INDEPENDENT ROOT CAUSE ANALYSIS REPORT

INTO

THE ADVERSE INCIDENT THAT LED TO THE DEATH OF A PAEDIATRIC CARDIAC SURGERY PATIENT

AT

UNITED BRISTOL HEALTHCARE NHS TRUST

ON

27 MAY 2005

MARK GRITTEN
INDEPENDENT CHAIRMAN

October 2007

CONTENTS

EXECUTIVE SUMMARY

INTRODUCTION

This report constitutes a root cause analysis investigation of the adverse incident that led to the death of BA on 27 May 2005 following paediatric cardiac surgery at Bristol Children Hospital (BCH). BCH is part of United Bristol Healthcare NHS Trust (UBHT).

INCIDENT

The finding of the Coroner's Inquest[i] on 16 February 2007 was that:

'On 25 May 2005 BA underwent an operation at BCH to close an Atrial Septal Defect (ASD) in her heart. During the operation she received an excessive infusion of calcium chloride from fluid used to prime the pump used for cardiac bypass. This caused an increase in calcium levels of the blood, which started a rapid sequence of events, which led to damage of the brain. This was a progressive process which became irreversible and caused her death.'

OUTLINE OF THE INCIDENT

BA was one of twins born on 10 December 2004 at 26 weeks gestation. She developed chronic lung disease and was transferred to BCH on 5 May 2005. Cardiovascular evaluation at that time suggested the presence of pulmonary hypertension together with the presence of an ASD. The surgical technique selected was a staged closure of the ASD that would require 2 interventions. The risk of operation was noted to be high.

On 25 May 2005 problems arose very early in the clinical procedure, around the time of initiating cardiopulmonary bypass. Although the surgical procedure was completed successfully and the heart reverted to an acceptable rhythm, and cardiopulmonary bypass terminated without serious complications, the patient died on 27 May 2005 as a result of cerebral oedema. This was most likely the result of the very high level of ionised calcium BA received via the prime solution during emergency suction bypass.

OVERALL CONCLUSION

This was a unique incident with no published reports of similar events[ii]. The staged surgical procedure is undertaken comparatively infrequently[iii] and the error occurred during the preparation of the cardiopulmonary bypass machine prime fluid for BA's operation. The evidence indicates that the error was caused by inadvertent human error, perfusion systems failures at national and local levels, and other local system problems. Together these created the necessary preconditions for the human error and a failure to find and react to it.

That the paediatric cardiac surgery unit and the perfusion department perform well in terms of its clinical practice is clear from the national statistics on morbidity and mortality, where it compares favourably with other national centres[iv]. There seems to be a real belief in the work being carried out in this unit, and in general, the relationship between staff members at all levels is palpably friendly and caring. There is a strong commitment, based upon the statements of those interviewed, to the delivery of a quality clinical service.

The incident occurred because of latent weaknesses that lay dormant for years hidden by healthcare professionals compensating for inadequacies within national and local systems:

- nationally: regulation and guidance on perfusion practice in cardiopulmonary bypass.
- locally: infrequent risk assessment, protocols and practice not updated, and a lack of checklists and double-checking procedures.

One of the main strengths of the healthcare system is that so many people display an outstanding level of commitment. However one of the subtlest mistakes made was the failure to realise that the best-motivated and most highly trained professionals are also potentially lethal agents. Humans are fallible; they cannot deliver flawless performances at all times, no matter how willing they are to try. Safeguards such as checklists and double-checking for perfusion were limited and not consistently applied and so a tragic incident occurred because there were no barriers in place to prevent the latent problems combining with unpredictable clinical and non-clinical events on 25 May 2005.

PROBLEMS OF GREATEST SIGNIFICANCE

Regulation. The process of reviewing the incident upon which this report is focused has shed light on a number of matters of importance on a national scale associated with the conduct of cardiopulmonary bypass. In particular some questions have been raised as to the status of the perfusionist as a member of the overall clinical team with apparent responsibility for the administration of potentially dangerous substances. Furthermore it appears that, despite being in existence for 50 years as a group of clinicians who have considerable responsibility in terms of not only patient care, but also patient survival, there is little in the way of legislation governing their practice or conduct.

Inconsistently applied perfusion protocols and guidance. National perfusion recommendations and guidance are inconsistently applied across cardiac surgery units.

The use of ionised calcium. There were two different concentrations of ionised calcium in the operating theatre at the time of the incident. The concentration of calcium ions present in these two solutions differed by at least three-fold. A question remains as to whether high strength ionised calcium solutions should be present in the operating room, and if not, can low concentration solution be employed instead.

Checklists and double-checking. It was clear that the perfusion team were not in the habit of cross checking drugs with another member of the clinical team prior to their administration. At the local level, this was directly at odds with the drug administration policy of the Trust. In all but the most extreme emergency situations, a system of check-listing the clinical scenario should be carried out prior to initiating cardio-pulmonary bypass.

Communication with the clinical team. Communication and planning of the operating schedule in the cardiac team could be improved.

Application of Trust core policies. There are weaknesses in the implementation of some Trust policies that led to inadequate risk assessments and performance management that if undertaken more robustly might have drawn attention to weaknesses in the use of checklists by the perfusion department

INFLUENCING FACTORS

The influencing factors include:

- Communication – a misunderstanding about whether the operation would be cancelled led to the release of the second or 'floating' perfusionist on duty and a disagreement between the perfusionist and the surgeon shortly before the start of the procedure.

- Staffing levels met national recommendations but staff were working to their limits of their ability to handle the workload. It could be argued this left them insufficient time to review protocols and practice.

- Trust policy dissemination, implementation and monitoring needs improvement, in particular the Risk Management policy and the Medicines policy.

- Pressure to operate – there was significant pressure brought to bear on the clinical team to ensure that the operation was not cancelled on 25 May 2005.

- The planned procedure was a high-risk intervention.

OTHER ADDITIONAL LEARNING OPPORTUNITIES

This incident shows that NHS staff would benefit from a wider understanding of the impact of human factors in errors and incidents.

RECOMMENDATIONS

Recommendations are tabulated on Pages 32 to 34 of the report. They are divided into national, Trust, paediatric cardiac surgery team and perfusion team. The most significant are:

- **Regulation.** There should be a national review of the regulation of clinical perfusion scientists.

- **Perfusion practice.** There are several significant issues of perfusion practice that need national review.

- **Perfusion Staffing.** The Trust needs to act promptly to review the present levels of staffing in the perfusion department.

- **Training and team development.** The Trust should invest in training that develops an understanding of human factors in error management to support the team development of paediatric cardiac surgery and perfusion.

- **Implementation of new protocols.** The perfusion department should improve the quality and frequency of update of clinical perfusion protocols and take into account the findings of this root cause analysis in particular the use of ionised calcium.

INTRODUCTION

1.1 This report constitutes a root cause analysis investigation of the adverse incident that led to the death of BA on 27 May 2005 following paediatric cardiac surgery at Bristol Children Hospital (BCH). BCH is part of United Bristol Healthcare NHS Trust (UBHT). The root cause analysis approach is designed to find the underlying cause of incidents so that lessons may be learned and suitable improvements made to secure a reduction in risk of harm to future patients.

Incident

1.2 The finding of the Coroner's Inquest[v] on 16 February 2007 was that:

'On 25 May 2005 BA underwent an operation at BCH to close an Atrial Septal Defect (ASD) in her heart. During the operation she received an excessive infusion of calcium chloride from fluid used to prime the pump used for cardiac bypass. This caused an increase in calcium levels of the blood, which started a rapid sequence of events, which led to damage of the brain. This was a progressive process which became irreversible and caused her death.'

Timing of Root Cause Analysis

1.3 The timing of this investigation is unusual because it is good practice to complete a root cause analysis as soon as possible after the incident. However following the death of BA the Coroner ordered a police investigation. The Crown Prosecution Service subsequently assessed the police investigation but no criminal prosecution was pursued. Twenty-one months after BA's death The Coroner's Inquest reached a verdict of 'unlawful killing' and was concluded and closed on 16 February 2007. Once the police investigation began it would have been inappropriate to run an internal Trust investigation in parallel. Although a faster response to the incident by the Trust might have enabled an analysis to be completed in a more timely fashion, it was not until the summer of 2007 that the Trust was able to begin a root cause analysis.

Terms of Reference

1.4 An independent chairman was appointed and has been supported by an expert witness. The analysis has used the evidence gathered for the Coroner's Inquest. The aim of the root cause analysis is to:

- Complete a detailed analysis of not only what happened but also why it happened and the actions necessary to eliminate the causes. This will look at systems, processes and team working in addition to the investigations already undertaken by the police.
- Ensure that the current (updated) procedures and protocols are robust.
- Ensure that there are clear lines of accountability and communication in place that will prevent such issues occurring again.

CONGENITAL CARDIAC SURGERY AT UBHT

1.5 UBHT provides a comprehensive congenital cardiology/cardiac surgical service to the south west of England and an interventional and congenital cardiac surgical service to south Wales, covering a population of 4 million. The paediatric service is based at BCH.

1.6 The Congenital Cardiac Surgery Report (April 2005 to March 2006) presents an audit of the outcome for 6 benchmark procedures including ASD closure at BCH and shows that in the 3 years preceding BA's death the surgical mortality rate was nil. Overall for the past 10 years (1996 to 2006) the overall mortality figure for all paediatric cardiac surgery was 2.2% and for the 5 years to 2006 was 1.77%. There continued to be an improvement with the mortality for the year March 2005 to April 2006 being 1.2%. National figures are available for comparison.[vi]

1.7 There has been no mortality attributable to perfusion issues before or since BA's death.

PERFUSION SERVICES AT UBHT

1.8 A comprehensive clinical audit of adult cardiac surgery cases perfused since 1999[vii] revealed that the clinical outcomes performance was one of clinical excellence of the entire team at UBHT. In addition the monitoring of blood gases by the perfusionists at UBHT is more thorough than at other Trusts.

CLINICAL PERFUSION SERVICES NATIONALLY

1.9 Clinical Perfusion Scientists have a clearly defined, uniquely specialised role within the multi-disciplinary team performing cardiac surgical procedures. Their major routine responsibility shares no commonality with any other unregulated groups practicing in the NHS. For several years the professional body, the Society of Clinical Perfusion Scientists of Great Britain and Ireland have tried to gain professional regulation. However the situation remains that Clinical Perfusion Scientists are unregulated. Indeed it has never been clarified on what basis perfusionists derive the authority to administer drugs.

1.10 The Society of Clinical Perfusion Scientists has received instructions from the Society of Cardiothoracic Surgeons and the Association of Cardiothoracic Anaesthetists stating that their members expect clinical perfusion procedures to be managed solely by practitioners who are accredited and registered with the Society for Clinical Perfusion Scientists. This society accredits scientists and training for the profession. However it does not enforce standards of working in part because of the non-mandatory nature of the present regulatory arrangements.

1.11 Consequently a Trust perfusion department can be accredited by its Society for training clinical perfusion scientists but there is no arrangement to accredit for the quality of the service it should provide.

1.12 It is noteworthy that the Department of Health has not acted to resolve the quasi-situation that has existed for many years. Perfusionists are acting as independent professionals but there is not a national structure to support them. However changes to regulation should not be just to define perfusionists as 'independent', but to provide a better safeguard for patients than currently is the case.

ROOT CAUSE ANALYSIS METHODOLOGY

1.13 The method used to investigate this incident follows national guidance from the National Patient Safety Agency (NPSA)[viii] and local Trust policy[ix]. Clearly the availability of detailed written statements and the transcripts from the Coroner's Inquest, and the time since the incident occurred required that the guidance be adapted. The steps followed were:

- Identifying the scope and reviewing the information already available.
- Constructing a timeline with staff[x] to track the events occurring prior to, during and after the incident to discover all parts of the process where problems or errors had occurred.
- Identifying contributory factors with staff involved through an event and causal factor analysis.
- Exploring critical issues with expert advisers.
- Identifying improvements and ensuring those already implemented by the Trust were effective.
- Generating the investigation report, recommendations and an action plan.

1.14 The documents analysed in the construction of the timeline and the event and causal factor charts were as follows:

- Transcript of the Coroner's Inquest 12 to 16 February 2007.
- Statements compiled by the Police as part of their investigation and used by the Coroner. These statements included detailed statements by expert witnesses in Perfusion, Paediatric Cardiac Surgery, Paediatric Cardiac Anaesthesia, Pathology and Chemical Pathology.
- Medical Records of BA.
- Protocols for the Perfusion Department in use in May 2005.
- Protocols for the Perfusion Department dated August 2005.
- Protocols for Perfusion Departments of other Trusts.
- Trust Risk Policies.

CONTRIBUTORS TO THE ROOT CAUSE ANALYSIS

1.15 Contributors to the root cause analysis are detailed in Appendix 1.

SUMMARY OF INCIDENT

1.16 The summary is extracted from personal statements[xi] and BA's medical records.

10 December 2004 to 4 May 2005

1.17 BA was one of twins born on 10 December 2004 at 26 weeks. She was 5 months of age and weighed 3.45 kg on admission to Paediatric Intensive Care Unit (PICU) at BCH on 4 May 2005. She had initially been ventilated for 2 days after delivery followed by Continuous Positive Air Pressure (CPAP) for 6 to 8 weeks and had been discharged home on oxygen. Prior to admission to BCH, BA was thought to have a chest infection that was managed at home for 2 weeks. She was admitted to Treliske Hospital, Truro on 2 May 2005 with tachypnoea, desaturations, apnoeas and bradycardia. Two days after admission her condition

had deteriorated and an echocardiogram showed right ventricular hypertrophy and pulmonary hypertension. She was referred to BCH for further management and was retrieved to PICU on 5 May 2005.

5 May to 24 May 2005

1.18 The diagnosis of pulmonary hypertension was confirmed and a cardiac catheter investigation was performed on 11 May 2005. This confirmed the marked right ventricular hypertrophy plus small left ventricular size and a large left to right shunt through an Atrial Septal Defect (ASD – 'hole in the heart'). Decisions were made to attempt fenestrated closure of the ASD to allow off-loading of the small left side of the heart and encourage growth. It was appreciated that this would be high risk in view of the raised pulmonary vascular resistance.

1.19 BA remained intubated and ventilated on PICU while awaiting surgery. She was initially treated with an empiric course of antibiotics. However there was no definitive evidence of infection at this stage. Initially she had frequent desaturations which were thought to be pulmonary hypertensive in origin, however a trial of nitric oxide showed no response.

1.20 Surgery was deferred on 2 occasions. On the first occasion on 16 May a secondary chest infection was suspected and a broncho-alveolar lavage was performed. This subsequently grew MRSA. On the second occasion on 23 May she was brought to theatre with a low-grade temperature but with low-grade markers. However following change of central and arterial lines, her core temperature was still 37.9 degrees despite exposure and it was decided to defer, remove old lines and treat with antibiotics for a further 48 hours. She remained stable during this time, showed no sign of sepsis and was able to be partially weaned off the ventilator.

25 May to 27 May 2005

1.21 On 25 May 2005 BA returned to theatre for partial closure of the ASD. There were concerns peri-operatively about hypertension on bypass and an increasing lactic acidosis. On return from theatre she was found to have fixed dilated pupils and electrolyte abnormalities in particular potassium and calcium. There was concern at this stage that she might be fitting, however on attachment of the 8-channel EEG, there was essentially no electrical activity. This was subsequently confirmed.

1.22 BA remained with fixed dilated pupils and after some initial instability she was cardiovascularly stable on low dose adrenaline support. She made no respiratory effort, nor signs of wakening, despite discontinuation of sedation.

1.23 On 27 May 2005 the ASD was closed and her chest closed without any significant cardiovascular problem. However a CT head scan performed that afternoon showed massive cerebral oedema throughout her entire brain (cortex, cerebellum and brain stem) consistent with a severe hypoxic-ischaemic or toxic insult.

1.24 Following discussions with BA's parents active treatment was withdrawn with their agreement and BA died with her parents at 1817 hours on 27 May 2005.

1.25 BA suffered a severe neurological insult peri-operatively while undergoing partial closure of her ASD on 25 May 2005. A review of medical notes and specifically her perfusion records identified some anomalies within the printouts of the blood gas readings that had been taken during the operation. It was at this stage that the matter was referred to the Coroner and the Police. The most likely cause of BA's death was considered to be a fatally high dose of calcium being administered peri-operatively, either from donor blood (subsequently discounted) or as a result of a mistake in the preparation of the prime for the bypass pump.

1.26 It was also known that the perfusion department had been under considerable pressure for a long period and staff shortages had been commented upon. Despite this service delivery was maintained with staffing levels that complied with Trust and national recommendations.

1.27 In addition to this, within an hour of BA's operation beginning there had been a heated but very brief exchange of views between the perfusionist and the paediatric cardiac surgeon.

Police Enquiry 2005 to 2006

1.28 The Coroner was concerned not only that a possible error in the administration of the prime solution had occurred but also that there may have been an opportunity for the mistake to be identified and rectified before any damage could have ensued. In considering this matter the Coroner referred the matter to the Police for investigation of any possible criminal offence.

1.29 One of the obstacles to overcome during the Police enquiry was to show beyond reasonable doubt that the excess calcium was the primary cause of death and not some other as yet unconsidered medical or chemical occurrence. Because of the lack of any precedents this was extremely difficult and added considerably to the time taken for the Police investigation. The Police report was considered by the reviewing panel of the Crown Prosecution Service who concluded that there should not be a prosecution for gross negligence manslaughter. Although there were errors, which led to catastrophic consequences, the CPS did not proceed with criminal proceedings.

1.30 A detailed chronology can be found at Appendix 2.

ROOT CAUSE ANALYSIS CHRONOLOGY

2.1 In order to simplify the analysis of contributory factors the chronology of events has been split into 5 parts or phases:

- **Staffing Issues February 2004 to April 2005**
    - The events demonstrate a history of pressure on resources from the separation of paediatric cardiac surgery from adult surgery. From February 2004 general and clinical managers considered the staffing pressures the perfusion department were under at the time.
    - An analysis of the chronology provides an indication of organisational and team culture prevalent at the time.
    - This phase finishes just one month before BA's operation and therefore provides a picture of the underlying frustrations facing the cardiac and perfusion teams on 25 May.

- **Pre-operative Phase in PICU 4 May to 24 May 2005**
    - This part of the time line tracks BA from her admission to PICU at BCH on 4 May up to the night before her operation.
    - The analysis in this phase is useful because it clearly demonstrates the dilemma of 'high-risk intervention that any paediatric cardiac surgery team would have faced'[xii]. The surgical procedure chosen reflected the elevated risk.

- **Communication Issues before the operation from 0800 hours to 1615 hours on 25 May 2005**
    - On the day of the operation there were unexpected delays and considerable pressures exerted on individuals and the team.
    - Totally out of character with the individuals involved[xiii] these issues led to an exchange of views between the paediatric cardiac surgeon (SURG), and the perfusionist (PERF), less than one hour before the start of BA's operation.
    - The analysis brings out the considerable risks and pressures faced by the team and its members.

- **Peri-operative phase from 1630 hours to 1830 hours on 25 May 2005**
    - Knife-to skin was at 1655 hrs and BA went on full bypass at 1715 hrs and off bypass at 1757 hrs.
    - The key period of time is from 1659 hrs to 1715 hrs as it is during this period emergency action was taken to start suction bypass.

- **Post-operative phase in PICU from 25 May to 27 May 2005**
    - This phase reviews the care of BA in PICU until she died on 27 May 2005.
    - There are examples of where communication and clarity over responsibilities could be improved.

LIST OF EVENTS AND EVIDENCE

2.2 A tabulated list of events is provided at Appendix 2. This table sets out the main events through the 5 phases with sources of evidence. It does not include the analysis of contributory factors that is developed in the Event and Causal Factor Analysis at Appendix 3. However the Event and Causal Factor analysis does include the timeline.

2.3 Appendix 2 has therefore been included to allow consideration of the events without having to read the causal analysis.

EVENT AND CAUSAL FACTOR ANALYSIS

3.1 The Event and Causal analysis is set out in Appendix 3. There is a key to the interpretation of the charts. The charts follow the 5 phases detailed above. These charts should be read now. The contributory factors that emerge from the analysis are discussed in more detail in the main body of this report below. The numbers in brackets below enable the reader to track factors to the timeline in the Event And Causal Factor Chart in Appendix 3.

PROBLEMS OF GREATEST SIGNIFICANCE

4.1 The most significant problems are detailed below.

4.2 Regulation

Perfusion practice has evolved in a variety of ways in different Trusts, over many years. Each perfusion team has developed its own local protocols ostensibly because it treats different categories of patients. Probably because the Society of Perfusionists is not a regulated body there does not appear to have been a national review of whether this is an appropriate arrangement. The present situation whereby each cardiac surgery unit has different perfusion working arrangements, and learning is not routinely shared, is concerning and should be reviewed quickly. Different protocols, drug administration and working arrangements between perfusionists and anaesthetists might have prevented the error. More detail is available at Paragraphs 5.14 to 5.18. [4 – this number refers to the causal factor charts at Appendix 3]

4.3 Inconsistently applied perfusion protocols and guidance

The measurement of pre-bypass prime blood gases is not routine in Trusts other than UBHT and there are no national guidelines that require the anaesthetist to view the blood gas measurement printouts. Had PERF been working in another Trust he would not have been expected to measure the blood gas of the prime fluid. The national standard does not specify the frequency or circumstances of blood gas measurement. It merely states that a near patient facility should be available. Guidance on frequency of measurement and local practice is devolved to local protocols. The national standard dictates that the measurement of calcium should be available on site but not necessarily as a near patient measurement. In a cardiac surgical unit with a less sophisticated blood gas analyser than the Radiometer 700 series available in the BCH cardiac theatre, and which lacks ionized calcium measurements, the abnormalities in calcium levels seen in this case would not have been detected at least until well into bypass and probably not until after the cessation of bypass.

4.4 Sources of ionised calcium in the operating theatre

Some paediatric cardiac surgery units in America do not add ionised calcium to the prime fluid even if blood is used in the prime, because they have found that it is not necessary or can be adjusted after the procedure. It would appear that ionised calcium need not have been added to the prime solution and this raises the question why this had not been more widely disseminated. [22]

Since paediatric cardiac surgery patients are rarely if ever going to need more than 1mls of calcium chloride it is questionable why the drug is provided to the paediatric cardiac theatre in 10mls ampoules. A change of this policy may have prevented such a considerable overdose of calcium to BA. [23]

There appear to be two sources of ionised calcium in the operating theatre. One is a low concentration of calcium gluconate, and the second, a higher concentration of calcium chloride. The calcium chloride solution contains approximately three times the concentration of ionised calcium of the calcium gluconate solution. Calcium gluconate is generally employed by the anaesthetists to correct systemic calcium imbalance in patients undergoing

surgery and is generally administered slowly and at low doses. The strong calcium chloride solution is employed in the most part by the perfusionists, who administer this into the pump priming, and cardioplegia solutions. It would seem that these solutions are generally available in the theatre environment and are not subject to a registry procedure.

It is most likely that the overdose in this case was the result of an excessive amount of calcium chloride being administered rather than calcium gluconate. Both calcium solutions are presented in 10ml vials, and it is unlikely that a 10ml dose of calcium gluconate would prove fatal. This does not eliminate the possibility that more than one vial of calcium gluconate was administered at the time, but this is thought to be highly unlikely.

The Bristol protocols were developed from the Melbourne Children's Hospital protocols of 1995 and no one seems to have questioned the continued use of calcium chloride since that time. The advantages of calcium chloride is that the salt is an anion, so believed to have implications on the stability of the perfusion fluid mixes, plus with a concentration of 1 millimole per millilitre calculations are easier than a solution with 0.22 millimoles per millilitre. There is a good case to review whether these reasons justify having 2 sources of calcium in the paediatric theatres. [24]

4.5 Utilisation of crosschecking prior to drug administration.

It was clear that the perfusion team were not in the habit of cross checking drugs with another member of the clinical team prior to their administration. At the local level, this is directly at odds with the drug administration policy of the Trust. The policy requires that another member of staff crosschecks all drugs and that this is recorded. The perfusion team suggest that they were not aware of this policy document. This failure to percolate such information throughout the clinical environment represents a failing in the vertical dissemination of important clinical information. Another member of the clinical team must undertake crosschecking of recognised potentially dangerous pharmacological agents and this must be registered in an identifiable fashion. It has been suggested that such a procedure may interfere with clinical practice, particularly under emergency or extreme conditions. There should be no exceptions to this requirement, and this should form part of the clinical protocol. [20, 21, 30]

4.6 Use of pre-bypass checklists within the operating theatre

The aorta cannula was placed at 1702 hrs followed by the vena cava cannula. Suction bypass was instigated shortly after 1705 hrs. Once the initial hypercalcaemic insult from the prime solution in the early stages of suction bypass had occurred it is unlikely that any actions taken would have influenced the outcome. PERF did not have a second opportunity to measure the blood gas of the prime fluid, identify the mistake and rectify it. Indeed having agreed that SURG could cannulate the aorta only 1 or 2 minutes after taking the prime blood gas measurement it is doubtful whether there was time to retrieve the printout from the analyser. The second blood gas measurement at 1715 hrs was already too late.

Checklists were being used in May 2005 however they were on a separate photocopied sheet from the perfusion charts and not always available.

Although a robust algorithm was in use by SURG to ensure that the perfusionist had given him authority to proceed, and both said they were ready to cannulate, a checklist would have

ensured that this process was a considered reflection. However this point does reinforce the point made in Paragraph 4.3 in that there is no requirement at the moment to measure blood gases in the prime. Consequently most Trusts would not have had the information to realize that the prime solution had been improperly made-up. Such a check might not be possible in emergency surgery but as stated above checklists were not easily to hand. [28]

In conclusion, in all but the most extreme emergency situations, a system of check-listing the clinical scenario should be carried out prior to initiating cardio-pulmonary bypass. This checklist system is in place in other clinical settings and permits the clinical team to ensure that all members are ready to initiate cardio-pulmonary bypass and to raise any concerns or misgivings regarding this important step. This would be the time to reflect, if only for a moment, on for example, the priming solution gases and electrolytes, and any other critical factors. Such a pause will draw the team together and will reinforce the fact that this is a team effort. It is imperative, if such a system is to enhance safety, that all members of the clinical team accept it and that there is no pressure put on any member of the team to hurry the process or initiate cardiopulmonary bypass if there are any concerns, however insignificant. This pre-bypass checking works only if all members of the team are present, and indeed, it ensures that this is the case at this critical time. A similar system can and should be introduced for all major elements of the surgical procedure, including removal of cross clamps, circulatory arrest, re-warming and termination of bypass. Mandatory implementation and review of this check-listing process should be carried out at fixed intervals, involving all members of the clinical team.

4.7 Communication

Communication and planning of the operating schedule in the cardiac team could be improved. Better communication might have prevented the second perfusionist available on 25 May being released during the afternoon and the disagreement that probably led to some of the team being pre-occupied. [7]

4.8 Trust decision-making

There are weaknesses in the implementation of some Trust policies that led to inadequate risk assessments and performance management and consequently relatively slow decision-making concerning the recruitment of perfusionists. Insufficient general and clinical management time was made available to review perfusion practice. [1, 2, 7]

INFLUENCING FACTORS

5.1 The influencing factors are shown under the headings used in the NPSA Contributory Factor Classification Framework. They are as follows:

Individual	Equipment and Resources
Working Conditions	Team and social
Organisational and Strategic	Communication
Patient Factors	Task
Education and Training	

INDIVIDUAL FACTORS

5.2 The on-going review of perfusion staffing levels from February 2004 to April 2005 led to a testing on-call arrangement but there was no evidence that PERF was particularly fatigued on 25 May or that staffing did not meet national recommendations. However PERF had been receiving mentoring/counselling support since November 2004 to support him through a challenging and testing time when he felt he was under significant emotional pressure to maintain the service in both BRI and BCH with insufficient staff. [5]

TEAM AND SOCIAL FACTORS

Culture

5.3 The Kennedy Review into paediatric cardiac surgery in Bristol in the early 1990s was underway when in 1995 a new paediatric cardiac surgery team was recruited by the Trust. Consequently in the latter half of the 1990s there was considerable pressure brought to bear on the Trust and the new team of surgeons, anaesthetists and perfusionists. They worked relentlessly to develop and provide a top class service. The clinical outcomes detailed in Paragraph 1.6 are a testament to their success. The individuals in the team possess a strong 'can-do' culture typical of that found in many teams across the NHS. Whilst in the vast majority of occasions this culture is to be praised it does self impose significant pressure on individuals not to let down the team, the Trust, the relatives or the patient. In the case of BCH cardiac staff this self-imposed pressure is strongly felt and in fact binds everyone together. Unfortunately on 25 May this culture worked against the team. Despite indications that it might be sensible to cancel BA's operation no one wanted to be the one who let the team down. This 'environmental capture' of individuals is found in many incident investigations involving human error. [3]

5.4 The culture of this successful team created an additional contributory factor in the incident. SURG and PERF had clinical outcomes for which they could be justifiably proud. Indeed a multi-centre study[xiv] into the effects of human factors in the outcomes of cardiac surgery found the Bristol unit produced the best results in the country. In 1995 the perfusion protocols in Bristol were inadequate. When they began work together they developed from scratch the best protocols and procedures they could. These protocols appeared to be standing the test of time because the surgical outcomes were very good. Under the pressure of work it did not appear to PERF that perfusion protocols should be benchmarked against other services and updated at least annually. In addition the Society of Perfusionists was not taking a lead in ensuring that their members were provided with a clear requirement to do this. [4, 6]

5.5 As a result the perfusion department and the cardiac surgery services failed to put in place barriers to reduce or prevent human error. Few checklists or double-checking arrangements existed in perfusion, or where they did were inconsistently applied, to protect individuals from inevitable human error. However this was also the situation in several other Trusts. [2, 21, 29, 30]

Leadership

5.6 Whilst uncertainties about whether BA's operation would be cancelled could be explained by poor communication or a lack of a clear protocol for 'theatre over-runs' and/or late working, there could be greater clarity on who takes responsibility for the final decision

of the clinical group determining the theatre schedule. There might be a useful developmental role for specialist registrars to take responsibility for leading the management, briefing and debriefing of an operating schedule. [11]

The Disagreement between SURG and PERF

5.7 There is no reason to assume that the culture within the unit at the time of the incident was any different to that at present. However, in common with many busy cardiac surgical units, the BCH and its associated adult centre, was working at the limitations of staff ability with regard to handling the workload. On the occasion of BA's operation, she was placed on the operating list at the end of what should have been a fairly routine list. In the event, the operating list over-ran for both clinical and logistical reasons and BA's procedure was then carried out at the end of the working day.

5.8 Healthcare professionals are adept at compensating for inadequacies within the system. One of the main strengths of the healthcare system is that so many people display an outstanding level of commitment. However this can also have a detrimental effect with individuals attempting to absorb more pressure than they should.

5.9 From the analysis it is evident that SURG and PERF had been under significant pressure for some time and especially so on 25 May. They had been a strong partnership with an excellent track record. There should not have been the exchange of views that occurred at 1615 hrs on 25 May 2005 but it must be borne in mind that the high workload, particularly placed upon the clinical perfusion team, was at the time of the incident an identified problem. Disagreements do occur between key members of any team and the issues are put aside for an operation. Nevertheless the tension created in such circumstances may have impacted on performance of the team. [19]

COMMUNICATION FACTORS

Misunderstanding about cancellation of BA's operation

5.10 When the perfusion department responded to its shortage of staff in November 2004 by reducing the on-call cover, an informal arrangement was agreed whereby operating would not regularly be extended past 1700 hrs. This was an attempt to prevent the working hours of the perfusionists becoming too onerous. Since this arrangement was not written down, individual perceptions varied on how late in the day operations could begin before a decision to cancel was likely. SURG took the view that the operation for BA was 'straightforward' if high risk because of her condition, and could therefore be completed relatively quickly without operating much later than 1700 hrs. PERF thought that BA's operation would be cancelled because the first 2 operations of the day had taken too long. The final decision for cancelling an operation did not rest with him. [11, 12]

Theatre list planning

5.11 Each morning of operating the surgeon and the anaesthetist meet to discuss the scheduled patients on the list that day. On 25 May this occurred at 0800 hrs. It is not routine practice for the perfusionist involved to attend that meeting although PERF did attend on that morning. PERF should have gathered a better understanding of the pressure to operate on BA

that day. Perhaps this problem might have been avoided through a more structured briefing process.

5.12 It may be necessary to introduce a centrally prescribed policy with regard to the scheduling of cases where staff are working excessive hours, or have limited on-call, or backup cover. To help prevent misunderstanding about cancellations in the future, trust management, clinical managers and clinicians will need to interface and prescribe a standard working practice with regard to routine clinical open heart surgical practice. There needs to be an understanding that all team members agree together about cancellations, not unilaterally or bilaterally. [11]

Release of second perfusionist

5.13 When the operations on the first 2 patients took longer than anticipated PERF assumed that the third operation would be cancelled and allowed the second perfusionist available in theatres that day to leave. This additional person might have had an influence on the preparation of the prime fluid and/or managing the suction bypass between 1700 hrs and 1715 hrs. [12, 27]

TASK FACTORS

Guidelines and protocols

5.14 Perfusion Protocols had not been updated since being written in 1995. Those checklists that were available were not consistently used. This work is the responsibility of the Principal Perfusionist but general management and clinical management should have found this weakness through routine performance management. [2, 19, 21, 28]

5.15 The perfusion expert witness advised[xv] that it is common practice (although not professionally mandatory) within the perfusion community to operate in accordance with agreed and regularly reviewed clinical protocols. The quality and scope of these protocols and standard operating procedures (SOPs) vary significantly between clinical centres across the UK. In general these protocols comprise of a series of set-up checklists (pre-bypass checklists), and cardiopulmonary bypass operating protocols. These protocols are generally supported by perfusion records (pump records) in which patient demographic data, blood and gas flow rates, patient haemodymanic and temperature data, and blood gas and electrolyte data, are recorded at regular intervals. Additionally these records may contain a record of the various drugs delivered by the perfusion team or other members of the clinical team into the heart-lung machine apparatus, before, during, and in some instances, after the perfusion period. There are no national regulations governing the quality, frequency or scope of these recordings and protocols. However, guidelines do exist in this regard. These guidelines are scant in content, and may be obtained from the Society of Clinical Perfusion Scientists of Great Britain and Ireland[xvi]. The only source of information pertinent to the conduct of clinical perfusion contained on this website are the Code of Practice and the Recommendations for the Standards of Monitoring and Alarms during Cardiopulmonary Bypass. These documents do not suggest practical protocols for the conduct of cardiopulmonary by-pass; rather they set out a series of minimum standards, which may be employed to maintain safe standards of clinical practice. The following extracts represent the critical passages from this document that are relevant to the context and scope this report:

- **The recommendations for standards of monitoring and alarms during cardiopulmonary bypass**

"*The safe conduct of cardiopulmonary bypass is a joint responsibility of surgeons, anaesthetists and Clinical Perfusion Scientists and requires a high level of communication between the team members."*

This passage confirms the importance of a "team approach" to clinical perfusion and recognises the level of shared responsibility required for safe practice in this complex and dynamic environment. This is an issue that may be fundamental to the circumstances surrounding the events upon which this report is based.

- **The Code of Practice**

"Every hospital must have standard working instructions for clinical perfusionists who are involved in the application of perfusion techniques.

The code of Practice requires the local rules and protocols set out clearly and precisely all procedures in force in the establishment as carried out by clinical perfusionists.

The clinical perfusion scientist should adopt methods and use techniques in order to promote and safeguard the well being and interests of patients.

Protocols for routine and emergency work should be prepared by an accredited clinical perfusionist.

Procedures for perfusion emergencies should be practised on a regular basis.

Protocols should be written with regard to checklists for each procedure by qualified and experienced personnel.

A detailed perfusion record should be maintained for each procedure to include relevant patient data and equipment used. Relevant perfusion data should be recorded at regular intervals as defined by local protocols. Where appropriate a checklist should be utilised.

Protocols, records and checklists should be reviewed annually"

5.16 This code of practice suggests that perfusion departments should carry out clinical perfusion in accordance with a set of protocols, however it does not propose any recommended protocols or standard operating procedures. Rather, this code of practice would appear to propose that such protocols should be formulated locally in their entirety.

5.17 These documents (the Codes of Practice and Recommendations for Standards of Monitoring), although helpful on some levels, do not assist the perfusion community in formulating safe standards of practice in terms of the actual conduct of clinical perfusion. Perfusion departments are therefore required to formulate their own individual protocols and SOPs. This has led to a wide variety of protocols being employed in clinical practice, derived from local requirements and information gathered from local, national and international sources. This lack of national standard practices for the perfusion community as a whole may result in inadvertent local implementation of inappropriate or indeed unsafe practices.

5.18 There is some confusion over the standard of protocols employed by the perfusion department at the BCH at the time of the incident in question. Two protocol documents have been described, one is the "paediatric bible", an undated document in terms of production and review date, and a second poorly presented protocol. It is unclear at the time which of these documents were most in use at the time, however the "paediatric bible" document was of a standard similar to that of protocols employed in other clinical centres at the time of the incident. However, critically, had either of these protocols been adhered to at the time of the incident, there is no reason to assume that the situation and outcome would have developed any differently. It should be stressed that since there are no firm national directives governing the layout, content and scope of these documents, it is therefore difficult to level focused concrete criticism.

5.19 The current protocol documents, produced in response to discussions since the incident, are good (see Paragraph 11.2).

EDUCATION AND TRAINING FACTORS

Perfusion department development

5.20 The Principal Perfusionist and the perfusion department do not appear to have been funded to enable them to review their team working. Responsibilities for ensuring that their practice is being tested against international practice and continuously developed rest with the Principal Perfusionist. However there should have been the time and funding available to undertake this work.

EQUIPMENT AND RESOURCES FACTORS

Equipment maintenance

5.21 No evidence has been found to suggest that the maintenance of equipment was a contributory factor. However responsibility for maintenance of equipment in perfusion is split between Trust and perfusion departmental responsibility. Better practice would be for the Trust Medical Equipment Management team to take full responsibility for all equipment.

WORKING CONDITIONS

Perfusionist staffing levels

5.22 It is felt that the perfusion team were working at the limits of their capability with regards to staff numbers. It had been recognised that there was a shortfall in perfusion staff numbers in this department, but recruitment to acceptable levels was slow to be arranged. The overall number of patients covered by this group of perfusionists may be considered to be excessive by current standards, however, it is important to bear in mind that there are no fixed national guidelines or legislation covering this matter. There are recommendations by the Society of Clinical Perfusionists of Great Britain and Ireland, together with various local guidelines, but no legislations governing the workload of the perfusion community in terms of routine practice and on-call cover. These factors may well have played a role in the outcome. PERF was the Chief Perfusionist of the group, who had by all accounts a high workload. He was responsible for a significant portion of the clinical workload[xvii] (including a share of the on-call cover), and for the management of the overall service. That this was a strain on this

individual, who has a national reputation for excellence, was clear. Indeed he was undergoing counselling at the time of the incident.

Theatre Staffing Levels

5.23 UBHT is no different from any other Trust in the country in its overall approach to managing the availability of staff on a daily basis. Senior theatre staff have an extremely difficult task of providing cover for unanticipated demands such as overnight emergency operations, staff sickness and leave. The fact this is achieved is a reflection on their good management skills. However there are limits, and the drive led by the Department of Health and the former Modernisation Agency to improve theatre utilisation and reduce theatre costs may have pushed theatres to reduce their staffing levels to such an extent that peaks of demand and unexpected events force them to reduce the priority given to clinical risk. Rescheduling patients is not only a potential threat to clinical outcomes but also increases pressure on clinical teams. This is not a criticism of theatre staff but of general management nationally not being clear about the appropriate balance between cost and staffing levels to reduce risk to patients, and the priority given to this dilemma. The focus has increasingly become the need to complete surgical procedures regardless of the principles of optimal surgical scheduling or personal circumstances faced by team members. It is not easy to achieve both high productivity and low clinical risk if rescheduling of patients is common practice to control expenditure. [16]

5.24 Continuing this theme, on 25 May the cardiac theatre had been used the night before and had not been cleaned by 0800 hrs and so there was a short delay whilst the theatre was cleaned. The Anaesthetic Nurse rostered for work that day had been on-call the previous night and involved in the emergency operations. She needed to be released. This meant that during the course of operating that day 5 Anaesthetic nurses were needed to provide cover in the cardiac theatre. [14]

5.25 In common probably with almost every Trust in the country no policy exists on the handover of theatre staff during operations. This led to the anaesthetic nurse and the on-call perfusionist arriving in theatre to take-over at the time that BA's operation was at its most critical. Between 1705 hrs and 1715 hrs the team were finding it difficult to establish bypass in a high-risk patient. Whilst it is clear that the change of staff was not a direct or indirect cause of the incident it is indicative of the need to change the overall approach to managing risk and for Trust management to understand the impact of present staffing levels on safely managing unexpected events. [31]

National tariff for paediatric specialist surgery

5.26 The Trust believes that the present Payment by Result tariff for paediatric cardiac surgery is too low and exacerbates the problem of funding BCH theatres appropriately. As a result the Trust are forced to cross-subsidise their paediatric cardiac surgery unit with income from other patient activity.

Theatre time

5.27 The indications are that there is insufficient funded theatre time available to paediatric surgery. As discussed in Paragraph 5.30 considerable pressure was brought to bear on the surgeon and the team to operate on BA on 25 May. It was felt that a 'window of opportunity'

to operate on BA would be lost if the operation was not undertaken on 25 May. This situation arose because of the following contributory factors:

- SURG was not routinely available in the Trust on Thursdays and Fridays. This meant that the next time he could operate on BA was Monday 30 May. [17]

- PICU Consultants were extremely concerned that a delay from 25 May to 30 May could have an impact on the health of BA. [13]

- BA was MRSA positive and protocol required that such patients had to be scheduled for operation as last on the list in order to allow time for the theatre to be cleaned on completion of the operation. [15]

5.28 The option did not exist to reschedule BA to another list without creating more cancellations. To avoid such implications requires sufficient emergency lists to be staffed and available during the week. Such lists do not need to be available every day but would have the impact of reducing elective and urgent cancellations. If the surgical team had felt that there was an increased risk in operating on 25 May there should have been the ability to operate later or the next day without it having significant implications for other patients. [16]

5.29 Every patient is unique so healthcare is plagued with variables and uncertainties. However, nationally not just in Bristol, there is little recognition of the impact of human factors on error. Since financial constraint is given a higher priority than reducing pressure on staff in certain complex environments, clinical managers may have insufficient flexibility to ensure surgical teams are in control of their workload. The Trust needs to decide what financial priority it will give to create an environment that could generate further reductions in clinical risk to patients.

Pressure to operate

5.30 In common with other paediatric cardiac surgery units consultants at BCH regularly, probably daily, face having to determine clinical priority for the treatment of patients. Decisions have to be reaffirmed or changed in the light of bed and PICU availability. Not surprisingly relatives or carers will also exert pressure particularly if there have been any cancellations. On 25 May there appears to have been an unusually high level of pressure put on SURG and his team. PICU continued to remind the team during the course of the day that BA's operation should not be cancelled. This was a contributory factor to the incident only because of the 'environment' it helped to create on 25 May. [13, 15, 16, 17]

Availability of emergency Cardiologist opinion intra-operatively

5.31 One of the delays during the course of the operating on 25 May was caused by the time it took for a Consultant Cardiologist to attend theatre for the second operation of the day. There was a need for a trans-oesophageal echocardiogram. This avoidable delay contributed to the pressure on the team. The Trust needs to review the availability of cardiologists to provide emergency opinions to cardiac surgery. [18]

ORGANISATIONAL AND STRATEGIC FACTORS

Decision-making and risk management

5.32 From 2004 into 2005 the Trust appeared to avoid or drag-out making a clear decision on appropriate staffing levels in particular for perfusion but also BCH cardiac theatre staffing. Since national guidance was being met this is not an entirely unreasonable approach when managing a very difficult financial position. However it would have been prudent to have undertaken a risk assessment and/or made an entry in the Trust risk register or assurance framework making it clear that risk existed and was being managed. In fact the reverse happened with the general managers responsible assuming that because there appeared to be no problems in the perfusion department it was coping. [1, 2, 7]

5.33 Furthermore when the line manager agreed that the Principal Perfusionist could have mentoring or counselling to support him it does not seem to have raised any significant concerns that he might be struggling to fulfil all of his duties. The focus of management was not sufficiently risk oriented in particular when perfusion staffing became further constrained by sickness and maternity leave.

5.34 Whilst the head of a department carries the immediate responsibility to ensure that the staff in his team are working and adhering to the latest best practice, protocols and guidelines are kept up-to-date, and staff are appraised and completing professional development, the line manager has a responsibility to review and test performance to see that this is the case. This did not happen possibly because the managers were also over-committed. [2]

5.35 Taken together these issues are an indication that the Trust's Risk Management Policy and the use of the Assurance Framework were not working optimally in this part of the Trust.

Organisational structure of perfusion services

5.36 Although the adult and paediatric services split in 1995 the paediatric perfusion service continues to be managed by the adult service. This arrangement has the advantage of pooling perfusion staff and so reduces costs. A quick assessment of the likely development of paediatric cardiac surgery activity suggests that 2 separate perfusion departments cannot be justified financially. However the Trust should review whether the present management arrangements provide clarity of responsibility and accountability and are responsive to the needs of the paediatric service. In particular the Trust should review the financial apportionment of perfusion costs between adult and paediatric surgery since one of the factors constraining decision making seems to have been the 1995 calculation to take funding from the adult service to provide for the paediatric service. [7]

Trust Medicines policy

5.37 Leaving aside the lack of clarity on what basis perfusionists derive the authority to administer drugs, the Trust Medicines policy in place in May 2005 required the double-checking of drugs given intravenously. Despite this, the perfusion department had not introduced the double-checking of drugs used in the prime solution or of the prime solution itself. However anaesthetic drugs were not being double-checked either. Indeed there is evidence that this policy had neither been disseminated effectively nor implemented successfully by the Trust. Senior staff were not aware of its existence and a review in 2007[xviii] found there to be patchy compliance across the Trust. [20]

The regulation of perfusion services

5.38 The Society of Perfusionists perhaps carries some responsibility for this incident because it does not appear to have disseminated learning from other perfusion incidents between its members. Several Trusts have reported similar crosschecking incidents associated with perfusion and the Society does not seem to have acted to review or develop minimum standards of service delivery or risk management. Trusts having experienced an incident have made local changes to their protocols creating a situation nationally where none of the Trusts appear to be working to similar arrangements for the provision of perfusion. This was explored in more detail in Paragraphs 5.15 to 5.18. [4]

5.39 The table below shows the working arrangements in 2007 that have developed across paediatric cardiac surgery and perfusion teams:

Trust	Single Perfusionist	Availability of Second supporting Perfusionist	Additions to Prime double-checked	Prime double-checked
1	Yes	No	No	No
2	Yes	Floating	No	No
3	Yes	No	Yes	Yes
4	Yes	?	No	No
5	Yes	No	If possible	Yes
6	Yes	No	No	No
7	Yes	No	If possible	Yes
8	Yes	No	If possible	If possible

5.40 The responsibility for the conduct of perfusion during a cardiac surgical operation lies between the cardiac perfusionist and in some units, the consultant anaesthetist responsible for the patient's care. This is another issue that needs to be resolved nationally.

PATIENT FACTORS

High-risk patient and procedure

5.41 This case would be considered a high-risk intervention by any paediatric cardiac surgery team. The elevated risk relates not specifically to the planned surgical procedure, but to the co-existing features associated with prematurity, chronic lung disease and pulmonary hypertension thought secondary to both excessive pulmonary blood flow, due to the ASD, and to structural parenchymal lung disease[xix].

5.42 The anaesthetic expert witness to the Coroner reported that such cases are unusual. He could not provide exact incidence data but believed that a paediatric cardiac anaesthetist would not expect to encounter such a case more frequently than once every 2 to 3 years. [10]

THE SITUATION AT 1630 HOURS 30 MINUTES BEFORE THE OPERATION ON BA BEGAN

6.1 It is worth summarising the analysis of contributory causes by reviewing the situation that existed at 1630 hrs on 25 May 2005. This is about 15 minutes after the exchange between PERF and SURG and 25 minutes before knife-to-skin.

- There was frustration over the staffing levels in perfusion and the working arrangements established to cover the shortfall across BRI and BCH.

- Although what national recommendations for perfusion services existed were being met, the Trust had failed to review the risk associated with its own perfusion staffing position. The variety of arrangements in place across the country suggests UBHT was not alone in this matter.

- Stretched to provide cover for the clinical workload the perfusion department had put insufficient management time into reviewing its own performance. It had assumed that protocols working successfully for 10 years were not a high priority to update. The Society of Perfusionists provided insufficient regulation to ensure that units and individuals met exacting standards.

- As a result the perfusion service had not adequately established checklists or double-checking arrangements to reduce the likelihood of human error having a catastrophic result.

- The Trust assumed that since there were no difficult service delivery problems and minimum staffing levels were met that performance management was not necessary. Consequently general management were unaware that the Trust Medicines policy was not fully implemented across the Trust.

- PERF was feeling significant emotional pressure in particular, to maintain the service with reduced staffing. The Trust was struggling with a difficult financial position and seemed to drag-out decisions about additional staff without undertaking a formal risk assessment. PERF was receiving mentoring/counselling support.

- BA was a high-risk patient and the procedure although technically 'straight forward' was a high-risk intervention.

- There was considerable pressure on the team to ensure BA's operation went ahead on 25 May. PICU were concerned that if the window of opportunity to operate that day was missed BA's health could deteriorate further. SURG did not have another elective operating list until 30 May. Insufficient funded theatre time was available on 26 May even if SURG had been scheduled to be on-site.

- Although this was a high-risk procedure it had to be scheduled for the end of the operating session because BA was MRSA positive. This was likely to lead to less key staff being available post-operatively and staff shifts changing in the afternoon.

- The 2 cases on the operating list before BA did not go to plan and took longer than anticipated. Poor communication about whether BA's operation would be cancelled

led to PERF releasing the second perfusionist on duty for theatres. PERF was unaware that SURG thought that even with delays BA's operation could be completed by 1730 hrs.

- It is perhaps not surprising that with the substantial pressures on SURG and PERF that there was a very short but very intense exchange of views. Whilst they would be able to continue to work it is likely that there would be an element of pre-occupation in all the team as a result of this unusual event.

6.2 It is in this environment that PERF was to prepare the pump prime solution for the cardiac bypass machine.

THE OPERATION FROM 1640 HOURS TO 1715 HOURS

7.1 This additional analysis of the chronology of events from 1640 hrs to 1715 hrs is to demonstrate the rapidity with which events proceeded and the likely time that BA received the very high level of ionized calcium. The pressure on the perfusionist to establish suction bypass and when this had a clinical impact on BA, are of fundamental importance.

7.2 **1640 hrs**
The anaesthetic drugs administered via the pump were pancuronium 1mg, morphine 1mg, and midazolam 1.5mg. These drugs do not contain calcium. The drugs were not double-checked. However they were a possible but extremely unlikely means of calcium administration because with normal practice in dilution and the use of commonly available drug strengths even the most unlikely scenario which provides the highest inadvertent extra dose of calcium chloride cannot realistically account for the excessive concentration of calcium ions found in the prime.

7.3 **1650 hrs**
PERF prepares the prime solution under pressure because BA arrives from PICU with lines already in place and is brought straight into theatre. Calcium chloride ampoules containing different strength solutions may have labels that are similar. However the Pharmacy Department of the Trust only purchases one strength and size of calcium chloride. See the comments at Paragraph 4.4.

7.4 **1655 hrs**
'Knife-to-skin'.
PERF circulates prime in pump circuit.

7.5 **1659 hrs**
Sternotomy underway.
PERF measures the blood gas analysis for the prime solution.

7.6 **1700 approximately**
SURG and PERF agree that SURG can begin cannulation.

7.7 **1702 hrs**
Aorta cannula reported to be in place.

7.8 **1705 hrs**
Vena Cava cannula inserted and suction bypass instigated. In suction bypass the arterial cannulation is already in place and connected to the perfusion circuit. If significant bleeding occurs during insertion of the venous cannula a temporary though inefficient form of bypass can be established. The blood loss into the surgical field reduces the intravascular volume of the infant, small changes in which can cause severe haemodynamic instability. The intra vascular volume can be supported initially by infusing prime fluid through the arterial cannula. Blood lost into the surgical field is returned to the bypass pump via the operative field suckers and then this blood is re-infused via the arterial line, having been mixed with prime fluid. This approach is required in few cases but is a recognized method of dealing with difficulties during venous cannulation. This period of suction bypass represents the first exposure of BA to the prime fluid containing a very high ionized calcium concentration. This fluid would have been infused into the aorta to maintain circulating volume during suction bypass.

7.9 In the initial phase of suction bypass if BA's cardiac output was low the perfusion of the vital organ such as the brain would have been preferentially achieved with prime fluid bearing this remarkably high calcium level. It should be noted that if the cannulation and initiation of bypass had proceeded without incident there would have still had been a short but significant initial exposure of the brain to the prime fluid with a very high level of ionized calcium.

7.10 There is no suggestion that suction by-pass contributed directly to the death of BA, but this well-known phenomenon in clinical paediatric cardiac surgical practice often leads to an extremely fraught period, during which the perfusionist is entirely adsorbed in maintaining blood flow to the patient.

7.11 As the case was proceeding more or less as expected up until the time of suction bypass, the exposure of BA to the very high level of ionized calcium in the initial stages of bypass could not be prevented without knowledge of the very high levels of ionized calcium in the prime. There were no warning signs until the onset of suction bypass that an unusual problem would be encountered.

7.12 **1710 hrs approximately**
PERF2 told by PERF of the high reading of calcium in the prime from the 1659 hrs measurement.

7.13 **1715 hrs**
Full bypass established.
Post by-pass blood gas analysis.

7.14 **Change of staff**
Between 1700 hrs and 1715 hrs when the surgeon and the perfusionist were struggling with suction bypass staff arrived and began a hand-over.

7.15 **Double-checking**
There were no properly applied checklists or double-checking arrangements in place to protect individuals from making an error. However it is possible that with the degree of 'environmental capture' that existed in particular from the disagreement, that PERF might well have made the same error even if double-checking had been common practice.

THE LIKELY ERROR

8.1 It is clear that this patient death was most probably the result of excessive administration of ionised calcium (most probably in the form of calcium chloride). It is also most likely that this drug was administered during the initial period of suction by-pass, during which there were clinical complications associated with the venous cannulation procedure.

8.2 The likely error that occurred is that between 1640 hrs and 1650 hrs PERF drew and administered 10mls of calcium chloride to the prime fluid instead of 1mml. He should have administered 7mls of sodium bicarbonate and 1mml of calcium chloride.

8.3 As described in Paragraph 4.6 only a formal imposed pause to consider a checklist supported by a check of the prime blood gas, with time for an appropriate response before inserting the aorta cannula, would have prevented the incident.

ANALYSIS OF HUMAN FACTORS IN THE ERROR

8.4 At this point in the Report it is worth reviewing briefly the theory behind the development of 'error chains'[xx]. The presence of one or more of the 'clues' set out in Appendix 4 is an indication that an error chain might be in progress and that caution is advised.

8.5 Before BA's operation began there were several indicators that an error could happen:

Factor	Comment
Ambiguity	No
Fixation or preoccupation	There was fixation or pre-occupation as a result of the disagreement between SURG and PERF. There would also be pre-occupation amongst those staff that had not anticipated working later than 5pm with their thoughts 'outside the theatre' on what they had originally planned to be doing.
Confusion	There was **c**onfusion and uncertainty as a result of the misunderstandings around whether BA's operation had been or should have been cancelled.
No one monitoring the current state of progress	It is likely that staff reacted to the heated exchange of views by reverting to 'silo working' or a 'keep my head down and get on with what I have to do' attitude. The theatre team did think to ask PERF and SURG if they wanted to proceed.
Use of an undocumented procedure	No
Violating limitations or minimum operating standards	No
Unresolved discrepancies	No
Failure to meet targets	No
Departure from standard operating procedures	They were not departing from SOPs but they were about to begin a high-risk intervention. It was not a routine situation.
Incomplete communication	There had been incomplete communication during the course of the day.

8.6 Following the disagreement between SURG and PERF the theatre nursing staff, the surgical registrar and ANAES had met to discuss how best to proceed. There was also a final intervention by PICU staff stressing the need to avoid a cancellation. Both PERF and SURG were asked if they were happy to proceed and both replied that they were. It was a new and unusual situation with no guidance on how to proceed. In future it could be useful to have a protocol on how to handle matters when staff feel an error chain is underway. It is a credit to everyone that they did consider the situation in an attempt to do their best for BA.

POST OPERATIVE ISSUES

9.1 There are several issues that arose as a result of the post-operative care of BA that did not affect the outcome but need improvement by the Trust.

- **Cardiac ward round on PICU**
  Patients whose operation finish after 1700 hours will miss the cardiac ward round on PICU. The Trust needs to ensure that there is access to the cardiologist providing emergency support each day (see Paragraph 5.31).

- **Delay before incident review**
  The attending doctors reported the death to the Coroner for investigation of a post-operative death. There was no delay in the post mortem, and an independent Pathologist carried out a post mortem and reported death was due to cerebral oedema with no obvious underling cause. Unfortunately the Trust failed to inform the Coroner promptly about the concerns over calcium levels in the prime and it seems that it was not until the Trust Mortality and Morbidity review meeting that the high level of Calcium in the prime that could explain the cerebral oedema, was considered. The Trust commenced a serious clinical incident review after the mortality and morbidity meeting. This was a relatively long time after BA's death. For a catastrophic serious untoward clinical incident a faster Trust procedure needs to be considered. However from April 2008 Local Safeguarding Children's Boards will take over statutory responsibility for investigating sudden unexpected deaths in childhood. The proposed arrangements requiring rapid response and the formulation of an investigation strategy is likely to circumvent many of the problems of investigation that followed the tragic death of BA.

PREVENTION OF THE ERROR - KEY LEARNING POINTS

10.1 There will be those reading this analysis that will feel that the situation set out in Paragraph 6.1 is representative of any typical day in a busy operating theatre or ward. In the NHS 'we just get on with it' because of the unpredictability and risks associated with poorly patients and staff availability.

10.2 However one of the subtlest mistakes made is the failure to realise that the best-motivated and most highly trained professionals are also potentially lethal agents. Humans are fallible; they cannot deliver flawless performances at all times, no matter how willing they are to try. Safeguards need not be expensive or complicated.

10.3 If risk to patients is to be reduced then cultural changes and team working such as those listed below ought to be considered:

- There has to be a culture that allows challenge from any member of the team.
- There has to be an acceptance that to pause and take stock before proceeding is sensible if there are indications that an error chain might be developing.
- There has to be an acceptance from general management that sometimes it could be appropriate to cancel/postpone a procedure because the likelihood of error is raised. Such an understanding has to be backed by resources to allow such flexibility of action.
- There has to be an understanding by all staff that human error is inevitable but that there are warning signs, and checklists and double-checking procedures that must be followed to reduce risk.
- In developing services for the future risk has to be considered. Clinical teams and management need to be clear with each other about the relative priorities given to cost, risk, targets and outcomes.

10.4 Changes to culture, training and a small number of additional theatre sessions should not be expensive, certainly from an economic perspective. An appreciation of the impact of human factors on error has to be backed financially if a step change in the reduction in incidents is to be made.

TRAINING

10.5 Professor Reason argued in his article for the BMJ in 2000 that error management has 2 components: limiting the incidence of dangerous errors and creating systems that are better able to tolerate the occurrence of errors. 'High reliability' organisations – systems operating in hazardous conditions that have fewer than their fair share of adverse advents – strive for a comprehensive management programme aimed at several different targets: the person, the team, the task, the workplace and the organisation.

10.6 It is proposed that the Trust adopts this 'high reliability' approach. It would involve training Trust-wide eventually but perhaps could be piloted in cardiac surgery. The overall aim would be to:

- Educate all staff beyond introductory phases of risk management. The present national approach really only focuses on reporting risks and compiling risk registers.
- Acknowledge human factors problems and commit to improve the situation.
- Agree on definitions of good and poor behaviour for all health care workers.
- Build in multiple layers of defence against error rather than relying on a single barrier such as individual expertise to provide perfect protection.
- Build barriers against both systems failings and individual error.

10.7 Trust induction training and annual statutory training should be increased to teach routinely:

- Awareness of human factors problems in systems.
- The inevitability of human error in human-controlled systems.
- The nature of human error and how to manage it.

10.8 The aviation solution to the problem of human error has been to train in human factors. It focuses on the non-technical skills needed to deal with threats and manage the human potential for error. The skills incorporate subsets of appropriate operational behaviours known as markers that include: leadership, decision-making, team co-ordination, safety critical communication techniques, situational awareness and self-assessment.

10.9 Clinical staff would need training programmes that include:

- Processes for expert decision-making.
- Developing suitable checklists.
- Focussing on common problems.
- Routinely checking performance against accepted standards.
- How to ask questions when they are uncertain, communication skills and how to manage fatigue.
- Detailing of common behaviours through an accepted list of behaviours.
- Provision of assertiveness training for all team members.
- Clarification of roles and responsibilities.

10.10 Such training could be included in annual statutory training for senior clinical staff perhaps by using case studies. There are a small number of organizations experienced in clinical risk management, clinical root cause analysis in the NHS and aircrew training for the air industry. It would not be difficult to use their expertise to develop suitable training modules to be used to improve the understanding of human factors in error and error chains in the NHS.

REVIEW OF PRESENT WORKING ARRANGEMENTS IN PERFUSION

Culture within the unit at present

11.1 Having interviewed many members of the clinical team, it is apparent that the culture within the cardiac unit, insofar as the working environment is concerned, is supportive. There seems to be a real belief in the work being carried out in this unit, and in general, the relationship between staff members at all levels is palpably friendly and caring. There is a strong commitment, based upon the statements of those interviewed, to the delivery of a quality clinical service. That the unit performs well in terms of its clinical practice is clear from the national statistics on morbidity and mortality, where it compares favourably with other national centres[xxi].

Current policies

11.2 The current protocol documents, produced in response to discussions since the incident, are good. This protocol is comprehensive in terms of the general set-up and conduct of clinical cardiopulmonary bypass. However, there is neither a sign of this document being reviewed in the interim period, nor a record of which members of staff are in possession of it.

11.3 It is of the utmost importance that documents such as these are dated, reviewed and that each relevant member of staff signs the documents to verify that they have been read. All members of staff should have access to an updated version of the clinical protocol at all times during working hours. A mandatory, protocol review should be carried out at regular fixed

intervals involving all members of the clinical team. Robust implementation of such a system of review is imperative. Roles need to be defined to clarify responsibilities and accountabilities and protocols adjusted accordingly.

Review of perfusionist working hours

11.4 The perfusion team are working at an almost unsustainable level. It is understood that this is a recognised problem and that attempts have been made in the past to reduce the workload by recruiting additional staff. However these measures have been and remain unsuccessful, with the level of staff below that expected to cover the clinical setting. The Trust should review the staffing levels urgently and support the development of the perfusion team.

Clear lines of accountability

11.5 As discussed in Paragraph 5.36 the Trust should review whether the present management arrangements provide clarity of responsibility and accountability and are responsive to the needs of the paediatric service. The situation may be clear with general management but there does not appear to be such clarity amongst clinical staff. In particular the Trust should review the financial apportionment of perfusion costs between adult and paediatric surgery.

OVERALL CONCLUSION

12.1 This was a unique incident with no published reports of similar events[xxii]. The staged surgical procedure is undertaken comparatively infrequently[xxiii] and the error occurred during the preparation of the cardiopulmonary bypass machine prime fluid for BA's operation. The evidence indicates that the error was caused by inadvertent human error, perfusion systems failures at national and local levels, and other local system problems. Together these created the necessary preconditions for the human error and a failure to find and react to it.

12.2 That the paediatric cardiac surgery unit and the perfusion department perform well in terms of its clinical practice is clear from the national statistics on morbidity and mortality, where it compares favourably with other national centres[xxiv]. There seems to be a real belief in the work being carried out in this unit, and in general, the relationship between staff members at all levels is palpably friendly and caring. There is a strong commitment, based upon the statements of those interviewed, to the delivery of a quality clinical service.

12.3 The incident occurred because of latent weaknesses that lay dormant for years hidden by healthcare professionals compensating for inadequacies within national and local systems:

- nationally: regulation and guidance on perfusion practice in cardiopulmonary bypass.
- locally: infrequent risk assessment, protocols and practice not updated, and a lack of checklists and double-checking procedures.

One of the main strengths of the healthcare system is that so many people display an outstanding level of commitment. However one of the subtlest mistakes made was the failure to realise that the best-motivated and most highly trained professionals are also potentially lethal agents. Humans are fallible; they cannot deliver flawless performances at all times, no matter how willing they are to try. Safeguards such as checklists and double-checking for

perfusion were limited and not consistently applied and so a tragic incident occurred because there were no barriers in place to prevent the latent problems combining with unpredictable clinical and non-clinical events on 25 May 2005.

12.4 A fault tree analysis is included at Appendix 4 to illustrate some of the system-wide issues.

RECOMMENDATIONS AND ACTION PLAN

13.1 A number of lessons must be learned from the unfortunate circumstances surrounding the incident that is the focus of this report. These should stimulate changes to procedures and techniques within the BCH cardiac unit, and may have implications on a broader national scale.

13.2 The process of reviewing the incident upon which this report is focused has shed light on a number of matters of importance on a national scale associated with the conduct of cardiopulmonary bypass. In particular some questions have been raised as to the status of the perfusionist as a member of the overall clinical team with apparent responsibility for the administration of potentially dangerous substances. Furthermore it appears that, despite being in existence for almost 50 years as a group of clinicians who have considerable responsibility in terms of not only patient care, but also patient survival, there is little in the way of legislation governing their practice or conduct.

13.3 It is recommended that:

Serial	Recommendation	Action	Responsibility
National 1	**Regulation** There should be a national review of the regulation of clinical perfusion scientists.		
National 2	**Perfusion practice** The following issues from this incident are reviewed: • The acceptable workload for a clinical perfusionist. • The acceptable level of staffing for a clinical perfusion team, particularly one that covers multiple sites. • The use of non-clinically qualified personnel, in this instance perfusionists, responsible for administering drugs before, during or after cardiopulmonary bypass. • The circumstances and conditions under which is it acceptable for a non-clinically qualified perfusionist to administer drugs before, during or after cardiopulmonary bypass. • The possibility of producing a minimum standard for routine perfusion practice, which includes fundamental clinical protocols and checklists. • The need to have high strength ionised calcium solution in operating theatres. • If it is necessary to have high concentration ionised calcium solutions in operating theatres, then should this be in vials which would be non-lethal if administered in its entirety, for example in 1ml vials. • The ambiguous status of the perfusionist needs to		

	be defined further with particular regard to clinical responsibility. • The possibility of implementing mandatory, recorded, check-listing and protocol procedures across perfusion practice. • The requirement and frequency of blood gas analysis measurement before, during and after cardiopulmonary bypass. • The requirement or not for different team working between perfusionists and anaesthetists.		
National 3	**Human factors in error training** The next review of the national strategy for improvement in patient safety should consider a more proactive approach on the impact of human factors in errors. Insufficient attention is being paid to the development by staff of an understanding of human factors in incidents. Reviews of incidents should include an analysis of the impact of human factors on an incident.		
National 4	**Incentives to increase awareness of human factors** The NHSLA should consider a decrease in Trust premiums if a high percentage of key staff in a Trust undertakes a one-day human factors awareness course.		
Trust 1	**Policy implementation** There should be a re-evaluation of the dissemination process for policies. There should be a review of how to turn policy into procedure. There should be regular monitoring of the implementation of the Medicines policy. There should be regular monitoring of the Risk Management policy. There should be a review of the serious untoward incident investigation process taking into account the changes associated with the Safeguarding Children's Board and the optimum time to inform the Coroner.		
Trust 2	**Training** The Trust should consider training through induction programmes and compulsory annual training on human factors in error and decision-making.		
Trust 3	**Resources** The resources for cardiac surgery and perfusion are reviewed to allow better management of unpredictable pressures.		
Trust 4	**Organisational structure** The accountabilities and responsibilities for the management of the perfusion department are reviewed in particular with respect to responsiveness to paediatric services.		
Trust 5	**Corporate management of clinical risk** There is a meeting or workshop involving Trust executives and the cardiac surgery team to clarify the management of risk versus cost and targets in the future development of the service. This is to ensure everyone carrying responsibility has an accurate understanding of the present pressures on the service.		
Trust 6	**Cardiology** The emergency rota for cardiology support to cardiac surgery and PICU is reviewed.		

Trust 7	**Perfusion staffing** There should be a review of perfusionist working hours and commitment. It is not felt that the perfusion team are working at a sustainable level.		
Paediatric Cardiac Surgery 1	**Training and team development** The team seeks funding from the Trust to support team and cultural development through training in particular on human factors in error. Leadership, accountability and responsibility issues could be clarified that might lead to a more formal approach to briefing and debriefing for theatre sessions.		
Paediatric Cardiac Surgery 2	**Implementation of new protocols** New protocols including the use of checklists and double-checking are rigorously implemented and audited.		
Paediatric Cardiac Surgery 3	**Simulation training** Investment is sought to enable simulation training for perfusionists to be undertaken.		
Paediatric Cardiac Surgery 4	**Scheduling of theatre time** The team review working practices with particular regard to case scheduling and any requirements for protocols or policies.		
Perfusion 1	**Immediate action** Immediate action is taken to review the following: The use of ionized calcium. The use of calcium chloride. The need for multiple concentrations of drugs in the theatre environment.		
Perfusion 2	**Protocols** Protocols are amended to include a requirement to pause in routine and urgent operations in order to enable a checklist to be completed before proceeding to bypass.		
Perfusion 3	**Perfusion team building** Funding is sought to support team building and development in order to help with recruitment.		
Perfusion 4	**Equipment maintenance** The responsibility for the maintenance of perfusion equipment is reviewed in order to give clarity to the arrangements and ensure that there are no gaps in responsibility.		
Perfusion 5	**Improve the Quality of Frequency of Update of Clinical Perfusion Protocols** To institute mandatory implementation and reviews of check-listing processes at fixed intervals, involving all members of the clinical team.		

Appendix 1

CONTRIBUTORS TO THE ANALYSIS

Mr Mark Gritten	Independent Chairman
Professor Terence Gourlay	Professor of Diagnostic Medicine, the University of Strathclyde
SURG	Consultant Paediatric Cardiac Surgeon caring for BA
ANAES3	Consultant Paediatric Intensivist
ANAES2	Consultant Paediatric Intensivist
ANAES	Consultant in Paediatric Anaesthesia and Intensive Care caring for BA
PERF	Perfusionist caring for BA
ANPRAC	Senior Anaesthetic Practitioner
SURG2	Consultant Paediatric Cardiac Surgeon
NURS1	Theatre Sister
In addition several others involved provided written statements to the Police and the Coroner that were used in the analysis, and/or they attended the Cause and Effect meetings.	
Senior clinical staff from UBHT not involved in the incident	
Independent opinion was available to the Coroner and so to this analysis as follows: Dr Brian Keogh Mr Richard Reeves Mr Babulal Sethia Dr Valerie Walker Dr P Cox	 Consultant Anaesthetist, Independent Expert Principal Clinical Perfusionist, Independent Expert Consultant Cardiac Surgeon, Independent Expert Consultant in Clinical Pathology, Independent Expert Consultant Histopathologist

Appendix 2

KEY EVENTS FOR THE CARE OF BA: 4 FEB 04 TO 27 MAY 05

The timings have been extracted from personal statements, transcripts from the Coroner's Inquest and Medical Records.

Key to initials used:

MAN1	Senior manager	ANPRAC	Anaesthetic Practitioner
MAN2	Senior manager	SURG2	Paed Cardiac Surgeon
ANAES2	PICU Intesivist	ANAES3	PICU Intesivist
ANAES	Consultant Anaesthetist	PERF2	Perfusionist on-call
SURG	Paediatric Cardiac Surgeon	PERF	Perfusionist
NURS1	Theatre Sister	BA	Patient

Date Time	General Events	Anaesthesia, Surgery and Perfusion	Evidence
4 Feb 04	PERF raises staffing concerns with MAN1		Email
6 Apr 04	Meeting to discuss Perfusion services to BCH with MAN2		Notes of meeting
26 Apr 04	Email from MAN1 to MAN2 about Perfusion staffing pressures		Email
8 Jun 04	Result of benchmarking service		Notes
25 Nov 04	Email from PERF2 to MAN2 attaching email from PERF about changes to Perfusion on-call because of shortage of staff		Email
1 Dec 04	Letter from SURG and SURG2 to MAN2 stating concerns		Letter
2 Dec 04	Letter to MAN2 from SURG2 restating position set out in letter of 1 Dec.		Letter
14 Dec 04	Meeting MAN1, MAN2, SURG, SURG2, PERF agrees way forward and accepts service meets staffing recommendations		Notes of meeting
30 Mar 05	Email to MAN2 from MAN1 about availability of Perfusionist to recruit		Email
5 Apr 05	MAN2 email supporting recruitment		Email
20 Apr 05	Perfusionist no longer available		Statement
End Apr 05	1-to-1 PERF and MAN1		Statement
1800 **4 May 05**	ANAES2 telephone conversation with Truro requesting admittance for BA to BCH for hypertension		Medical Records
5 May		Retrieval of BA from Truro. BA admitted PICU BCH	Statement
2028 5 May	ECG		Medical Records
6 May	ASD diagnosis written in notes		Medical Records
10 May	Completed course of Cerfuroxime		Medical Records
11 May	Cardiac catheter study and TOE		Medical Records
12 May	Surgical Meeting. SURG meets parents of BA to explain high risk.		Medical Records
13 May	Chest X-ray shows collapsed upper lobe of right lung		Medical Records
15 May	Chest X-ray shows consolidation in both lungs. Antibiotics started.		Medical Records
16 May	Planned surgery cancelled because of respiratory infection. Bronchial		Medical Records

Date Time	General Events	Anaesthesia, Surgery and Perfusion	Evidence
	washings for culture.		
16 -18 May	Periods of desaturation when trying to wean off ventilator		Medical Records
18 May	Improving; considered for operation on 23 May		Medical Records
23 May	Found in theatres to have raised temperature. Intravascular lines changed. Tips of lines sent for culture.	MRSA positive	Medical Records
Evening 24 May	ANAES visits BA in PICU		Medical Records
25 May 05			
	During course of day 2 procedures; a complete AV Septal Defect (open); a Pulmonary Artery Band (closed).		Statement; Cause and Effect meetings
1500	SURG phones PERF and told PERF will let him know at 1545 if/when he can provide perfusion.		Statement; Cause and Effect meetings
1515	NURS1 phones PERF who says he will be in theatre by 1600		Statement; Cause and Effect meetings
1520		Second case in theatres finishes	Theatre Records
1530	NURS1 speaks to PERF on phone		Statement; Cause and Effect meetings
1545	PERF arrives in theatre		Statement; Cause and Effect meetings
	Discussion PERF and ANPRAC		Statement; Cause and Effect meetings
	Second discussion ANPRAC and PERF when he says he has to return to BRI and patient cannot be called until 1700		Statement; Cause and Effect meetings
	ANPRAC tells SURG patient not to be called until 1700		Statement; Cause and Effect meetings
1615	Disagreement SURG and PERF		Statement; Cause and Effect meetings
1632		Theatre sends for BA	Theatre Records
1640		ANAES gives PERF pump drugs (midazolam, morphine, pancuronium). ANAES asks PERF if happy to proceed.	Medical Records
1645		ANAES collects BA from PICU (administers fentanyl and pancuronium). Transfer ventilate by hand	Medical Records
		BA arrives in theatre	Theatre Records
		Report BA stable after transfer	Medical Records
1655		Knife to skin	Theatre Records
		Median Sternotomy. Thymus excised to the level of the innominate vein. The duct was occluded in continuity.	Surgeon's operating note
1659		Prime blood gas analysis (11620) Calcium 12.95	Medical Records; interviews
1700		Heparin given and confirmed above 400	
1702		Blood gas analysis check of BA's blood for ventilation Calcium 1.05 (11621)	Medical Records; interviews
1702		Calcium reading of 12.95 not recorded	Medical Records
		Insertion of aortic line	Surgeon's operating note
1702 to 1715		Insertion of inferior vena cava cannula. Purse string cut and proceeds to suction bypass whilst SURG repairs IVC and resites cannula.	Surgeon's operating note; interviews
		Problem with venous return initially requires air locks in gravity drain to be sorted.	Statement; interviews
1715		ANPRAC arrives to take over shift	Statement
1715	Hypertension	Bypass commenced. Ventilation ceases. Blood pressure becomes high. Heart stops in systole. Right ventricle fails to relax.	Statement and Surgeon's operating note
		Isoflurane administered by pump but not	Statement

Date Time	General Events	Anaesthesia, Surgery and Perfusion	Evidence
		recorded on Perfusion chart	
		PERF2 takes over testing of blood and completion of perfusion chart. First test after onset of bypass Discussed print out and pointed out Calcium reading. No data entered on chart.	Statement
		PERF says 'that is lower' (3.48). PERF2 copies data to perfusion chart. PERF reduces blood flow through machine to control hypertension.	Statement; Medical Records
		Right atrium opened after snugging the cavae. ASD was closed partially along its inferior aspect. A transverse suture was placed along the upper half and was brought outside the heart and snugged.	Surgeon's operating note
1728		Aortic cross clamp on	Medical Records
1732		Calcium reading 2.67 (11624)	Medical Records
1740		Aortic cross clamp off. Aortic cannula removed. Patient rewarmed.	Surgeon's operating note
1743		Calcium reading 2.71 (11625)	Medical Records
		(11626 transfusion blood used)	Medical Records
1757		Off bypass. Total Bypass time 42 minutes.	Medical Records and Surgeon's operating note
1800		PERF leaves theatre	Statement
1807		Post by-pass arterial sample Calcium 2.17 (11627)	Medical Records
1820		Surgery finish time	Theatre Records
1830 to 1840	BA arrives back in PICU. ANAES reports hypertension during operation but not hypertensive at that time.		Statement
1839	Raised Potassium and Calcium is at 1.57.		Medical Records
1925	Calcium still at 2.17. ANAES reports that Calcium before operation was 1.17 to 1.21		Medical Records
2100	Peritoneal dialysis started; good urine output but frank haematuria.		Medical Records
2100 to 0300 **26 May**	Calcium falls but Potassium rises and lactate concentration high. ANAES2 administers Frusemide, salbutamo; and calcium resonium		Medical Records
0300 26 May 04	Potassium fallen and Calcium normal		Medical Records
26 May	Drug adjustments to get response to stimuli (including therapeutic diazepam and stopping sedating drugs). Baseline cranial ultra-sound		Medical Records
26 May	Cranial Ultra-sound		Medical Records
26 May	Dermatology review of rash that fades on 27 May		Medical Records
27 May	Closed sternum		Medical Records
27 May	EEG and CT		Medical Records
Evening 27 May	BA dies		Medical Records

Appendix 3

EVENT AND CAUSAL FACTOR CHARTS

The Event and Causal Charts were compiled by staff involved in the incident and are based on statements to the Coroner and the Police, the transcript from the Coroner's Inquest, medical records and interviews.

The Charts are in 5 parts or phases as follows:

- Staffing Issues February 2004 to April 2005.
- Pre-operative Phase in PICU 4 May to 24 May 2005.
- Communication Issues before the operation 0800 hours to 1615 hours 25 May 2005.
- Peri-operative phase 1630 hours to 1830 hours 25 May 2005.
- Post-operative phase in PICU 25 May to 27 May 2005.

KEY

The key to the charts is set out below:

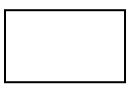
Key to initials used:

BA	Patient
MAN1	Senior manager
MAN2	Senior manager
ANAES	Anaesthetist directly involved
PERF	Perfusionist directly involved
SURG	Paediatric cardiac surgeon directly involved
ANAES2	PICU Anaesthetist
PERF2	Perfusionist on-call
ANPRAC	Anaesthetic Practitioner
SURG2	Paediatric cardiac surgeon
NURS1	Theatre Sister

Definitions and symbols

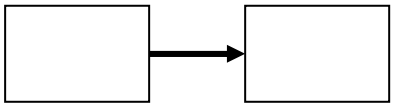
The following definitions are necessary to interpret the charts:

Event



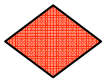
An action or happening.

Primary Event



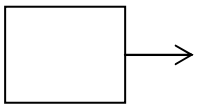
The primary sequence of events is depicted with a straight horizontal heavy arrow.

Undesirable Event



An undesirable event or inappropriate action or situation that was critical for the incident being analysed to occur.

Secondary Event



An action or happening that impacts on the primary event but is not directly involved in the incident. Connected by small arrows

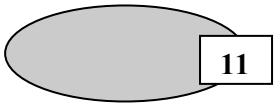
Conditions

Circumstances pertinent to the situation that may have influenced the course of events. Connected by dotted arrows.

Presumptive Factor

A factor that is assumed because it occurred or appears logical but cannot be proven to have directly impacted on the incident. Shown as a dotted oval

Causal Factor

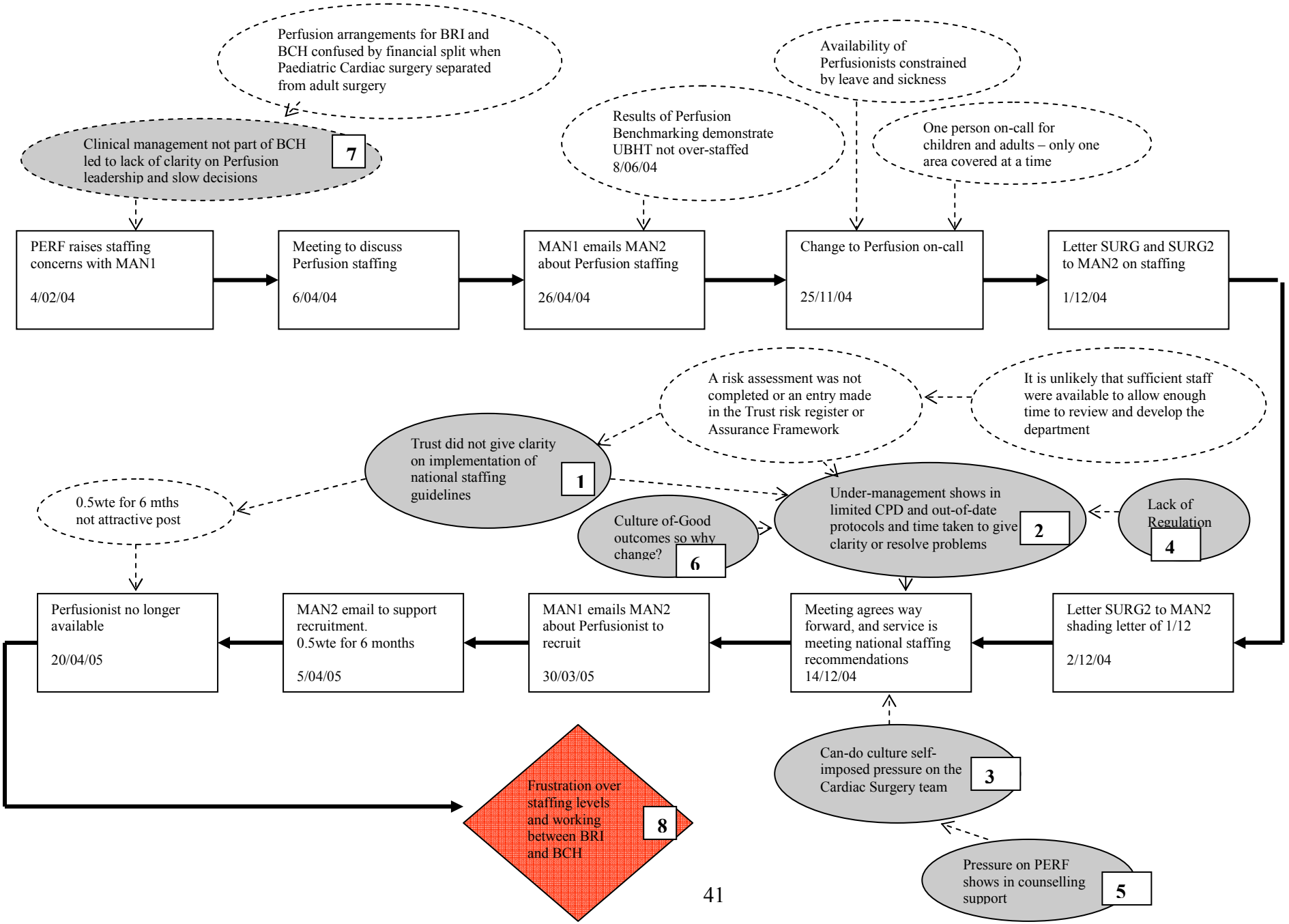


A factor that shaped the outcome of the situation or incident. Shown as a solid oval. Number relates causal factor to other parts of the Report.

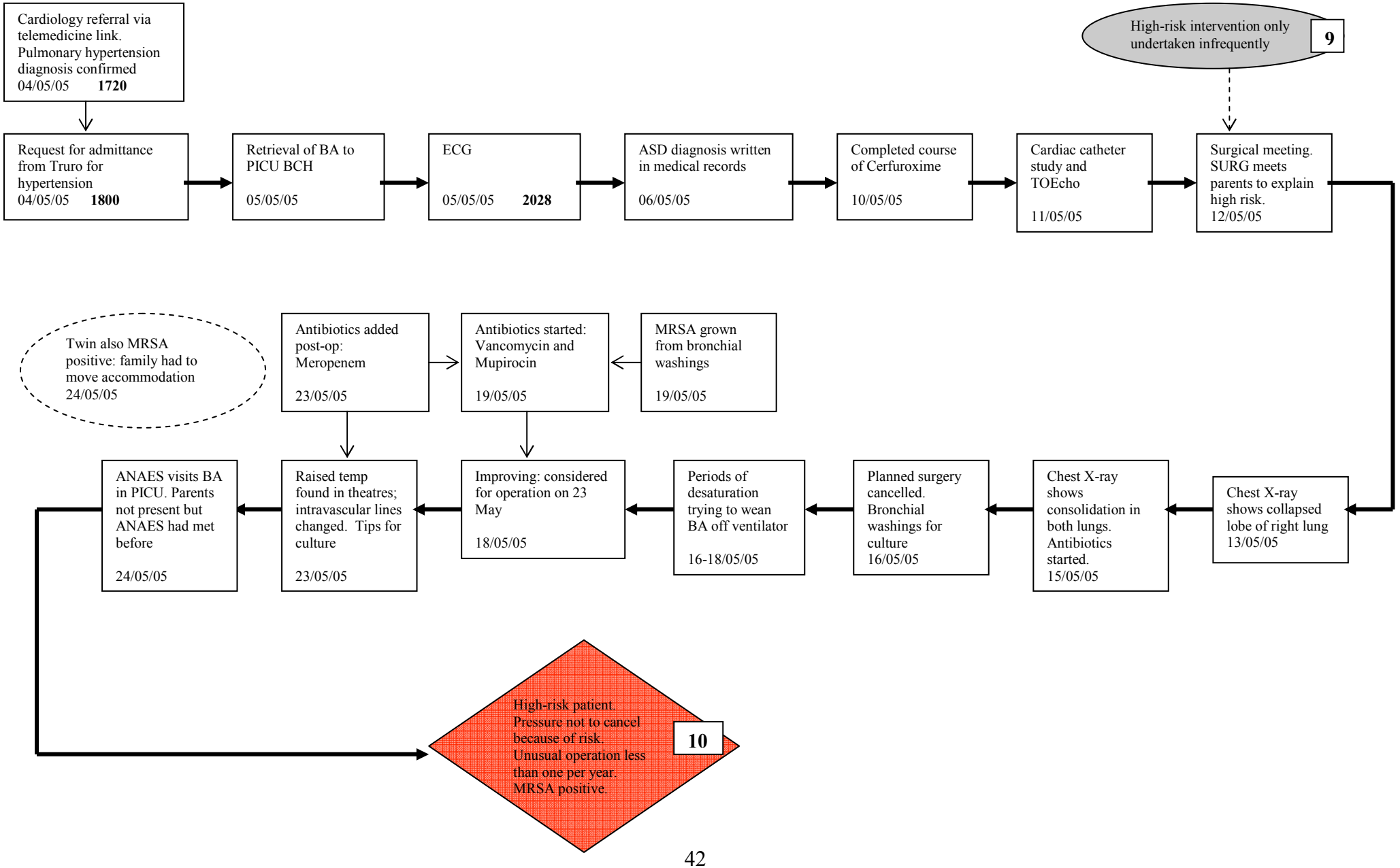
Presumptive Causal Factor

A factor that is assumed because it appears to logically affect another condition or event. Shown as dotted oval.

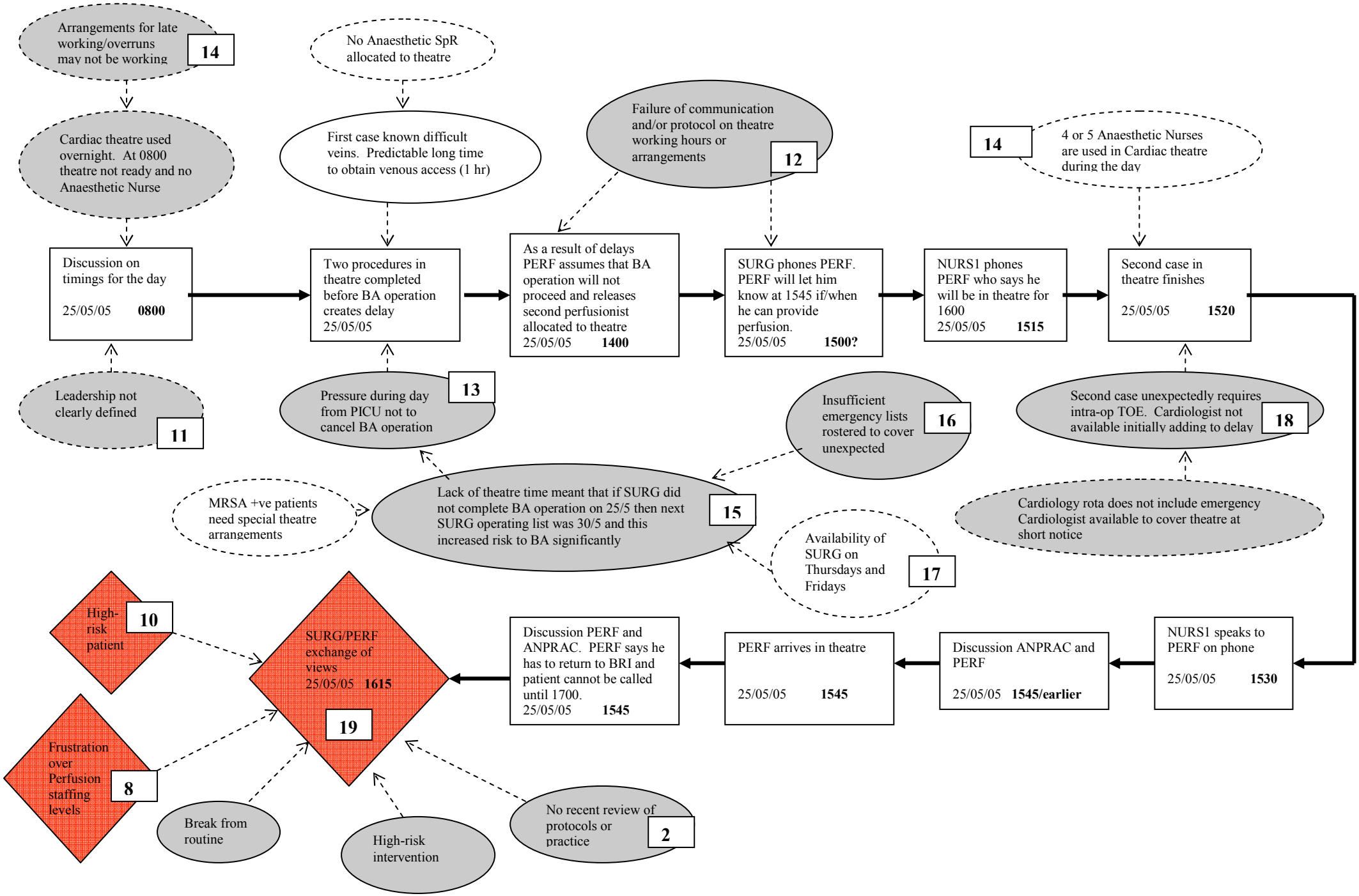
EVENT AND CAUSAL FACTOR CHART - STAFFING ISSUES FEBRUARY 2004 TO ARIL 2005



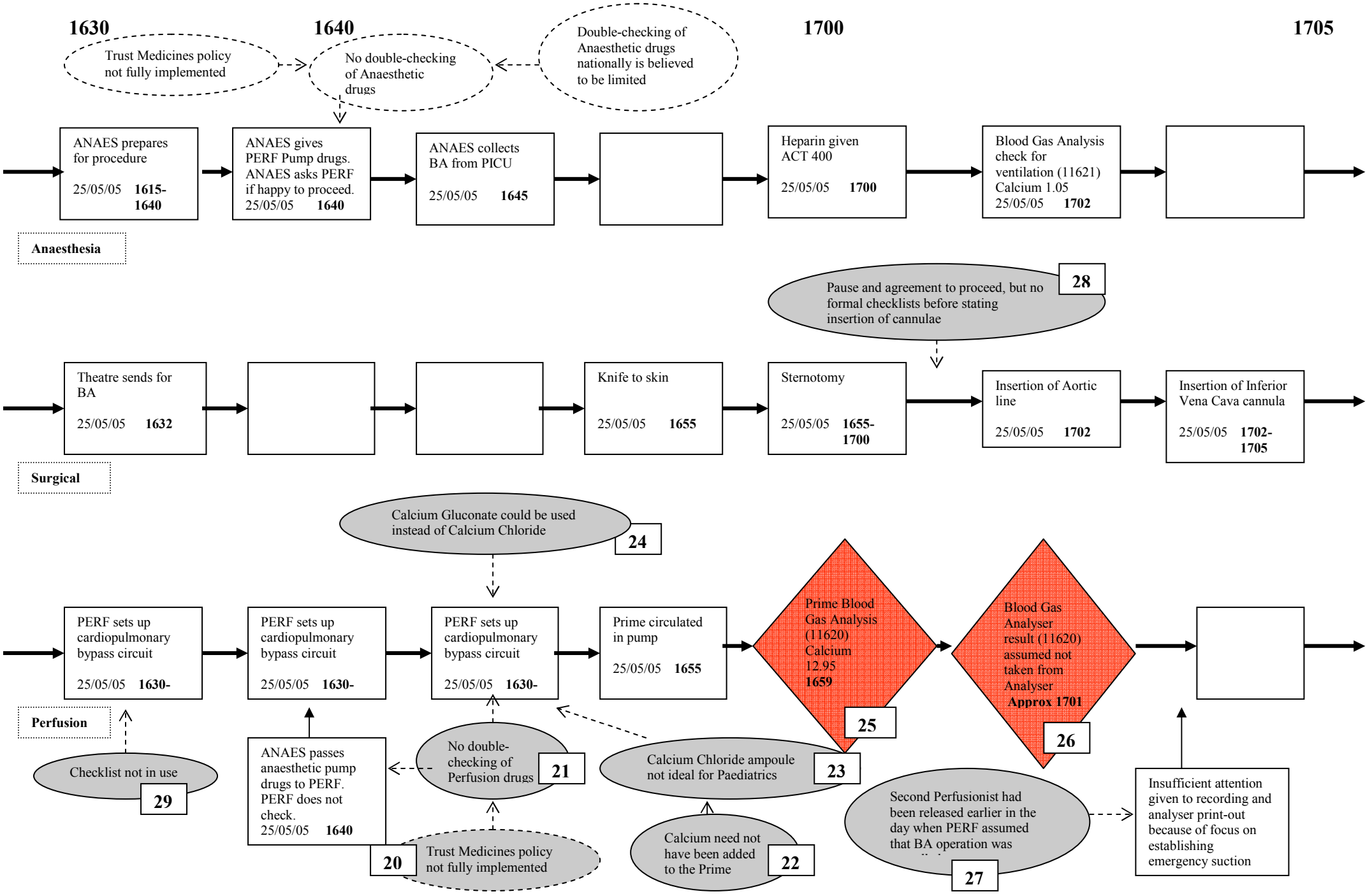
EVENT AND CAUSAL FACTOR CHART - PRE-OPERATIVE PHASE IN PICU 4 MAY TO 24 MAY 2005



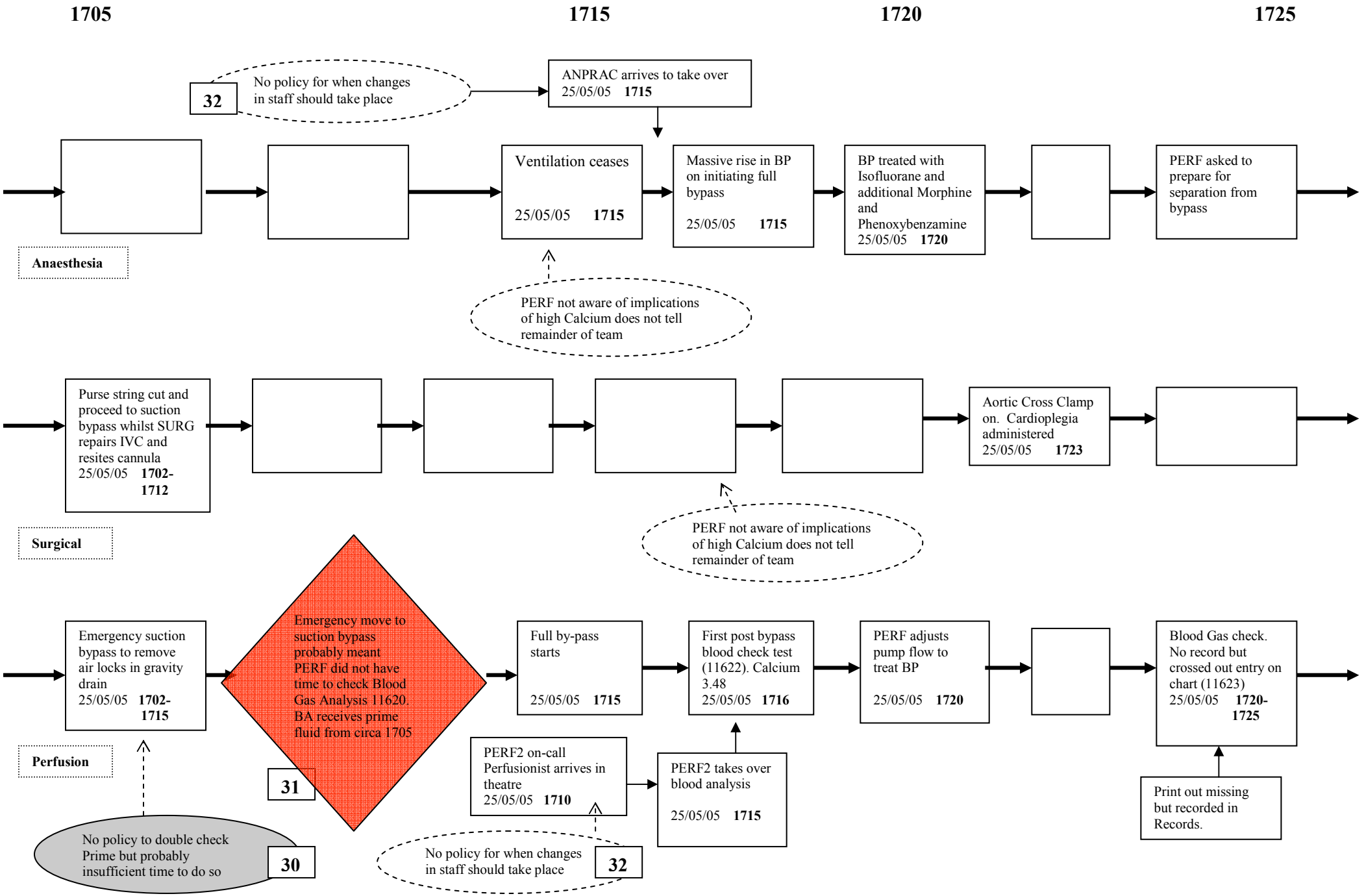
EVENT AND CAUSAL FACTOR CHART - COMMUNICATION ISSUES BEFORE OPERATION 0800hrs to 1615 hrs 25 MAY 2005



EVENT AND CAUSAL FACTOR CHART – PERI-OPERATIVE PHASE 1630 hrs to 1705 hrs 25 MAY 2005

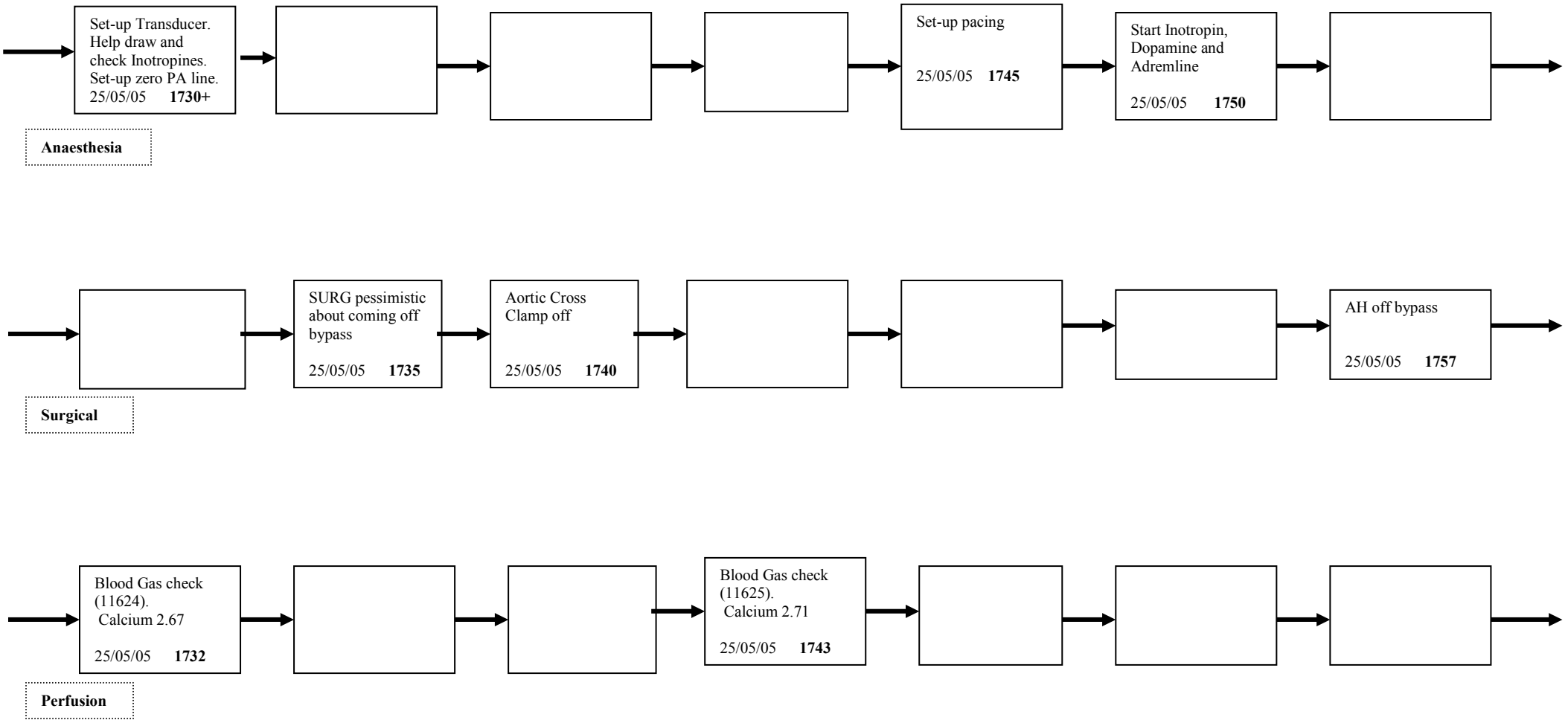


EVENT AND CAUSAL FACTOR CHART – PERI-OPERATIVE PHASE 1705 hrs to 1728 hrs 25 MAY 2005



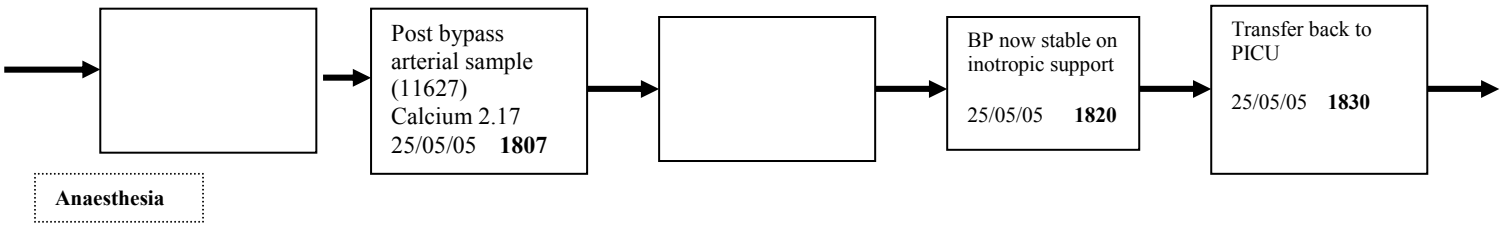
EVENT AND CAUSAL FACTOR CHART – PERI-OPERATIVE PHASE 1728 hrs to 1757 hrs 25 MAY 2005

1730 **1735** **1740** **1745** **1750**

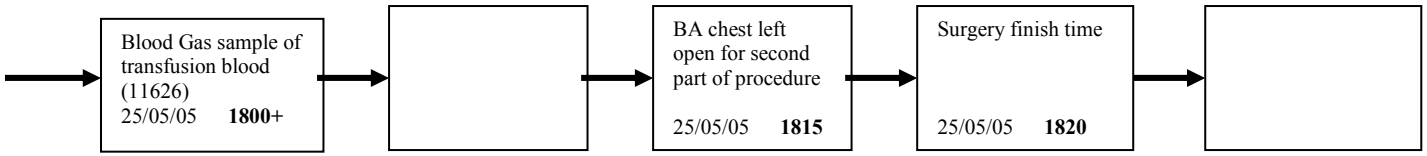


EVENT AND CAUSAL FACTOR CHART – PERI-OPERATIVE PHASE 1757 hrs to 1830 hrs 25 MAY 2005

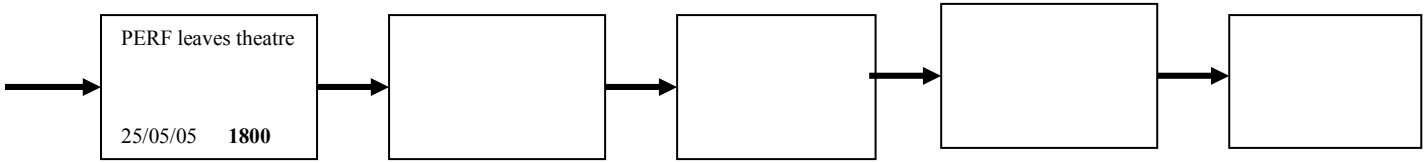
1800 **1805** **1815** **1820** **1830**



Anaesthesia

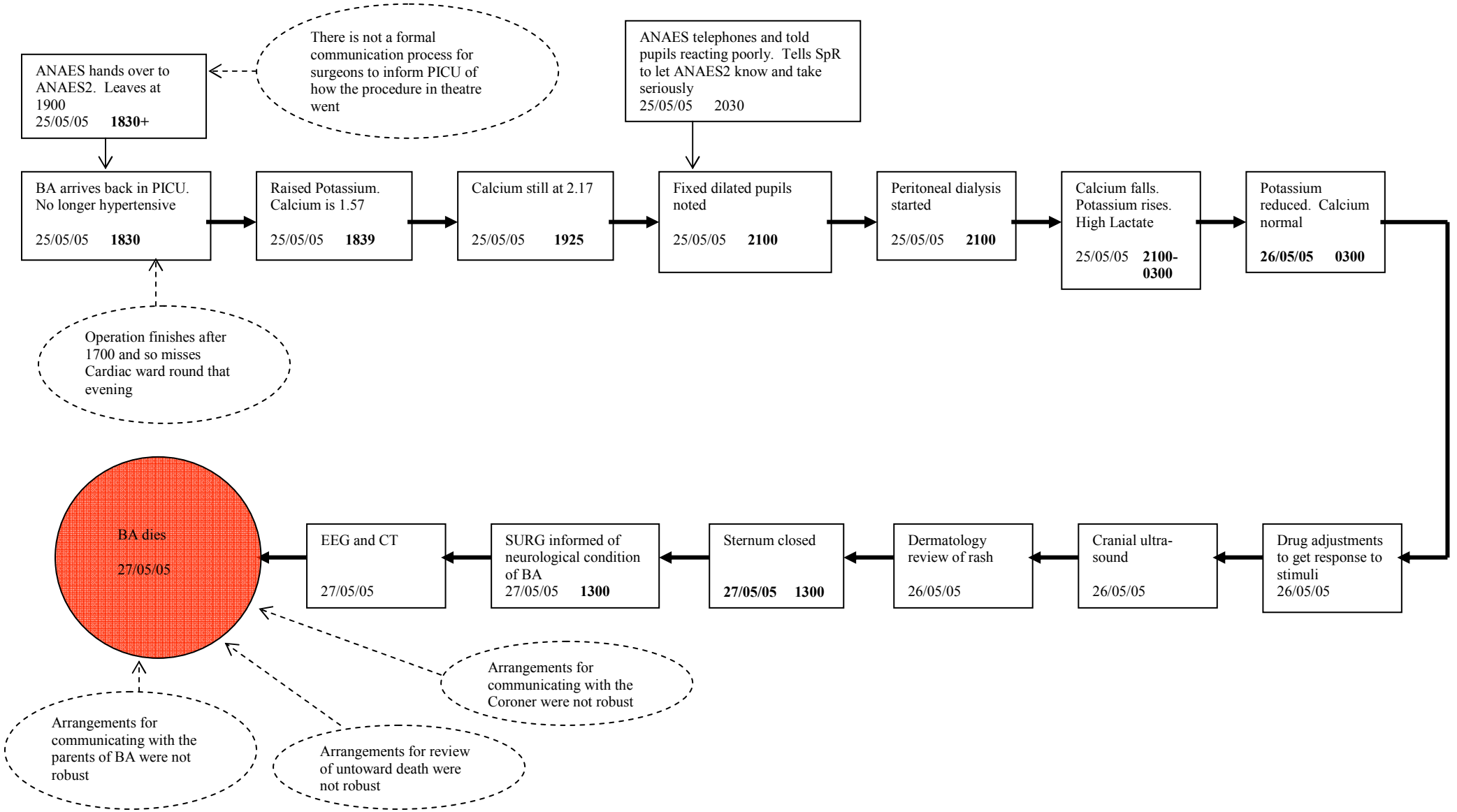


Surgical



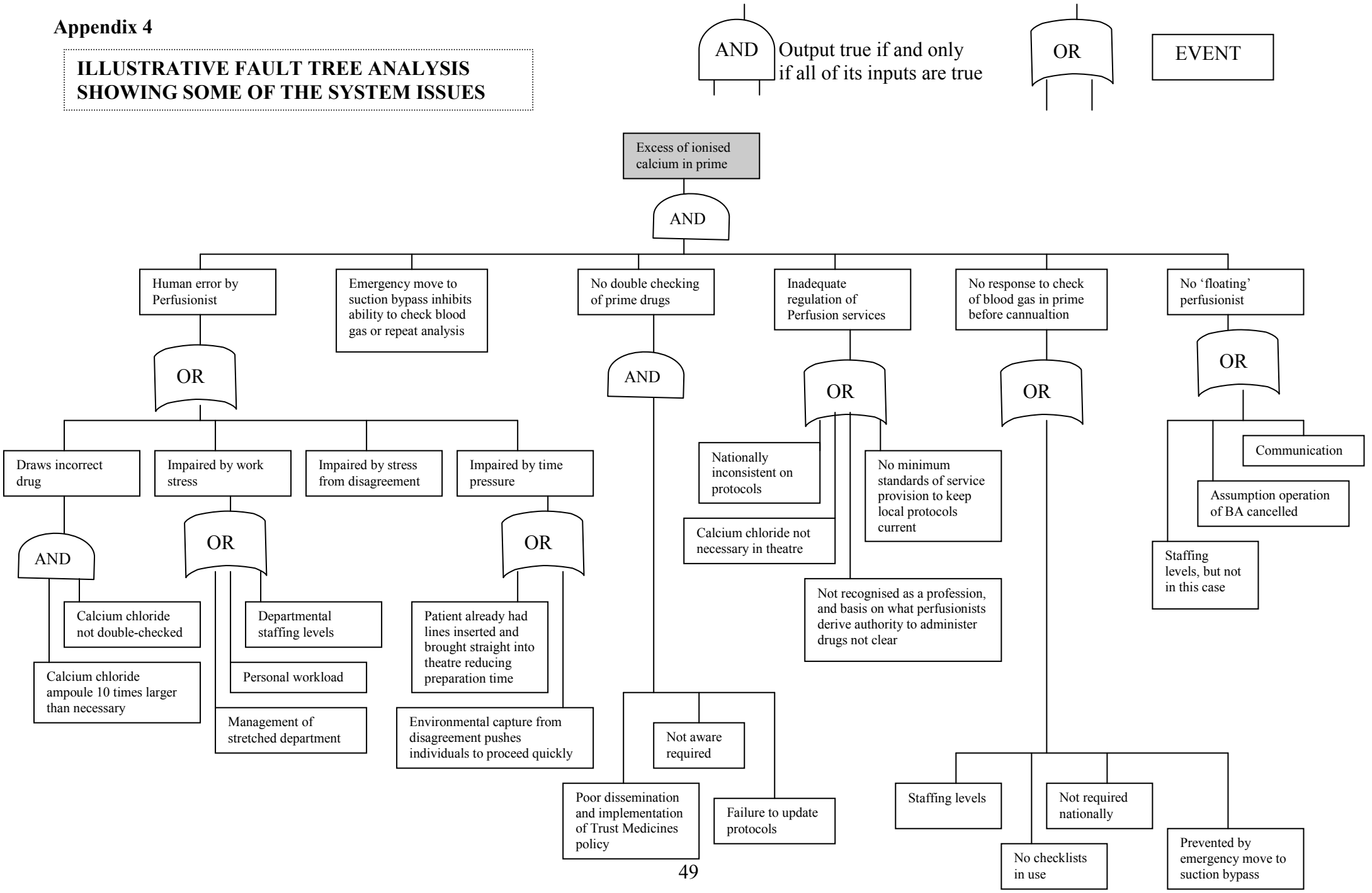
Perfusion

EVENT AND CAUSAL FACTOR CHART - POST-OPERATIVE PHASE IN PICU 1830 hrs 24 MAY TO 27 MAY 2005



Appendix 4

ILLUSTRATIVE FAULT TREE ANALYSIS SHOWING SOME OF THE SYSTEM ISSUES



Appendix 5

ERROR CHAINS

The presence of one or more of the 'clues' set out below is an indication that an error chain might be in progress and that caution is advised.

- **Ambiguity**

Ambiguity exists when 2 or more independent sources of information do not agree. This can include, instruments, people and senses that do not correspond with associated indicators.

- **Fixation or pre-occupation**
  - The focus of attention on any one item to the exclusion of all others. These may include any number of distractions that can draw attention away from the progress of a procedure.
  - Distractions can be the result of high workload or by abnormal and emergency conditions.
  - Distraction can also be the result of personal problems, inattention, complacency and fatigue.

- **Confusion**

When there is a sense of uncertainty, anxiety or bafflement about a particular situation. It may be the result of 'falling behind' the progress of the procedure, lack of knowledge or experience. Perhaps it is being pushed to the limit of one's ability or experience.
It can be evidenced by physiological symptoms such as stomach discomfort, throbbing temple, headache or nervous habit. Researchers suggest that these signals are symptomatic of uneasiness and should be trusted as indicators that all may not be right.

- **No one monitoring the current state of progress as a whole**

No one monitoring the current state of progress of the procedure as a whole; often referred to as 'silo working'.
No one taking responsibility to stand back and review how all the functions might be working together.

- **Use of an undocumented procedure**

The use, in order to deal with abnormal or emergency conditions, of a procedure that is not prescribed in approved guidelines or protocols.

- **Violating limitations or minimum operating standards**

Intent to violate, or actual violation of defined minimum operating conditions or specifications, prescribed by policies, guidelines or protocols whether local or national.

- **Unresolved discrepancies**

Failure to resolve conflicts of opinion, information, or changes in conditions.

- **Failure to meet procedure targets**

Failure of the team to attain and/or maintain identified targets for the procedure. Targets include clinical signs, steps in the process, anticipated timings.

- **Departure from standard operating procedure**
    - Intent to depart or inadvertent departure from prescribed standard operating procedure. Well-defined SOPs are the result of a synergistic approach to problem solving with the influence of time removed.
    - As a result, in difficult situations, SOPs represent an effective means of problem resolution without the sacrifice of time, which is often not available. This is not to suggest that SOPs will resolve all problems. However they are an effective starting point.

- **Incomplete communication**

Incomplete communications are the result of withheld information, ideas, opinions, suggestions or questions, and of failure to seek resolution of misunderstandings, confusion or disagreements.

Appendix 6

REFERENCES

[i] Transcript of Coroner's Inquest into the death of BA.
[ii] Report of the Chemical Pathologist expert witness to the Coroner.
[iii] Report of the Anaesthetic expert witness to the Coroner.
[iv] Congenital Heart Disease website http://www.ccad.org.uk/paedanalysis
[v] Transcript of Coroner's Inquest into the death of BA.
[vi] Congenital Heart Disease website http://www.ccad.org.uk/paedanalysis
[vii] Clinical Audit Report of cardiac surgery cases perfused since 1999.
[viii] National Patient Safety Agency Root Cause Analysis Tool Kit: http://www.npsa.nhs.uk
[ix] Trust Risk Management Policy.
[x] Cause and Effect Staff Events on 27 July 2007 and 7 August 2007.
[xi] Personal statements from formal police report to the Coroner.
[xii] Report of the Anaesthetic expert witness to the Coroner.
[xiii] de Laval, Carthey et al 2000
[xiv] de Laval, Carthey et al 2000
[xv] Report by Professor T Gourlay 20 September 2007
[xvi] Society of Perfusionists and Great Britain and Ireland website: scpgbi.com
[xvii] Clinical Audit Report of Cardiac Surgery Cases Perfused since 1999.
[xviii] Independent Review into the circumstances surrounding 4 serious adverse incidents, Professor Toft Report August 2007
[xix] Report of the Anaesthetic expert witness to the Coroner.
[xx] Extracted an adapted from a report by Global Air Training.
[xxi] Congenital Heart Disease website http://www.ccad.org.uk/paedanalysis
[xxii] Report of the Chemical Pathologist expert witness to the Coroner.
[xxiii] Report of the Anaesthetic expert witness to the Coroner.
[xxiv] Congenital Heart Disease website http://www.ccad.org.uk/paedanalysis