest x-ray were repeated later that day, which documented significant consolidation of the left chest and volume loss on the right side. With that, the Consultant Cardiologist requested physiotherapy review and treatment, so that the collapsed areas of lung could be re-opened.</p>

10/11/2009	<p>At 02:00 in the morning of 10th November 2009, she had sternal recessions and was grunting intermittently. She was pale and a bit clammy with a capillary refill time of some 2 seconds. Her gas at the time was acceptable with a PCO₂ of 5.9 kPa. Her feeding was topped and she was commenced on intravenous fluids. A chest x-ray was repeated, which was comparable to the one taken on 9 November 2009. The patient was again reviewed at 03:00 and she appeared somewhat more settled. She underwent full assessment and treatment by the Physio Team at 09:40 and then shortly afterwards by Cardiology Registrar (3). At that stage, the patient was in 40 % headbox oxygen with saturations of 93 %. She had a low grade pyrexia of 37.5. She was tachypnoeic and the decision was taken to repeat the blood tests to rule out infection and to also undertake viral tests to rule out Swine Flu. In the context of suspecting a possible viral illness, she had to be isolated. She had a repeat gas on 13:00, which again showed a PCO₂ of 5.9 and a pH of 7.47, both of which are acceptable. She was further reviewed by a Cardiac Surgical Registrar at 15:30 the same day. The blood results came back that same afternoon showing a rise in her CRP from 29 to 69 and with that, IV Augmentin was added to the patient's prescription and Flucloxacillin was also continued. The physiotherapist had noted the ongoing respiratory distress when assessing the patient that morning, and therefore had discussed the patient with the senior physiotherapist. They both returned in the afternoon and carried out a joint assessment. They concluded after treatment that no further physiotherapy was needed that day, but more was planned for the following day. The patient was reviewed again by the Cardiology Consultant in the late afternoon, and despite her being in a degree of respiratory distress, the perception was that all the right steps had been taken to support the patient. Her blood gas and further blood results did not suggest an acute deterioration, which would have required PICU admission at that stage. At the time the perception was that with the antibiotics and physiotherapy treatment, the patient would improve. The patient had been started on antibiotics for recurrence of lower respiratory tract infection (augmentin).</p>
11/11/2009	<p>The patient was reviewed by the Cardiology Registrar (3) during the middle of night and the impression was that she was less tachypnoeic and her breathing was more comfortable than had been during the day. It was also noted that her mum was happier with her status and progress.</p> <p>At around 07:00 the patient was again reviewed by the SHO (1) who noted her to have increased work of breathing, and subcostal and intercostal recessions. She had nasal flaring and her respiratory rate was 50. At the time, she was warm and well perfused, and her capillary refill time was < 2 seconds. Her situation worsened quite quickly after this, therefore the SHO did a blood gas test on PICU which demonstrated significant acidosis with a pH of 7.12 and PCO₂ of 11.4. The PIC Registrar and Cardiology Registrar (3) were present on PICU and were alerted of this gas result immediately and returned together with the SHO (1) to the ward. The PICU registrar noted that the patient was very unwell: severe recession, mottled, pale perfusion, decreased movements, pulse oximeter saturation 85 % in high flow O₂.</p> <p>He provided resuscitation with bag and mask CPAP, and iv fluids bolus. As cardio-respiratory was thought to be imminent, the PIC Registrar intubated the patient on the ward, with rapid sequence induction (ketamine and rocuronium). The patient became bradycardic and hypoxaemic very rapidly, and lost cardiac output. CPR was commenced, and the crash call was put out.</p> <p>During the resuscitation the chest was noted to be very poorly compliant, requiring very high pressure by bagging circuit. CPR was underway, and adrenaline bolus was given appropriately when the PIC Consultant arrived.</p>

11/11/2009 <i>(continued)</i>	<p>During the resuscitation attempt lasting 20 minutes, the patient remained on bag ventilation throughout. CPR continued throughout this time except for pulse checks and very brief echocardiogram (to exclude pericardial effusion / tamponade). Intravenous access was limited, so the PIC Consultant placed a 22G cannula in the right femoral vein, through which resuscitation drugs (bicarbonate, adrenaline and calcium) were given. Intra-osseus access was also obtained prior to this. Intra-osseus access was obtained in both tibia – the first needle only lasted a few minutes, hence the insertion of a second.</p> <p>After 20 minutes, the cardiac rhythm had deteriorated from PEA to asystole. Echocardiogram showed cardiac standstill. Blood gas revealed a severe mixed acidosis. The chest compliance remained very poor. In agreement with the rest of the team, the PIC Consultant terminated the resuscitation and the patient was sadly certified dead at 08:15.</p>
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**Investigation Action Plan Summary and Report
Made on behalf of Hayley Fullerton**

Patient Details

Name: Hayley Fullerton
Address: 115 Newcastle Road, Kilkeel, County Down, Northern Ireland BT34 4NJ
Date of Birth: 06/11.2008
Hospital Reference: L1199628

Complainant's Details

Name: Paula Stevenson
Relationship: Mother
Address: 115 Newcastle Road, Kilkeel, County Down, Northern Ireland BT34 4NJ

Complaint reference: FC/031209/699

Date received: 03/12/2009

Date acknowledged: 03/12/2009

Issues for investigation:

Issues		Evidence/data/information required/respondent
1	All aspects of Hayley's treatment whilst an inpatient from 12/10/2009 – 11/11/2009 (inclusive)	Medical & Nursing Staff

Details of Complaint:

Date of Incident: Inpatient episode from 12/10/09 – 11/11/09

Location: Ward 11

Brief Summary of parental concerns: Serious lack of care towards Hayley and that she was “overlooked, neglected and that there was no need for her to die”.

Results of Investigation

This case has also had a Root Cause Analysis undertaken and most of the questions within Paula Stevenson’s complaint letter have been answered and I attach a further copy for your information.

There were, however, some issues that were raised, that did not come into the Root Cause Analysis and so I have responded back to those by way of explanation/clarification as follows:

Question – “What arrangements does the Practice have in place to deal with “Deliberate Acts of Malice” which result in anguish and suffering?”

Response from Tony Middleton, Human Resources Manager:

If this relates to a specific employee, then the Trust may possibly find it necessary to investigate these matters in accordance with the Trust’s Disciplinary Policy and Procedure.

Should the investigation find that an employee’s conduct is unacceptable, then a disciplinary sanction may be issued, up to and including dismissal. If the person concerned was a stage registered practitioner or either a statutory or voluntary register, then the matter may also be referred to the relevant professional/regulatory body depending on the severity of the outcome of any disciplinary hearing.

Question – “What is the average time for resuscitation?”

Response from Resuscitation Team:

The Resuscitation Team has 3 minutes to which to respond to a cardiac arrest. The team will gain the background to the patient’s diagnosis, condition and treatment and then decide how to best proceed. It is not possible to stipulate a timeframe for which the Resuscitation Team has to resuscitate a patient for, as each patient has differing needs and medical history.

Question – “Why did Alison Stanton not wait for Mum to forward the official complaint letter?”

Response from Alison Stanton, Patient Relations Manager:

My name is Alison Stanton and I am the Patient Relations Manager responsible for processing and managing the complaints at BCH in accordance with the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009.

I first received a copy of Paula Stevenson’s letter in November 2009. This was shared with me by Helen Watson, Head of Nursing, Directorate 3, as Helen was concerned about the content of the letter and the ‘reward’ vouchers that had been given to the Ward as a gift from Ms Stevenson.

It has since been decided that the vouchers will be used to purchase something for the ward.

My concern related to the fact that Ms Stevenson did not want us to process her concerns formally and simply wanted the letter to be filed on Hayley’s medical notes. Due to the serious nature of the concerns, I advised that the Ward manager revert to Ms Stevenson to ask her whether we could process this formally. The initial response was no and it was therefore decided, after discussion within Governance, that this should be dealt with in accordance with the Risk Management process as a Serious Untoward Incident Investigation.

On 27th November 2009, I then subsequently received a telephone call from Ms Stevenson to say that she wanted to take her concerns through the formal complaints process after she had discussed this with the Coroner.

Ms Stevenson did not want me to process the version of her concerns she had given to the Ward Manager and informed me that she wanted to amend her letter as it contained some incorrect dates. I was to wait for the amended letter.

On 3rd December 2009, I received an amended version of the complaint letter via the Head of Nursing for Directorate 3, where some dates had been altered with Tippex. I was informed that this was the amended letter. I then processed the letter as usual in accordance with the Regulations. I had assumed that Ms Stevenson had submitted this letter via another route rather than coming directly to me. This does happen on occasion and I did not question it as some parents decide to share correspondence differently. As Ms Stevenson had built up a relationship with the ward staff, I had assumed that she preferred to engage with me via the ward.

In the interests of initiating the investigation and to avoid any further delay to the start of the investigation, I processed the letter as usual and formally asked Directorate 3 to investigate this.

I acknowledged receipt of the complaint in the usual way by sending an acknowledgement letter to Ms Stevenson.

Ms Stevenson telephoned me on 4th December 2009 expressing concern that I had acknowledged her letter of 17th November 2009 as this was not the letter that she wanted to represent her formal complaint. We had a very amicable chat about the process and I apologised for the misunderstanding and explained that this letter appeared to me to have been the amended version Ms Stevenson had referred to. Ms Stevenson was concerned that she had missed an opportunity to have the ‘right’ letter considered as her formal complaint. I reassured her that this did not matter, as the Investigating Officers make contact with the family on each occasion now to discuss the areas of concern and agree the issues for investigation. I explained that Ms Stevenson would have the opportunity to add anything she wished during this contact call. The letter was not the ‘only chance’ for her to express her concerns and it did not matter if it did not fit a certain criteria. It would appear that Ms Stevenson had been advised that, she would only have one opportunity to get the letter ‘right’ in the first place, and I reassured her that this was not the case at BCH.

I agreed to hold the investigation until I received the letter she was preparing and I reassured her that a delay did not matter. I also informed Ms Stevenson that I would let the Investigating Officer know about the ‘on hold’ situation.

After this telephone conversation, I then received an email from Ms Stevenson on the same day instructing me to retract her previous letter and to inform her colleagues that I had forwarded this letter without her permission.

I responded the same day to explain why I had done what I had done and to reassure Ms Stevenson that I had listened to her and that I was sorry and disappointed to read that she thought otherwise. I invited Ms Stevenson to telephone me to discuss this further as I was keen to re-establish her trust and confidence in me and the complaints procedure.

Ms Stevenson responded and thanked me for my explanation saying that she did not believe that I meant any harm.

On 4th December 2009, I telephoned Bryony Winnall, Assistant Directorate Manager, in Directorate 3 to inform her of the situation and my concerns. I also asked Bryony to hold the investigation until we received Ms Stevenson's official letter of complaint and that she would need to discuss this case with Nina Barbosa, Risk Manager, as the investigation is to be subject to an SUI.

On 16th December 2009, I received the official letter from Ms Stevenson and forwarded this to the Directorate.

I apologise to Ms Stevenson for any misunderstanding and distress caused and wish to reassure her that I had been acting in good faith only.

Question – “How many children die during surgery?”

Response from John Stickley, Audit & Information Manager, Cardiac Services:

For the period 01/01/09 – 31/12/09, 3 patients died during surgery.

Question – “How many children die 24-48 hours after surgery?”

Response from John Stickley, Audit & Information Manager, Cardiac Services:

For the period 01/01/09 – 31/12/09, 5 patients died 24-48 hours after surgery.

Question – “How many children die 2 weeks after surgery?”

Response from John Stickley, Audit & Information Manager, Cardiac Services:

For the period 01/01/09 – 31/12/09, 11 patients died 2 weeks after surgery.

Question – “How many children die 28 days after their heart surgery?”

Response from John Stickley, Audit & Information Manager, Cardiac Services:

For the period 01/01/09 – 31/12/09, 15 patients died 28 days after surgery.

Question – “How many children die in the room next to the door on the ward?”

Response from Karen Byrne, Acting Nurse Manager:

For the period 01/01/09 – 31/12/09, there has been one death on Ward 11 in the room next to the door on the ward.

Question – “Why was there no pink ink available for the handprints?”

Response from Karen Byrne, Acting Nurse Manager:

Ward 11 occasionally have inks and paints available to make cards for Mothers/Fathers etc but they do not routinely keep a stock. There are no processes in place to maintain stock levels and on this particular occasion, they had a small stock but unfortunately not an array of colours.

Recommended Action

1. Following the SUI Report, a comprehensive report has been written and within that report are recommendations regarding clinical practice and other practice (pages 15-16 of the SUI Report). A copy of the SUI Report is attached.
2. There is also a detailed Action Plan (pages 17-19 of the SUI Report) regarding specific actions by named individuals with specific timescales to be completed. Evidence of completion of the specific points of the action plan are required.

The Directorate Management Team would like to offer their sincere condolences to Hayley's family for their loss.

Signature of Investigating Officer

Name: Bryony Winnall

Position: Assistant Directorate General manager

Date: 7th May 2010