QUEENSLAND COURTS

CORONERS COURT OF QUEENSLAND

FINDINGS OF INQUEST

CITATION:	**Inquest into the death of Joshua Ryan Statis**
TITLE OF COURT:	Coroners Court
JURISDICTION:	Brisbane
FILE NO(s):	2015/4529
DELIVERED ON:	24 October 2018
DELIVERED AT:	Brisbane
HEARING DATE(s):	3 May 2017, 20 – 24 November 2017
FINDINGS OF:	Ainslie Kirkegaard, Acting Coroner
CATCHWORDS:	Coroners: health care related death; paediatric cardiac surgery; Queensland Paediatric Cardiac Service; congenital aortic stenosis; fourth-time sternotomy & redo Konno; right ventricular outflow tract (RVOT) patch; CardioCel; wound management; sternal wound infection; mediastinitis; surgical debridement; VAC dressing; persistent post-debridement fevers and tachycardia; acute bleed from sternotomy wound 18 days post-operatively; after hours surgical assessment of acute bleed; Massive Transfusion Protocol; after hours theatre team call-in; emergency cardiac surgery; rupture of RVOT patch; catastrophic cardiac bleed

REPRESENTATION:

Counsel Assisting:	Melinda Zerner
Jacqui Statis & Irene Dalton:	Katrina Kluss, instructed by Caxton Legal Centre
Children's Health Queensland Hospital and Health Service:	Matthew Hickey, instructed by Minter Ellison Lawyers
Dr Balram Rajanbabu:	Stephanie Gallagher
Dr Christian Stocker:	Andrew Luchich, instructed by Ashurst Australia
Dr Michael Ranger:	David Schneidewin, instructed by Avant Law
Registered Nurse Sarah Duncombe & Registered Nurse Jiby Matthew:	Sally Robb, instructed by Roberts & Kane Solicitors

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Introduction

Joshua Ryan Statis was a 12 year old boy who died unexpectedly at the Lady Cilento Children's Hospital[1] in the early hours of 16 November 2015. At his family's request, these findings refer to Joshua as Joshie.

Joshie had been an inpatient since 26 October 2015 when he was admitted for complex open heart surgery for complications of a congenital heart condition. This surgery, performed on 29 October, involved replacing Joshie's mechanical aortic valve and placement of CardioCel patches to cover a ventricular septal defect and to enlarge the right ventricular outflow tract. His sternotomy wound started oozing on 7 November and was initially managed conservatively with antibiotic therapy. He was then returned to theatre on 13 November for debridement and VAC dressing of the sternotomy wound with a plan to return to theatre on 16 November to reassess the wound and change the VAC dressing. At around 2:00am on 16 November Joshie developed acute bleeding from the sternotomy wound into the VAC canister. Despite heroic efforts on the ward and in the Paediatric Intensive Care Unit (PICU), the bleeding was unable to be controlled and he died two hours later shortly after being taken back to theatre for emergency chest reopening. The catastrophic bleeding occurred because the CardioCel patch applied to the right ventricular outflow tract had ruptured. This complication was initially attributed to mediastinal infection.

Joshie was one of six children born to Jacqui and Nick Statis. He was a brother to Emmanuel, Irene, Faith, Anastasia and Jonathon. The children's maternal grandparents were closely involved in their lives.

Joshie had a complex medical history having been born with a severe congenital heart condition requiring three open heart surgeries before he was two years old. He also had developmental delay and had been diagnosed as being on the autism spectrum at age 4. He attended the Redcliffe Special School.

The statement provided by Joshie's grandparents describes a very much loved "complex quirky boy" with a cheeky sense of humour, the odd burst of colourful language when he became frustrated and active curiosity about life and his family's strong faith. To his family, Joshie was "just perfect". It is evident they were deeply dedicated to his care and happiness. Joshie is dearly missed by all who knew and loved him.

Joshie's medical history

Joshie was born with severe aortic stenosis and hypertrophy of his left ventricle. This had been identified antenatally. He underwent an aortic valvuloplasty at three days of age. He then had a mechanical valve

[1] Since the inquest it has been proposed that Lady Cilento Children's Hospital be renamed Queensland Children's Hospital

implantation with a Konno procedure at three months of age. His aortic valve was replaced with a 16mm ATS mechanical valve. He subsequently developed right ventricular outflow tract (RVOT) obstruction related to the Konno procedure requiring revision when he was 13 months old. This involved enlarging the RVOT with a bovine pericardial patch. He had a primary left ventricular myocardial abnormality.

Joshie had been under the care of paediatric cardiologist Dr Rob Justo all his life. Dr Justo had cared for Joshie from birth at The Prince Charles Hospital and later at the Mater Children's Hospital.

As Joshie grew he developed progressive left ventricular outflow tract obstruction but remained stable. The concern was this would impact his exercise intolerance. It appears consideration was being given to further surgical intervention as at June 2014.

The Lady Cilento Children's Hospital (LCCH) opened in November 2014, amalgamating the former Royal Children's Hospital and the Mater Children's Hospital services.

In May 2015, Joshie was referred to Dr Nelson Alphonso, Director of the Queensland Paediatric Cardiac Service at LCCH. Dr Alphonso considered surgery was necessary to redo the Konno and upgrade the mechanical aortic prosthesis to a larger size, as Joshie had outgrown the valve that had been placed when he was three months old. It is described in the medical record as being clinically indicated due to diffuse gradients across the aortic valve.

As at October 2015, Joshie's regular medications were Lisinopril 5mg daily, Warfarin and Risperidone (which had been commenced when he was 10 years of age). Joshie had been on Lisinopril since his first surgery in February 2003. It was commenced at an infant dose and then changed to tablet form.

Obtaining peripheral venous access for Joshie was challenging. Medical interventions and being in hospital caused him considerable anxiety.

The investigation

Joshie's death was appropriately reported as a health care related death under the *Coroners Act 2003* due to the treating team's opinion that he died from cardiac haemorrhage resulting from sternal wound dehiscence in the context of recent cardiac surgery to manage complications of congenital aortic stenosis.

Being an extraordinarily rare and completely unexpected complication, Joshie's death was initially discussed with the on-call coroner who directed that it be reported by way of the Form 1A (Medical practitioner report of death to a coroner) process. This is a fast-track preliminary investigation to assess whether it is appropriate to authorise the issue of a cause of death certificate without coronial autopsy and further coronial investigation.

Preliminary clinical review of the hospital record undertaken by an independent doctor from the Department of Health Clinical Forensic Medicine Unit (Dr Adam Griffin) identified concerns about aspects of Joshie's post-operative and emergency management, namely:

1. the adequacy of the management of the emergency response to Joshie's acute bleeding and deterioration on the ward in the early hours of 16 November 2015, including delay in identifying the site of the bleeding and the time taken to get Joshie into the operating theatre; and
2. potentially missed opportunities for earlier identification of the extent of mediastinitis revealed during the emergency surgery.

Having regard to this preliminary advice, the then Deputy Registrar of the Coroners Court of Queensland declined to authorise the issue of the proposed cause of death certificate and ordered a coronial autopsy and further investigation.

Joshie's family subsequently expressed concerns about his clinical management at LCCH, namely:

- the decision not to insert a Peripherally Inserted Central Catheter (PICC line) pre-operatively;
- adequacy of the wound management by nursing staff on the ward;
- the effect of the abrupt cessation of his Lisinopril medication after the surgical debridement on 13 November;
- Joshie kept complaining that his heart hurt but they were constantly told it was fixed and the pain was from his lung collapse; and
- whether Joshie was tested for, or symptomatic of infection with Mycobacterium Chimaera.

Joshie's care and the events leading up to his death were discussed by the Queensland Paediatric Cardiac Service Quality Assurance Committee on 9 December 2015. This meeting was attended by paediatric intensivists, anaesthetists, cardiology consultants and Fellows and the two cardiac surgeons and the two cardiac surgery Fellows involved in Joshie's care. The Committee identified a need to improve the hospital's Massive Transfusion Protocol, for a simulation of the cardiac surgical team call-in list and to establish a multidisciplinary working group to review the process for urgent cardiac surgery theatre team call-in.

LCCH also commissioned a Root Cause Analysis (RCA). This is a systemic analysis of what happened and why and is designed to make recommendations to prevent adverse health outcomes from happening again, rather than to apportion blame or determine liability or investigate an individual clinician's professional competence. It is conducted by a review team who had no involvement in the patient's care. The RCA team did not source expert and/or external opinion. The RCA was completed on 20 January 2016 before the autopsy report was finalised.

The RCA review team identified the following contributory factors and made a series of recommendations to address them:

1. ***failure of integrity of the CardioCel patch*** – the RCA team considered several theories about what caused the RVOT patch to rupture – a specific flaw in the patch; cardiac motion causing rubbing on the patch leading to its rupture; or infection (with deep infection – mediastinitis – the mechanism of infection that could potentially contribute to patch dehiscence). It recommended investigation of the CardioCel patch with feedback to the Therapeutic Goods Administration.

2. ***more robust interaction with the Infectious Diseases team*** – the RCA team considered Joshie had received the appropriate four doses of prophylactic Cephalozin and his post-operative fevers were managed appropriately. It identified undertaking a more robust interaction with the Infectious Diseases team as an area for improvement (while there was liaison with this team but no formal patient review) and recommended LCCH review the interaction between infectious diseases and all surgical services and theatre to identify opportunities for quality improvement.

3. ***delay in calling in the full cardiac surgical theatre team*** - the RCA team observed there was no clinical consensus about whether a surgical cause for the bleeding was likely, so there was a delay in calling in the full on-call cardiac surgical theatre team. The RCA team noted that Joshie remained physiologically compensated for over 90 minutes, both initially while on the ward and during the initial phase of treatment in the PICU. Joshie's apparent physical condition did not align with the underlying severity of the situation. With hindsight, it was noted that bleeding from the RVOT patch rupture occurs at a pressure that is lower than the aorta so while the bleeding is massive, it occurs at a lower pressure allowing containment with pressure dressing without causing a tamponade; haemodynamic stability depends on maintaining blood volume which may explain how Joshie remained compensated for so long.

   The RCA team observed that while some of the Medical Emergency Team (MET) considered a surgical cause for the bleeding to be most likely, there may have been diagnostic bias by others of the clinical team who were aware of the preceding wound infection, perhaps clouding consideration of a different, more serious cause for the bleeding.

4. ***issues with then current processes for direct ward to theatre transfer for urgent cardiac surgery*** – the cardiac surgical theatre team call-in could only be activated by designated surgical staff. The RCA team identified a poorly shared understanding about who could initiate an emergency cardiac surgical theatre team call-in and there was no emergency activation process for this particular team. There was a lack of clarity about theatre call-in processes and which team to activate. The call sheet was incomplete for on-call theatre staff on 15-16 November, with restricted access to the computer drive to access on call. Consequently, the RCA team recommended a review of the processes for the call-in of theatre staff after hours. It also recommended that consideration be given to the need for a 24/7 on site theatre team at LCCH.

5. ***a lack of clarity around the Massive Transfusion Protocol (MTP) purpose, role delineation and processes for initiation, implementation and ongoing management*** – the RCA team identified the execution of the MTP process was flawed resulting in delays in receiving adequate blood products. There was no central person responsible for liaising with the Blood Bank and after hours there were limited rostered Blood Bank staff which contributed to the confusion and communication breakdowns that led to delays in administering blood products. The RCA team recommended that LCCH review the process for MTP activation, implementation and management.

The RCA team also made recommendations for a standardised procedure for vascular line documentation and for a review of the LCCH cardiac theatre layout.

Autopsy results

An external examination and partial internal autopsy (chest only) was performed by an experienced forensic pathologist, Dr Nadine Forde, at the John Tonge Centre on 24 November 2015.

With the then Deputy Registrar's consent given under the *Coroners Act 2003,* section 21, the consultant paediatric cardiothoracic surgeon (Dr Venugopal) and the cardiac Surgical Fellow (Dr Rajanbabu) responsible for Joshie on the night he died were present at the autopsy as 'observers'. In complex surgical deaths, it is not unusual for the pathologist to seek the coroner's permission for treating surgeons to attend the autopsy to inform the pathologist's understanding of the surgery performed. In practice, the coroner's decision under section 21 of the Act is made having regard to both the forensic needs and integrity of the coronial investigation. I am satisfied the presence of Dr Venugopal and Dr Rajanbabu did not unduly or improperly influence Dr Forde's findings or cause of death determination. As such I do not consider it necessary to make the recommendation sought by the family to prevent treating doctors from attending coronial autopsies.

The final autopsy report issued on 13 December 2016.

The autopsy confirmed recent cardiac surgery including an aortic valve replacement, interventricular septal patch and RVOT patch. The surgical sutures present were all intact.

The RVOT patch showed a large defect centrally with friable remnants of the patch present at the periphery. Dr Forde reported her observations in the following terms "*On the anterior aspect of the right ventricle, is a full thickness defect, 35mm x 25mm. Around the periphery of the defect are the remains of a membranous surgical patch which formed part of the right ventricular outflow tract. The sutured margins of the patch appear intact, however the central region of the patch is absent, forming the defect described. Through this defect, a second roughly triangular shaped membranous surgical patch (35mm x 25mm) is seen in the interventricular septum adjacent to a*

mechanical aortic valve. This patch has been inserted to expand the root of the aorta in order to fit the new valve. The interventricular patch appears to be intact. The valve appears well seated, with mobile leaflets, no thrombus formation and no disruption to the surgical line. Just superior to this valve, the two surgical patches meet and are sutured together. This suture line appears to be intact. There is no evidence of dehiscence along the sutured margins. The residual right ventricular outflow patch appears slightly friable however there is no adherent purulent material. There was no macroscopic evidence of purulent material or other reason to explain the disintegration of the patch in this region.

The microscopic examination findings were reported as:

- lungs - patchy lung collapse with no evidence of acute pneumonia
- RVOT patch - "*Dense collagenous material with a florid acute inflammatory infiltrate and necrotic debris*"
- interventricular septum patch – "*Dense collagenous material, the surface of which shows some endothelial growth. There is also acute inflammation, fibrin and necrotic debris, although less severe than that present on the right ventricular outflow patch*."
- aorta – "*Arterial wall with some calcification. There is some acute inflammation, fibrin and apoptotic debris, as well as granulation tissue. Near the adjacent patch there is acute inflammation, necrotic debris and fibrin*."
- tissue on heart surface – "*there are red cells and a few scattered white cells amongst eosinophilic material. In some adjacent fat there is a foreign body giant cell reaction with some giant cells surrounding foreign material. This may be suture material. There is also some haemosiderin deposition and chronic inflammation*."
- coronary arteries: '*there is mild intimal thickening of the right coronary artery. Otherwise normal morphology with no inflammation or thrombus formation*."
- heart: "*there is mild myocyte hypertrophy but no disarray. Many intramural vessels are thickened and show perivascular fibrosis. There is no evidence of acute infarction. There is no significant inflammation within the epicardial fat. Near the right ventricular outflow tract there is a mixed inflammatory infiltrate in the epicardial fat. Some foreign material is also seen in this region, consistent with suture material*."

In short, there was acute inflammation and necrosis in the region of the RVOT patch.

Post-mortem microbiology testing performed on the right ventricular outflow tract patch grew *Rothia dentocariosa* and *Corynebacterium* (the latter considered to be contamination). Dr Forde described the presence of *Rothia dentocariosa* as being of uncertain significance, suggesting that given it did not grow from tissue taken intra-operatively around the time of death, it may be a contaminant. However, it is an organism known to infect heart valves.

Dr Forde was unable to identify a definitive cause for the degeneration of the RVOT patch. She considered infection remained a possible cause although no organism was grown from tissue taken at the time of the emergency surgery. She commented that given Joshie had been on a number of antibiotics, this may have inhibited growth. There was no definite evidence of pneumonia in the lungs. Dr Forde posited that the ongoing fevers Joshie experienced post-operatively may have been related to an infection of the patch.

Having regard to the autopsy findings and the clinical history, Dr Forde determined the cause of death to be cardiac haemorrhage due to or as a consequence of congenital aortic stenosis (surgically repaired).

Further histology review

On 2 May 2017, with my consent, Dr Alphonso met with Dr Forde, to review the histology sections of the CardioCel patches used in Joshie, being slides of the ruptured RVOT patch and the one that was still intact. Dr Alphonso showed Dr Forde pictures of previous CardioCel explants for comparison as part of this exercise. Dr Alphonso later advised the Therapeutic Goods Administration (TGA) that he observed marked inflammatory changes through one of the patches consistent with infection, and that as CardioCel is a biological material it will not be immune to infection. He advised the TGA that in their experience of nearly 350 implants, this is the only patch that has become infected. He proferred the opinion that this incidence was extremely low and he had no concerns in this regard.

Dr Forde provided a further report regarding her observations during the review of the histology slides with Dr Alphonso. She noted that the ruptured patch showed marked inflammatory change throughout the patch. The intact patch showed features similar to others Dr Alphonso had seen with some superficial inflammatory changes only. Dr Forde's impression was that Dr Alphonso felt reassured that the ruptured patch showed much more inflammation and was likely infected, rather than rupture spontaneously. Dr Forde clarified that as she had indicated in her autopsy report, she also felt infection was a possible cause of the inflammation and rupture, although a specific organism could not be identified. She did not consider it necessary to issue an amended autopsy report as she had no new objective information affecting the opinion expressed in her autopsy report.

Notification to Therapeutic Goods Administration

In May 2016, I formally notified the TGA about the circumstances of Joshie's death.

The TGA advised that as at July 2016 the CardioCel cardiovascular patch was classified as Class III (high risk) medical device intended for the repair of intracardiac defects including septal defects and valve and annulus repair. The TGA was in the process of assessing the manufacturer's application for conformity assessment. At that time the patch was included in the Australian Register of Therapeutic Goods as an export only device, meaning the manufacturer did not have approval to supply the patch in Australia. As an

'unapproved therapeutic good', it could only be supplied to Australian patients with Special Access Scheme exemption. It has been approved for use in Australian under the TGA Special Access Scheme and Authorised Prescriber Schemes since October 2012.

The TGA advised there was no record of Special Access Scheme notification for the supply of the patch to Joshie. However, there was approval under the Authorised Prescriber Scheme to supply the patch at LCCH. Under this scheme, prescribers have an approval to supply the patch to their patients under a particular set of approved indications for a period of 12 months. The prescribers do not need to report the details of individual patients supplied with the patch; they are only required to report the number of patches supplied over each six month period of approval.

The TGA advised it had received nine deidentified Device Incident Reports for the CardioCel patch used through the Authorised Prescriber Scheme. I have been provided with copies of the investigation reports which all note "*it appears that the current rates of adverse events, including restenosis and thrombosis are low compared to that seen in the published literature. The higher rate of adverse events in Australia as seen world-wide have been discussed and reviewed by Advisory Committee on the Safety of Medical Devices, the pre-market clinical team and post-market medical device team. The rate and pattern of adverse events will be monitored through the IRIS system, in addition to the pre-market team undertaking their clinical review of the application for inclusion on the ARTG*." None of the incident reports documents complications similar to those that occurred for Joshie.

Dr Alphonso independently made a notification to the TGA on 19 April 2017.

Dr Alphonso liaised with the manufacturer, Amedus Regen Ltd, including a visit to the Admedus facility in Perth on 16 May 2017. During this visit he received a demonstration of their quality assurance & control processes for CardioCel including a tour through the facility which lasted several hours. The technology and methods were explained to him by the inventor of CardioCel, Prof WML Neethling. Dr Alphonso also reviewed the batch release records for the two CardioCel patches that were implanted in Joshie. He subsequently advised the TGA he had no concerns about the testing processes and the structural integrity of CardioCel and indicated his continued use of it in his practice for the repair of congenital heart defects.

The CardioCel device is FDA approved and CE certified and commercially available in the USA, European Union and Canada. It is also registered and commercially available in Singapore, Malaysia, Hong Kong and several Middle East countries.

The manufacturer advised that over 8700 CardioCel patches have been implanted worldwide with no device-related adverse events in terms of structural integrity or sterility having been reported or questioned.

The CardioCel patches implanted in Joshie were from batches M15050 and M15079. The manufacturer undertook a review of the batch details which determined there had been no Customer Events or Adverse Events associated with either batch. Its review of SAS Scheme data revealed 53 devices were used by the Princess Margaret Hospital for Children, Perth and the Royal Children's Hospital, Melbourne over the period 30 June 2015 – 30 June 2016 with no Adverse Events or Customer Events reported. Its review of the Authorised Prescriber Scheme data showed there were only two authorised prescribers over this same period – Dr Alphonso and Dr Venugopal, who between them had implanted 76 CardioCel patches over the 30 June 2015 – 30 June 2016, with no Adverse Events or Customer Events reported.

The manufacturer advised both batches were compliant with current manufacturing standards approved by the FDA and BSI (CE mark) and as at May 2017, the complications arising in this matter, are the only clinical adverse event to be reported on devices manufactured from either batch M15050 or M15079.

Expert reports

The investigation was further informed by independent cardiothoracic surgeon review and opinion provided by Clinical Associate Professor Richard Chard. A/Professor Chard is a senior consultant in the specialty with experience in both paediatric and adult cardiac surgery patients. A/Professor Chard practises in New South Wales including at The Westmead Children's Hospital. A/Professor Chard provided an initial report in August 2015 followed by two supplementary reports provided in March and November 2017. He provided these reports after reviewing material contained in the coronial brief of evidence.

In summary, A/Professor Chard considered that the RVOT CardioCel patch rupture was likely related to mediastintis, there having been clinical evidence of this infection starting from day 8 post-operatively and obvious by day 12 post-operatively. He was critical of the timing and adequacy of the surgical debridement. He felt the presence of a significant fever after the debridement and VAC dressing would have supported further exploration a day or two before the events of 16 November 2015. A/Professor Chard considered the cardiothoracic surgeon and his Fellow seriously underestimated the severity of Joshie's bleed in the early hours of 16 November which in his opinion warranted immediate surgical exploration with bypass available.

In June 2017 LCCH, through its legal representatives, engaged a joint expert review undertaken by Dr Kirsten Finucane, Paediatric Cardiac Surgeon and Surgeon-in-Chief, Starship Hospital in Auckland, New Zealand and Professor Igor Konstantinov, Paediatric Cardiac Surgeon, Royal Children's Hospital in Melbourne, both having significant experience in paediatric cardiac surgery.

In summary, the LCCH experts considered Joshie's post-operative management and timing of the surgical debridement were appropriate; it might have been advisable to open the sternum on 13 November 2015 despite it

being stable; it was not possible to conclude whether infection in the mediastinum was present and missed by the surgeons on 13 November; Joshie's management over 13-15 November would likely be very similar in any other paediatric cardiac surgical unit; there were several significant communication errors during the first hour after the MET call at 2:00am on 16 November leading the consultant cardiothoracic surgeon to believe the bleeding was superficial and could be dealt with in PICU; Joshie's initial management on the ward that night was excellent; and it was appropriate for Joshie to be transferred to PICU from the ward given it is not the practice for most paediatric cardiac institutions to keep a theatre open 24 hours and it would have been impossible to transfer him directly from the ward directly to theatre. The LCCH experts concluded it was very unlikely Joshie's life could have been saved in a situation they described as being extraordinarily rare.

The LCCH experts considered the likely cause of the RVOT CardioCel patch rupture was negative pressure due to a progressive sternal dehiscence (probably non-infective) after the surgical debridement performed on 13 November. They put forward a scenario in which there may have been a small breach that allowed the RVOT CardioCel patch to be sucked against the chest wall and towards the VAC dressing, this exposure to vacuum being known to create damage, tissue necrosis and a hole that can result in sudden bleeding. They were unable to completely rule out infection of the mediastinum but favoured the vacuum mechanism as a more compelling explanation given the post-mortem histology findings.

When commissioned by LCCH, Dr Finucane and Professor Konstantinov were asked to review not only the coronial brief of evidence but also other documents not available to the coronial investigation, to conduct a site inspection at LCCH and to interview people, a number of whom had already been identified as witnesses for this inquest.

It is evident from Dr Finucane and Professor Konstantinov's joint report that not all of the people identified in the Terms of Reference for their review were interviewed and at least three of the people who were had not been identified in the Terms of Reference (including the Director of Cardiology and the Director of Anaesthesia). Neither of the cardiac surgery Fellows involved in Joshie's care were interviewed. There is no audio or written record of the interviews or any clear indication of the documentary material these experts relied on. As observed by Counsel Assisting in her submissions, it is not possible from the report to establish the factual basis on which these experts relied in forming the opinions presented in that report.

Doctors, nurses and allied health personnel involved in Joshie's pre-operative and post-operative care and the clinicians involved in the emergency response to his acute bleeding on 16 November 2015 were asked to provide formal statements responding to the issues identified by the preliminary and independent expert reviews. Children's Health Queensland Hospital & Health Service was asked to provide a statement outlining its progress in implementing changes at LCCH to address issues arising from Joshie's death.

Joshie's mother, Jacqui, and her mother, Irene Dalton, were present with Joshie during his hospital stay. Joshie's parents and Mrs Dalton provided statements about their observations and recollection of events over the course of Joshie's admission. Prior to the surgery, Jacqui and her sister created a Facebook page "Joshua's Journey" to keep friends and family updated on his progress. The Facebook pages relevant to the hospital admission were tendered as evidence.

The inquest

The inquest was held over five days, 20-24 November 2017. Surgical, medical, nursing and allied health staff involved in Joshie's care gave evidence, as did the three clinical experts, and the Executive Director Medical Services, Children's Health Queensland, Dr Andrew Hallahan. Joshie's mother and grandmother also gave evidence.

Due to the perceived unreliability of some of the information contained in the expert reports, the experts were examined at length regarding their opinions on a number of key issues. A/Professor Chard was present to hear the evidence of Drs Forde, Finucane and Konstantinov before giving his evidence. All three experts made a number of concessions based on the factual scenarios put to them.

Members of Joshie's family and friends attended each day of the hearing.

In addition to the findings required by the *Coroners Act 2003*, s. 45(2), the inquest examined the following issues arising from Joshie's clinical management and death at the LCCH:

(a) whether the cardiac bleed was diagnosed in a timely way;
(b) whether attempts to manage the cardiac bleed were undertaken in a timely way;
(c) what was the cause of the cardiac bleed; and
(d) whether the postoperative care provided to Joshie following the initial surgery on 29 October 2015 was otherwise appropriate.

Extent to which the family is entitled to make submissions

I have been greatly assisted by Counsel Assisting's comprehensive submissions and those provided by Counsel representing LCCH, separate Counsel for various clinicians involved in Joshie's care and Counsel representing the family.

In response to the family's submissions, Counsel Assisting submitted that section 36 of the *Coroners Act 2003*[2] should be read as maintaining the common law position espoused in *Annetts vs McCann*[3] that a family's legal

[2] [insert s.36]
[3] (1990) 170 CLR 596

entitlement is confined to making submissions in respect of matters which may be the subject of adverse findings against them personally or against the deceased, and further, as there is no evidence on which an adverse finding could be made against Mrs Statis personally or Joshie, I should regard the family's submissions.

In response, Counsel representing the family submitted the ability of a family member to make submissions at an inquest in Queensland is not limited by the decision in Annetts; rather the position in Queensland appears to have been deliberately broadened or at least distinguished from the position in Western Australia following Annetts so as to allow a family member to make submissions without the limitation imposed by the Annetts decision and later incorporated in the Western Australian legislation. Further, it was submitted that an interpretation of section 36 of the Coroners Act so as not to restrict or limit the matters about which the family can make submissions is consistent with Parliament's intention and the State Coroner's Guidelines.

The State Coroner discussed this issue in detail in his findings in the inquest into the death of Hamid Khazaei which were delivered after the parties had provided their submissions in this matter. In that inquest, the State Coroner considered a submission that the family's submissions extended beyond their right to make submissions and that they should be removed from the record. After considering relevant case law, the State Coroner concluded that the limitation on the right to make submissions that was held to exist in *Annetts v McCann* does not apply to an inquest under the Coroners Act 2003, a conclusion supported by consideration of the legislative history of section 36 and the State Coroner's Guidelines. The State Coroner held that in the absence of any limitation sought or imposed on the family in relation to the matters on which the family would be able to make submissions, the family had a sufficient interest to make submissions with respect to the factual findings which the coroner is required to make, as well as recommendations under s.46.[4] I adopt his Honour's reasoning in relation to the operation of section 36 which entitles to Joshie's family to make submissions in relation to those matters in this inquest.

Joshie's treating team

It must be acknowledged that paediatric cardiothoracic surgery is an extremely small specialty in Australia. At the time of this inquest, there were only two consultant surgeons registered in this subspecialty in Queensland, out of ten across Australia. Both surgeons, Dr Nelson Alphonso and Dr Prem Venugopal, were involved in Joshie's care once he was referred to the Queensland Paediatric Cardiac Service in 2015.

Dr Nelson Alphonso obtained his medical degree in India in 1991 and completed specialist cardiothoracic training in Ireland in 2003. He is licensed

[4] State Coroner Ryan *Findings in the inquest into the death of Hamid Khazaei* 30 July 2018, paragraphs 29 – 46.

to practise in the United Kingdom and California. He became a Fellow of the Royal Australian College of Surgeons in 2013. From June 2012, Dr Alphonso was employed as a Senior Medical Officer in Saediatric Cardiothoracic surgery at the Mater Children's Hospital and transferred to LCCH in this capacity when it opened in November 2014. He has held the position of Director of Cardiac Surgery since June 2012.

Dr Alphonso was Dr Venugopal's clinical supervisor. He explained that as Dr Venugopal had obtained his specialist Fellowship overseas, the Royal Australian College of Surgeons required that he be supervised for the first 12 months of his work in Australia. Dr Alphonso was part of the surgical team performing Joshie's initial surgery on 29 October 2015.

Dr Prem Venugopal obtained his medical degree and undertook specialist surgical training in India, completing a Masters in General Surgery in 1997 and a Masters of Cardiac Surgery in 2000. He became a Fellow of the Royal College of Surgeons (Edinburgh) in 2000 and a Fellow in Cardiothoracic Surgery in 2008. He completed his cardiothoracic surgery training in the United Kingdom in 2009 and practised as a consultant congenital cardiac surgeon there from June 2009 – August 2015. Before coming to Australia he was the Director of the Cardiac Surgical Unit and Service Lead (Cardiology & Cardiac Surgery) at AlderHey Children's NHS Trust in Liverpool, United Kingdom. Dr Venugopal commenced as a Senior Medical Officer in Paediatric Cardiac Surgery at LCCH in August 2015 under the supervision of Dr Alphonso and one of the cardiac surgeons at the Royal Children's Hospital in Melbourne.

Dr Venugopal performed the initial surgery on 29 October 2015. He was then involved in Joshie's daily post-operative care over 6-15 November. He was present in theatre during the surgical debridement performed on 13 November, observing and supervising the procedure. He was then involved in events following Joshie's acute bleed on the ward in the early hours of 16 November.

Dr Alphonso and Dr Venugopal had two Cardiac Surgical Fellows, Dr Sudesh Prabhu and Dr Balram Rajanbabu. Fellows are senior doctors completing their specialist training in preparation for becoming consultants in the specialty.

Dr Sudesh Prahbu obtained his medical degree and undertook specialist surgical training in India completing a Masters of Cardiovascular and Thoracic Surgery in 2012. He was employed as a Cardiac Surgical Fellow by LCCH as at October-November 2015. He was involved in Joshie's outpatient treatment prior to admission in October 2015. He performed the surgical debridement on 13 November.

Dr Balram Rajanbabu obtained his medical degree and undertook specialist surgical training in India, completing a Masters of Cardiothoracic Surgery in 2010. He held a cardiac surgery training position at The Westmead Children's Hospital for 12 months over 2014-2015 before taking up a cardiothoracic

Surgical Fellow position at LCCH in August 2015, under the supervision of Dr Alphonso.

Dr Rajanbabu assisted Dr Venugopal with the initial surgery on 29 October and as part of the surgical team attended Joshie following that surgery while he was in the PICU. Dr Rajanbabu was the cardiac Surgical Fellow on-call for the evening of 15-16 November 2015 and involved in the events following Joshie's acute bleed on the ward.

Joshie was managed under a shared model of care between the cardiology, cardiac surgical and PICU teams. In practice, this meant he was under the primary care of the cardiology team when on the ward and under the primary care of the intensivists while he was in the PICU. The cardiology team looked after him from a medical perspective. The cardiac surgical team were responsible for all aspects of his surgical care, including providing advice on surgical intervention, wound care and management, pacing wires, chest or mediastinal drains. The cardiology and cardiac surgical teams performed daily ward rounds though not always concurrently or together.

Although Joshie had been under the care of Dr Robert Justo since birth, the model of care practised by the Queensland Paediatric Cardiac Service was such that Dr Justo was not personally involved in his day to day management during this admission. Rather, the paediatric cardiology consultants were rostered on a weekly rotating system meaning Joshie passed through the care of four different consultants over the course of his 18 day admission, Dr Scott Fox, Dr James Morwood, Dr Alex Gooi and Dr Cameron Ward.

Dr Alex Gooi obtained his medical degree in 1994 and qualified as a paediatric cardiologist in Australia in 2005. He completed his core paediatric cardiology training in Australia, the United Kingdom and Canada. He is a Fellow of the Cardiac Society of Australia & New Zealand. He has been employed as a full time Staff Specialist Paediatric & Foetal Cardiologist/Echocardiologist at the LCCH since it opened. Dr Gooi was the cardiology consultant responsible for Joshie's care over the period 6-12 November.

Dr Christopher Ward obtained his medical degree and undertook his specialist paediatric training in Australia. He obtained his Fellowship of the Royal Australasian College of Physicians in 1992, specialising in paediatric cardiology. He has worked in Australia, Canada and the United States of America. In 1996 Dr Ward commenced a joint appointment at the Mater Children's and The Prince Charles Hospitals. He established the Queensland foetal echocardiography service and jointly established the Queensland paediatric interventional services. He transferred to the LCCH when it opened in 2014. Dr Ward was the cardiology consultant responsible for Joshie from Friday 13 November 2015 onwards. He attended cardiology ward rounds twice daily with paediatric cardiology Fellow, Dr Ari Horton, every day from 13 November.

Dr Ari Horton obtained his medical degree in 2008 and commenced his paediatric specialist training in Victoria in 2010 with dual training in general paediatrics and paediatric cardiology. As at November 2015, Dr Horton was a paediatric Registrar (Advance Trainee in the role of Paediatric Cardiology Fellow) at LCCH. Dr Horton was the Cardiology Fellow involved in the initial surgery on 29 October and performed a trans-oesophageal echocardiogram (TOE) during that surgery. He was part of the cardiology team who reviewed Joshie post-operatively. He was the cardiology Fellow on-call over the weekend of 13-16 November, with Dr Ward as his consultant on-call. Dr Horton performed the echocardiogram in PICU in the early hours of 16 November.

Collectively, the consultants and Fellows responsible for Joshie's care were highly qualified, experienced doctors within the paediatric cardiology and cardiac surgery subspecialties. It is evident that Drs Alphonso and Venugopal are enormously proud of the Service. Clinical witnesses from both teams attested to their dedication to their surgical patients, describing them as readily available and visiting the ward several times a day.

At the time of Joshie's admission, the accepted culture and practice within the Queensland Paediatric Cardiology Service was for the cardiology team to document in the patient record on behalf of both teams - this explains the absence of any entries in Joshie's progress notes by the cardiac surgical team for the entire admission. Despite the absence of documentation by the cardiac surgeons, the evidence given at inquest demonstrates Joshie was seen by a member of that team every day. Jacqui recalled seeing Dr Venugopal quite often. Her evidence was that she could raise any issues or concerns with the cardiology team during their daily rounds; the cardiac surgical team would also do a ward round but they were less interactive than the cardiology ward rounds.

Clinical narrative and discussion of inquest issues

In considering the evidence and making my findings, I have been mindful of both hindsight bias and outcome bias. Hindsight bias refers to the tendency of those with knowledge of an outcome to overestimate the predictability of what actually occurred relative to alternative outcomes that may have seemed likely at the time of the event. Outcome bias refers to the influence of knowledge of the eventual outcome on the retrospective evaluation of clinical care.

Admission to Lady Cilento Children's Hospital

In preparation for his open heart surgery, Joshie was admitted to LCCH in May 2015 for diagnostic cardiac catheterisation. An occupational therapist assessed his functional ability during this admission, noting Jacqui's advice that while Joshie usually communicated his needs quite well through a mix of speech and gesture or signing, his speech was the first thing to go when he was anxious. He generally had a high level of anxiety but this increased with medical procedures. The occupational therapist assessed Joshie was able to identify tasks that were causing him stress and communicated these well to her.

Jacqui's evidence was that Joshie could speak quite clearly; he definitely knew what he did or did not want to do. While he may not have been able to talk in full sentences, he was able to get his message across. Jacqui said he was able to express his symptoms when in hospital, for example, if he was experiencing pain he would say "I'm sore".

Dr Venugopal indicated that because of Joshie's autism and behavioural issues, it was anticipated that ensuring his compliance with post-operative physiotherapy and mobilising would be more challenging for him than for other children.

Jacqui described the May 2015 admission as very traumatic for Joshie because there were many attempts to gain intravenous access or bloods. These efforts were sometimes managed with sedation and anaesthetic input.

Joshie was seen by Dr Alphonso and Dr Prahbu in the Outpatient Department on 19 August 2015. The conference was attended by Joshie's parents, Mrs Dalton, his paternal grandparents, Dr Alphonso, Dr Prahbu and a clinical nurse coordinator. His parents signed the surgical consent that day. Jacqui had raised concerns about the difficulty getting intravenous access and obtaining bloods from Joshie as occurred during the May admission. He had to be transitioned from his usual Warfarin to a heparin infusion in preparation for the open heart surgery. For this reason, the cardiac surgical team decided to plan for a Peripherally Inserted Central Catheter (PICC line). He was subsequently booked for a PICC insertion on 26 October 2015.

At some point, a decision was made to insert two midline peripheral cannulas rather than a PICC line. This change had not been communicated to Jacqui until Joshie was in the anaesthetic induction room, causing her quite some distress. While not relevant to how Joshie died, this event illustrates the importance of timely communication with patients and their carers about clinical decision making.

The redo Konno procedure – 29 October 2015

Joshie was returned to the operating theatre on 29 October 2015. Dr Venugopal was the primary surgeon, assisted by Dr Rajanbabu and Dr Alphonso.

The procedure was to replace the mechanical aortic valve through redo Konno and enlargement of the right ventricular outflow tract (RVOT). It involved a fourth time redo sternotomy, removal of the previously placed mechanical valve and placement of a larger 22mm ATS valve, enlargement of a patch to cover a ventricular septal defect (a hole between the two lower chambers of the heart) and the enlargement of the RVOT with CardioCel. During the surgery a subclavian central line and peripheral intravenous cannula were inserted.

Dr Alphonso and Dr Venugopal described this type of surgery as a very complex and technically demanding procedure. In Dr Venugopal's experience, there are probably only one or two paediatric Konno procedures undertaken each year in the whole of the United Kingdom. It is reportedly so uncommon that the Congenital Cardiac Audit database for the United Kingdom does not record it as an individual procedure. He estimated there would be, on average, less than one of these procedures done annually in Australia.

Paediatric redo Konno procedures are even rarer. Dr Venugopal had personally performed two redo Konno procedures, both with successful outcomes.

In contrast, the placement of an RVOT patch, which was part of the procedure, is commonly performed and performed for various congenital cardiac conditions, not just in Konno procedures.

The CardioCel patch was made from bovine pericardium. It is a patch used in Brisbane and Melbourne paediatric hospitals. This product had been used at the LCCH for approximately two years. Dr Venugopal had not identified any substantial difference between this patch, compared to those he had used in the United Kingdom, through his use of this product in previous cardiac surgeries.

Dr Venugopal said the surgery was always going to be difficult and challenging given Joshie had already had three previous open heart surgeries.

The intraoperative findings demonstrated very dense cardiac adhesions, particularly around the aortic root and RVOT. There were areas of calcification of the previous patch used for the Konno repair. There was also calcification of the RVOT patch. The previous prosthetic valve was well positioned and seated. The aorta was noted to be extremely thin and fragile, which was expected. Joshie received the first of the standard doses of prophylactic intravenous cephalozin during the appropriate intraoperative period and a subsequent three post-operative prophylactic doses as per the Paediatric Cardiac Surgical Antibiotic Prophylaxis Guideline.

Dr Venugopal was happy with the surgical outcome and the team considered Joshie's surgery to have been a success.

Dr Venugopal advised that the thin aorta increased the risk of bleeding in the immediate post-operative period (24-48 hours following surgery) given the extensive suture lines required for the repair. It was possible that a suture could give way or for the thin aorta to bleed. For this reason, Joshie was admitted to the PICU post-operatively to be kept sedated and still and to control his blood pressure over the evening following surgery. Neither of these immediate post-operative risks eventuated.

I have no concerns about the initial surgery.

The early post-operative period – 29 October – 2 November

Joshie was transferred to the PICU post-operatively where he was under the primary care of the intensivists with daily rounds by the cardiac surgical team.

There were some initial challenges controlling Joshie's blood pressure. It was not until Jacqui spoke to a PICU nurse about the usual effectiveness of Joshie's regular Lisinopril that it was identified this medication had not been charted. This was rectified immediately and recommenced on 1 November (day 3 post-op), with good effect.

Joshie continued to receive his prophylactic antibiotic therapy. Over the course of 30 October (day 1 post-op), he progressively became febrile with an elevated white cell count and inflammatory markers and an increasing ventilation requirement. A chest x-ray demonstrated left lower lung consolidation. He was commenced on additional intravenous antibiotics (Piptaz and Vancomycin) and regular chest physiotherapy.

By 31 October (day 2 post-op), Joshie had improved haemodynamically but continued to spike a fever. One of the intravenous long lines was removed because it had become blocked. The mediastinal and left chest drains were removed and his warfarin was recommenced. Joshie was extubated that day to high flow oxygen. His sternotomy wound was intact with no ooze.

The Vancomycin was ceased on 1 November (day 3 post-op) and Joshie was discharged back to the cardiac ward the next day (day 4 post-op), where he was placed in a close observation room. His remaining chest drain was removed, his morphine infusion was discontinued and his analgesia changed to oxycodone PRN and regular paracetamol. The heparin was ceased. He remained on intravenous PipTaz.

Joshie's management on the ward and return to PICU – 2-6 November

Joshie was cared for in Ward 10B. Nursing Unit Manager, Kirk Larkin explained this ward uses surgical care pathways to assist documentation by nursing staff. If the patient is progressing as expected then completion of the pathway is sufficient; if there is any deviation from the pathway, nurses are expected to write in the progress notes and some document in both locations. In evidence, NUM Larkin acknowledged the clinical pathway for Joshie was not completed at various times over the course of his admission and variances in his observations were not documented on the clinical pathway or in the progress notes.

Joshie commenced mobilising with physiotherapy input once back on the ward. However, he remained febrile with progressive tachypnoea and tachycardia over the course of the day on 3 November (day 5 post-op). A repeat chest x-ray showed persistent left lower lobe collapse/consolidation and small bilateral pleural effusions. Maintaining venous access was difficult

with the remaining line tissuing and being removed. He was switched to oral Augmentin for two doses until a new vascular line could be placed.

Joshie's condition deteriorated with a prolonged desaturation episode that evening culminating in a MET call and transfer back to the PICU for high flow oxygen support. He was diagnosed with nosocomial pneumonia. He had a PICC line inserted under general anaesthetic on 4 November (day 6 post-op). He continued to mobilise regularly while in PICU.

He was discharged back to the ward on the afternoon of 5 November (day 7 post-op). He remained on intravenous Piptaz. His observations remained stable and he was afebrile. The drain sutures were removed.

Jacqui observed Joshie was becoming more like his usual self by 6 November (day 8 post-op). He was noted to be mobilising well with encouragement. Jacqui was determined to get Joshie home as soon as possible so she and other family members continued mobilising him regularly and in between physiotherapy attendances once he was back on the ward.

Jacqui explained that a 'lap of the ward' involved mobilising him around the cardiology and oncology units on that floor. She estimated this would take a couple of minutes at Joshie's slow speed.

The sternotomy wound starts to ooze – Saturday 7 November (day 9 post-op)

The sternotomy wound developed an ooze, first noticed and documented on day 9 post-op. The ooze progressed over the following five days, changing in appearance and volume. Although initially managed conservatively, Joshie was returned to theatre on Friday 13 November for wound exploration and debridement and a VAC dressing.

Although the cardiac surgical team were responsible for Joshie's wound management, they did not make a single entry regarding their observations of the wound or their management plan. Rather, it was the nursing staff and physiotherapists who documented the fact of the ooze and, though not consistently, information about its appearance and instructions given to them about how to manage it. Not even the cardiology team documented information about the volume or appearance of the wound ooze though they did include brief references to aspects of the surgeons' wound management plan in their ward round entries.

The sternotomy wound was covered with a clear dressing. Dr Venugopal confirmed the cardiac surgical team were reviewing the wound each day. Jacqui recalled seeing Dr Venugopal or the Surgical Fellow looking at the wound when they reviewed Joshie. Her evidence was that staff were aware when it started to ooze and they were keeping an eye on it.

Joshie was febrile (38.7) overnight on 6-7 November. When seen by Dr Gooi and the cardiology team on the morning ward round, Saturday 7 November, he was noted to have no increased work of breathing at rest. By this stage he

had received eight days of PipTaz. The plan was to continue the intravenous antibiotics and ongoing chest physiotherapy, with blood cultures to be taken if Joshie became febrile. Repeat bloods and chest x-ray were ordered. There is a notation for the team to consider consulting the Infectious Diseases team depending on the results of those investigations.

Joshie was moved from the close observation room to room 4 after the morning ward round. Mrs Dalton was with Joshie during the day. She recalled he complained that his chest hurt and she saw ooze coming from his sternotomy wound.

A nursing entry made at 2:34pm that day notes Joshie remained tachycardiac when awake (up to 140bpm) with rattly breath sounds and a moist cough. The entry notes "*ooze from sternotomy with coughing – dressing reinforced with gauze and tegaderm*". The physiotherapist's entry documented Joshie's report of feeling hot and nauseous that morning and Jacqui's report of "*new ooze bubble under dressing on sternum Drs aware*". Neither entry describes the amount or appearance of the ooze.

Joshie was noted to be mobilising well that day. His observations were stable, he remained afebrile and he was eating and drinking well. He was commenced on a heparin infusion overnight for a low INR.

On the morning ward round, Sunday 8 November (day 10 post-op), the cardiology team documented "*concerns regarding ooze from surgical wound*". They noted the repeat chest x-ray showed improving left-sided pneumonia. The plan remained the same (continue antibiotics, chest physiotherapy and warfarin stabilisation, blood cultures if febrile) and for the surgeons to review the wound ooze.

Joshie had lots of visitors that day. He continued to mobilise around the whole ward and spent much of the day sitting out of bed. Joshie's observations were stable, apart from a low grade temperature of 37.6.

A nursing entry made that afternoon noted "*sternotomy started oozing again this afternoon, contacted cardiac surgical fellow, ordered to cover Dx with gauze and tegaderm and change prn or 3 x day*".

A subsequent nursing entry documented that at 7:30pm the gauze over the lower half of the sternotomy was intact. However, at 8:00pm there was a small amount of ooze. A nurse went to clean and change the gauze before Joshie went to sleep. When she removed the gauze exposing the bottom half of the sternotomy, she noted "*ooze ++, sticky haemoserous discharge from the bottom quarter of the dressing*.' Jacqui told the nurse the ooze had doubled since the wound was reviewed eight hours earlier.

Nursing staff requested the Night Ward Call doctor to review the wound ooze. The entry from this Resident Medical Officer (RMO) is the only doctor-made entry in the entire record to actually describe the wound. It documents that the treating team saw the wound ooze and planned for surgical review in the

morning. However, nursing staff reported the oozing had increased since then. Joshie was noted to be afebrile with no signs of infection. His observations were within normal limits. On examination, there was oozing underneath the dressing described as "*spilling over from the sides, appears to be haemoserous, no infection, total appears to be about 10-15ml*". The RMO documented a discussion with Jacqui indicating there were "*no obvious signs of infection, don't want to run into trouble if taking down dressing, already for surgeons to review in the morning, even if surgeons called overnight, uncertain if going to be doing anything other than redressing.*" Jacqui is noted as agreeing with this. The RMO documented a plan for more absorbent dressing only overnight at present. If there were any changes, for example soaking through another layer of dressing, then she would come back with the general paediatric Registrar for review and possible consideration of taking the dressing down.

Nursing staff commenced a specific wound observation chart, documenting hourly observations of the wound from 7:00pm. The nursing entry notes the dressing remained intact overnight with nil ooze observed until 5:00am and 6:00am, when there was visible ooze causing the Alleven dressing to be raised. The next entry on this chart is not made until 8:30am on 12 November, some three days later.

Joshie was seen by Dr Gooi and the cardiology team the next morning, Monday 9 November (day 11 post-op), on their morning ward round. The only reference to the events overnight in the ward round entry is "*concerns regarding ooze from surgical wound*." There were no changes to the management plan at that time.

RN Elizabeth Andresen recalled the surgical team reviewed the wound that morning and changed the dressings. She said it did not ooze during her shift (which finished at 7:30pm). A wound swab was sent for microbiology cultures that morning.

Joshie continued to spend most of the day sitting out of bed and mobilising regularly, three laps of the ward at a time. At Jacqui's request, he was given 3mg oxycodone at 12:20pm as a pre-emptive measure before he went for a walk around the ward. He received a further 3mg oxycodone at 6:50pm, possibly because he was going for another walk around the ward. Mrs Dalton visited with Joshie during the day and stayed with him overnight. It was his first day without supplemental oxygen and he was exhausted after working hard at physiotherapy. She recalled he continued to complain of chest pain, though this specific complaint is not documented in the nursing notes.

RN Rachael Johnson cared for Joshie during the night shift, 9-10 November. She recalled being told at handover that there had been some ooze at the bottom quadrant of Joshie's sternotomy wound. Knowing this, she kept a close eye on the wound throughout her shift. Joshie was stable overnight apart from remaining tachycardic. RN Johnson noted the tachycardia as having been *"..a long standing issue and team aware. All other observations stable.*" The nursing entry notes no complaint of pain and that the wound had

not oozed overnight. Joshie was given another 3mg dose of oxycodone at 6:45am on 10 November (day 12 post-op).

On Tuesday, 10 November (day 12 post-op) Joshie was commenced on oral Flucloxacillin 1g, six hourly, (to cover staphylococcal bacterial infection). Dr Venugopal explained that any wound discharge is a concern particularly for patients with prosthetic material in their chest. This is why they have a very low threshold for initiating antibiotic treatment and doing a wound swab to rule out any deeper extension of an infection. The decision to commence Joshie on oral Flucloxacillin was "prophylactic" while they were waiting for the wound culture results. The medication chart indicates he received six doses of Flucloxacillin, with the final dose given at midday on 11 November.

The cardiology ward round that morning noted Joshie was complaining of central chest pain. An ECG showed no concerning changes. A repeat chest x-ray showed persisting left lower lobe collapse, a disheartening finding for Jacqui who was hopeful of getting him home by the weekend. He was seen again by physiotherapy who noted his oozy wound. The aim was to have him mobilising fast every two hours, regular repositioning while sitting out of bed and PEP breathing. He would become quite short of breath with moderate exertion, needing regular rests. The cardiology team noted an intention to consult with the respiratory team if he did not improve. The wound swab cultures were still not available.

A nursing entry made that evening noted Joshie remained tachycardiac (120-140bpm) but was afebrile. It documents "*wound small ooze – dressing in tact – drs aware*".

At the cardiology team's request, Joshie was reviewed by the respiratory team on Wednesday 11 November (day 13 post-op). By this time he was only on oral flucloxacillan having already completed 10 days of Piptaz. A repeat chest x-ray showed some improvement compared with previous imaging on 7 and 10 November. The respiratory team considered his atelectasis was improving and recommended commencing Joshie on intravenous Cefotaxime for four days followed by oral Augmentin, supplemented by chest physiotherapy and cough and sputum clearance. He was started on the Cefotaxime that night after receiving a final dose of oral Flucloxicillan at midday.

The physiotherapist who attended Joshie that morning noted he was mobilising well, completing three full laps of the ward independently. Her entry noted he was complaining of "*heart hurting', indicating pain at base of sternum".* There is no mention of this complaint when he was seen by a different physiotherapist in the afternoon. She noted Joshie had been mobilising well with family members but was breathless with increased distance and speed. He had received some pain relief before that session.

The sternotomy wound dressing was changed twice during the day on 11 November – in the morning by the surgical team and in the afternoon by a nurse. The nursing entry notes a *moderate amount of yellow ooze* present

under the dressing in the afternoon. Although Joshie was afebrile, he was noted to look pale and warm to touch. His heart rate was 120 when settled.

Jacqui's Facebook post commented Joshie was not impressed by having to do 'a ton of physio'. It also mentioned the cardiac surgical team having reviewed the wound ooze and their intention to open the wound, flush out and put on a vacuum dressing if the wound kept oozing.

Mrs Dalton described Joshie as not looking well that day. She stayed the night with him. He was missing his family and seemed very sad. She recalled he was complaining of chest pain but there is no reference to this specific complaint in the overnight nursing notes.

The wound swab results were still pending.

Decision to take Joshie back to theatre for wound exploration +/- surgical debridement – Thursday 12 November (day 14 post-op)

The sternotomy wound observation chart notes the surgeons changed the dressing ("*ooze+++")* on the morning of Thursday 12 November (day 14 post-op).

The physiotherapist noted Joshie was in generally good spirits and mobilising well having mobilised two laps of the ward that morning at a good pace with his family.

Jacqui's evidence was that she requested a surgical review of the wound that day because the ooze was increasing in volume and requiring more dressing changes. By 12 November it had "*pooled into a bubble sort of over the scar*" rather than running out. This was the first time the surgeons took down the clear dressing. The smell and appearance made Jacqui feel like passing out. She described it as yellow with the consistency of snot.

Two things struck her as strange – firstly, she expected the wound to be hot and red and bumpy like you would expect from an infection but she observed the wound was just a thin light pink scar. Secondly, there was no opening to indicate where the ooze was coming from, "*it was just like a perfect scar*". It took one of the surgeons running his finger down the scar to see where the ooze was coming from.

Although afebrile that morning, Joshie spiked a fever of 38.4 at midday, rising to 39.2 at 1:00pm. His temperature remained significantly elevated until 6:30pm that evening.

It appears the cardiac surgical team reviewed the wound at 12:30pm and again at 6:30pm, on both occasions cleaning it and changing the dressing ("*ooze+++"* noted on the sternotomy wound observation chart). Blood cultures were taken from the PICC line and another swab taken from the wound when it was redressed. A urine sample was also taken.

The nursing entry made at 5:20pm that evening notes Joshie had complained of a *"sore scar*" throughout the day for which he was given PRN oxycodone with good effect and voiced no further complaints of pain. That entry documents "*oozing out bottom of dressing when patient stands up/walks (dressing reinforced). ooze mucky/pussy, nil offensive smell. patient complaining of it being sore*."

This nursing entry is the first documented reference to a possible washout/VAC dressing of the sternotomy wound as Joshie was to be nil by mouth from 6:00am in anticipation of this. Dr Venugopal clarified the plan was made that evening in order for Joshie to go back to theatre the next day.

Dr Venugopal described the decision to take Joshie as part of a stepwise escalation of treatment from conservative management with wound swabs and antibiotic therapy and if there was no improvement then to wound debridement. He accepted that by 12 November Joshie had evidence of wound infection. He explained that patients with prosthetic materials in the heart are highly susceptible to infective endocarditis due to transient bacteraemia which carries a very high mortality. As such, the rationale for taking Joshie back to theatre was to assess the extent of the wound infection – was it superficial or deep? If deep, how deep was it? If the wound was not obviously infected, it could be ruled out as the source of Joshie's fevers.

Joshie returns to theatre for surgical debridement – Friday 13 November (day 15 post-op)

Joshie remained febrile overnight and throughout the next day, 13 November. The wound continued to ooze overnight but the dressings remained intact.

The cardiac surgical team changed the dressing that morning. A nursing entry documented *'large amount of "snotty" looking exudate'* at this time. Joshie is noted to have done physiotherapy with his family that morning and thought to be progressing well with it. An echocardiogram performed that day showed aortic insufficiency.

Jacqui provided consent for sternal wound re-exploration +/- sternal rewiring +/-vacuum therapy application under general anaesthetic that day.

A debridement is laying open of the surgical wound, removing necrotic tissue if present, and opening up any pockets of collection in the tissues.

A VAC dressing is a special type of dressing used to accelerate the wound healing process. This is a process by which a foam dressing in the wound is kept dry by a vacuum removing fluids from the dressing and into a collection canister. It produces a constant negative pressure in the wound, evacuating all secretions from the wound and also accelerating new granulation tissue formation which aids in wound healing.

Dr Venugopal clarified that the scope of the surgical consent obtained from Jacqui was to keep the surgical team's options open depending on what they encountered once they opened the wound.

Joshie went to theatre at around 5:00pm.

The procedure was performed by Dr Prahbu under Dr Venugopal's direct supervision. Dr Venugopal was not scrubbed so could not physically inspect the wound himself. The plan was for Dr Prahbu to debride the wound with Dr Venugopal looking on and if it was a deeper infection, Dr Venugopal would scrub in and take out the sternal wires. They discussed the "obvious concern" it could be mediastinitis, a life-threatening condition causing inflammation of the tissues of the mediastinum. It is a rare post-operative complication with a reported rate of 1.4-1.9% in the clinical literature, but one which carries a very high mortality rate (40%).

Dr Venugopal recalled the sternotomy wound looked like a healing scar – the skin was intact without any redness. He was initially standing at Joshie's head and then moved to stand behind Dr Prahbu once Dr Prahbu opened the wound. He said from this position looking over Dr Prahbu's shoulder he could see exactly what Dr Prahbu was seeing so he was confident he had a good view of the wound.

Dr Prahbu explained he began by performing the "two finger test" to test the stability of the sternum. This involved him placing his hands on either side of the sternotomy wound and pushing down to see if there was any independent mobility or rocking motion with the sternum. Dr Prahbu said he did not detect any sternal instability.

He then opened the lower two-thirds of the wound as this is where the ooze was coming from. Two swabs were taken for cultures. Both surgeons saw evidence of soft tissue infection with pus and slough present in the fat tissue. Dr Prahbu described seeing infection in the fat tissue but no evidence of infection in the muscle. Dr Venugopal watched Dr Prahbu debride the affected tissues until he achieved healthy bleeding, meaning he had reached healthy tissue. He stopped at the periosteum or membranous coverage of the sternum. He then used forceps to "poke around" for any sinuses leading away from the wound into deeper areas. He said there were none.

The wound exploration and debridement only went as high along the wound and as deep as it took to reach healthy tissue. The surgeons explained they did not want to disrupt normal healing tissue. At this point in the procedure, they were both satisfied it was only a superficial wound infection and there was no need to open the full length of the wound or to open the sternum. The operation note indicates this part of the procedure was done in nine minutes (5:06pm – 5:15pm).

Dr Venugopal considered there was no strong clinical evidence of mediastinitis to warrant opening the sternum and risk contaminating a sterile mediastinum. In addition to what he observed during the debridement, Joshie was not behaving clinically like someone with mediastinitis. He said he was also aware of Joshie's very thin aorta and the fact he was anticoagulated and the challenges they experienced controlling haemostasis during the initial

surgery. These were all reasonable factors against opening the sternum at this time.

The VAC dressing was then applied with a suction pressure of -125mmHg. The VAC dressing compromised a clear dressing covering a black wedge of material over the wound. The clear dressing extended a couple of inches either side of the wound. The operation report indicates the wound dressing took 13 minutes (5:14pm – 5:27pm). The plan was to return Joshie to theatre for a VAC dressing change on Monday, 16 November.

Joshie was returned to the cardiac ward that evening. He was continued on intravenous Cefotaxime.

Should the wound ooze have been treated more aggressively prior to surgical debridement on Friday 13 November?

Despite the absence of any clinical documentation by the cardiac surgical team, the evidence supports a finding that they were actively checking the sternotomy wound each day and well aware of the fact and progression of the wound ooze.

By Saturday 7 November when the wound started to ooze, Joshie had been on intravenous Piptaz for eight days. The ooze began as haemoserous in appearance and doubled in volume over the course of the following day. It was initially managed over the weekend by applying additional dressings over the clear sternotomy dressing. A swab was taken the following Monday, 9 November, and Joshie was commenced on oral Flucloxacillin the following day pending the swab results. While it is not particularly clear from the medical record how many dressing changes Joshie was needing on 9 and 10 November, by Wednesday 11 November he was requiring at least two dressing changes. By 11 November, the ooze had come yellow and by Thursday 12 November, its consistency changed to become mucky/pussy/snotty and required more frequent dressing changes. It was once Joshie became febrile on 12 November, in the context of the changing wound discharge despite antibiotic therapy that the cardiac surgical team decided to proceed with surgical exploration and debridement of the wound. At no point was the sternotomy wound itself noted to be raised, hot, inflamed or to have dehisced. There was no positive growth on the wound swab.

The evidence of Drs Alphonso, Venugopal and Prahbu was consistent regarding the cardiac surgical team's very low threshold for swabbing a wound suspicious for infection and commencing antibiotic therapy pending the swab results. Dr Prahbu suggested that the absence of obvious infection (the wound was not red, hot, inflamed) informed the team's decision to start Joshie on oral rather than intravenous Flucloxacilin, opting to wait for the swab results before changing from oral to intravenous delivery. Dr Alphonso explained it depends on how the wound looks; as soon as it is identified as looking "mucky, pussy" the patient needs to go to theatre for surgical exploration.

Dr Venugopal explained there was no clinical indication for a CT scan of the chest prior to taking Joshie back to theatre on Friday 13 November – he was not systemically unwell and there was no evidence of a more deep seated infection.

The expert evidence supports the reasonableness of the cardiac surgical team's approach to managing the wound ooze up to their decision to return Joshie to theatre on 13 November:

- a small amount of wound ooze can be due to fat necrosis, a superficial problem;
- a small amount of wound ooze does not 'translate' to immediate wound debridement;
- when there is a small increase in the amount of ooze, the first step is to prescribe antibiotics and wait a couple of days to see if there is an improvement;
- Flucloxacillan was an appropriate antibiotic choice;
- the decision to use oral or intravenous antibiotics depends on the volume of ooze – Dr Finucane considered the use of oral antibiotics for a relatively small amount of ooze in a child with difficult intravenous access was a very reasonable course of action; however, if the patient was requiring two or three dressing changes a day, she would definitely use intravenous prophylactic antibiotics;
- it is not unusual to have ooze from a sternotomy wound but when there is enough to require multiple dressing changes a day that is cause to consider infection involving deeper structures; and
- with an increase in wound ooze, despite antibiotic therapy, the next step was wound exploration – Drs Finucane and Konstantinov did not consider CT imaging of Joshie's chest was warranted before the surgical exploration on 13 November. Professor Konstantinov thought it would be an *'extraordinary strange thing'* to do a CT scan before wound debridement for an oozing wound and potential wound infection. They both identified CT scan as being an option for further investigation after wound debridement.

Dr Finucane and Professor Konstantinov both confirmed that the intravenous antibiotic therapy Joshie had been on previously (Piptaz) and was subsequently placed on by the respiratory team (Cefotaxime) would also treat a wound infection and further, antibiotics tend to suppress wound infections but not necessarily prevent them and can actually making the diagnosis of them quite a lot more difficult.

Having regard to the wound ooze progression, Drs Finucane and Konstantinov considered the timing of the decision on 12 November to return Joshie to theatre for surgical exploration the next day was reasonable in the circumstances. That said, Professor Konstantinov qualified his opinion by saying it was very difficult to judge when action should have been taken without being present and knowing what the ooze looked like and the amount of ooze. A/Professor Chard said he would have investigated the wound sooner than 12 November because he considered it unusual to get significant discharge from a sternotomy wound at any age and if left untreated, it is

possible it will progress. That said, he conceded, and all the experts agreed, it is a matter of clinical judgement for the person inspecting and assessing the wound.

The absence of regular and consistently documented descriptions of the amount and appearance of the wound ooze has presented somewhat of a challenge in independently assessing the reasonableness of the bedside clinicians' judgement and decision making, after the event. However in circumstances where the ooze was not accompanied by obvious localising signs of infection and Joshie remained systemically stable, I am satisfied his management up to Friday 13 November was reasonable and consistent with accepted clinical practice.

One of the clinical management issues explored during this treatment phase was whether Joshie should have been changed from oral to intravenous Flucloxacillan on 11 November after the wound ooze changed in appearance and in amount (requiring at least two dressing changes a day). Given Joshie was commenced intravenous Cefotaxime that day, an antibiotic which Drs Finucane and Konstantinov advised would also treat a wound infection, I am comfortable this aspect of his care is not an issue of any outcome changing significance.

Adequacy of the surgical debridement on Friday 13 November

Dr Venugopal's evidence is that he and Dr Prahbu went into the surgery that day with the intention of ruling out mediastinitis. A key issue for the inquest was whether the wound exploration and debridement should have extended to opening the sternum in order to achieve this objective.

The evidence of both surgeons is that the sternum was stable and neither saw evidence of deeper extension of the superficial infection. As such they were both satisfied there was no clinical indication or need to open the sternum.

The experts' evidence about surgical practices in other centres demonstrates that the fact a Surgical Fellow performed the wound exploration and debridement in the presence of a consultant who was not scrubbed, but who could scrub in if required, is not an unusual or concerning practice.

All of the experts agreed the decision whether to open the sternum is a clinical judgement call by the surgeons reviewing the wound before them. I accept this is a major undertaking with not insignificant risks, not least of all exposing sterile structures to possible infection. Dr Finucane described it as a careful balancing exercise at day 15 post-operatively.

Sternal instability is a cardinal sign of mediastinitis. Dr Finucane's evidence is that it is extraordinarily rare for the bone not be involved and for at least one or two sternal wires not to be a little bit loose. The bone softens and these are indications there is pus in behind the sternum. While the evidence of all the surgical witnesses was to the effect that if the sternum is stable there cannot be mediastinitis, each of the expert witnesses had experienced a patient who

did have mediastinitis without sternal instability. Professor Konstantinov said while a stable sternum does not exclude mediastinitis or deep tissue infection, it makes it unlikely; the vast majority of mediastinitis cases will have some degree of sternal instability. In the experts' collective experience, it is a very rare occurrence otherwise.

Each of the experts considered Dr Prahbu's surgical approach of examining the wound layer by layer until he reached healthy tissue and stopping at the periosteum of the sternum to be reasonable. Dr Finucane explained that only opening two-thirds of the wound was acceptable because in a thin child a collection is fluctuant. She explained another sign of mediastinitis is fluid welling up into the base of the wound from underneath the sternum as this demonstrates there is a communication through into the deep layers of the chest. There is no evidence of this finding in Joshie's case.

While acknowledging the use of a VAC dressing in a paediatric cardiac surgical patient is not common, none of the experts were critical of its use in Joshie's case.

I am satisfied that in the context of a patient who was not behaving clinically as having mediastinitis, the surgical findings of sternal stability and debridement of superficial infection to the periosteum of the sternum reasonably informed the surgeons' decision to leave the sternum closed and treat Joshie as having a superficial wound infection as at Friday 13 November.

Joshie's management on the ward – the weekend of 14-15 November

Dr Horton was the Cardiology Fellow on-call over the weekend from 4:00pm Friday 13 November with Dr Ward as his consultant on-call. Dr Rajanbabu was the Surgical Fellow on-call over this period, with Dr Venugopal as his consultant on-call.

Joshie's INR was subtherapeutic at 1.7 on the Friday evening so he was commenced on a therapeutic heparin infusion. He was seen by the RMO overnight who discussed him with Dr Horton who advised to continue the heparin at the current rate and repeat coagulation studies in the morning. He was afebrile and his observations remained stable and within normal range overnight. His regular Lisinopril was ceased on the Friday.

On the morning cardiology ward round, Saturday 14 November (day 16 post-op) Joshie was noted to be miserable but afebrile with no work of breathing. The plan was to cease the heparin, repeat blood tests and blood cultures and biochemistry.

Following the ward round, Dr Ward performed a repeat echocardiogram, predominantly to check the aortic valve as there had been a mildly abnormal flow noted on the imaging performed the previous day. It did not show any concerning findings. Dr Ward recalled the echocardiogram took quite some time and he had to press quite hard on Joshie's chest to obtain the images as

he had “difficult windows”. He recalled Joshie was quite cooperative and did not show any discomfort during this process.

Joshie was seen by the physiotherapist that day who noted Jacqui had mobilised him two laps around the ward, he had been sitting out of bed and done his PEP exercises. He had a dry cough with very mild work of breathing. He was asleep both times the physiotherapist came to see him.

By 5:00pm that afternoon Joshie had become febrile (38.2) and tachycardic (pulse 148). By 6:00pm, his temperature was up to 38.4 and pulse 138. He was normotensive. He was maintaining his oxygen saturations. His chest was still rattly with slightly decreased air entry on bases, but improving. There was no work of breathing. Blood cultures were taken. He was noted to be complaining of chest pain when mobilising during the day shift, prompting review by the Medical Registrar who increased his oxycodone dose from 5mg 4-6 hourly (maximum 20mg per day) to 5-7.5mg 4 hourly (maximum 45mg per day). In addition to some Panadol in the morning and afternoon and some Clonidine, Joshie had received one 5mg dose of Oxycodone at 12:10pm and after being medically reviewed, received one 7.5mg dose at 4:00pm (total 12.5mg).

Dr Horton was informed about the elevated temperatures and ordered 2-3 peripheral blood cultures and broadened the antibiotic cover with Vancomycin. The Vancomycin was commenced six hourly from 9:00pm. This was in addition to the continuing Cefotraxime. Dr Horton explained his rationale was to better cover for potential hospital acquired bacterial infection given the length of Joshie’s hospital stay and his multiple access points.

Joshie remained febrile overnight and the following morning, Sunday 15 November (day 17 post-op). His temperature at 6:10am was 38.5. It was noted his only complaint of pain overnight was when changing position. He was mobilising to the toilet.

When seen on the morning cardiology ward round, Joshie was noted to be alert, vigorous and well perfused. He had bronchial breath sounds and crepitations to the left base but no work of breathing. There is a notation “heart racing” and “drain output about 100ml inaccurate”.

Joshie remained febrile and tachycardic through the day, his temperature peaking at 39.5 and his pulse rate 175 at 1:05pm. Dr Horton was notified and asked for Joshie to be placed on telemetry which demonstrated sinus rhythm. Joshie’s blood pressure was slightly low but stable. He was maintaining his oxygen saturations at 95% and above with no increased work of breathing. The VAC dressing was noted to be intact with no redness at the wound site and approximately 100ml in the chamber in the morning.

When seen by the physiotherapist at around 2:30pm, Joshie was unable to mobilise the distances he had on previous days. Jacqui reported he had been sitting out of bed for much of the day and had mobilised short distances with her twice but became tachycardic on both occasions, prompting the nursing

staff to tell her to return him to bed. This had not happened previously. He was doing his PEP regularly. The physiotherapist noted Joshie was alert and cooperative. He mobilised approximately 30m with her but became tachycardic with a pulse ~200 and was returned to his room. He was noted to have mild work of breathing on mobilising, something that has not been documented previously. The plan was for him to continue to sit out of bed and for short walks outside the room if nursing staff were happy with his heart rate (<150bpm 10 minutes post-walk).

RN Andresen contacted Dr Horton during the afternoon to let him know Joshie remained febrile. Joshie was medically reviewed and a septic screen performed with repeat blood cultures, urine culture, nasal swab and repeat chest x-ray. He was also commenced on a third antibiotic, Piptaz to cover for pseudomonas. The chest x-ray subsequently showed resolving left lower lobe collapse.

Joshie received two doses of Oxycodone during the day shift – one 7.5mg dose at 9:30am and another 7.5mg dose at 5:45pm (total 15mg). When asked to consider Joshie's analgesia requirement that weekend, Dr Horton explained that the increasing dose of oxycodone was consistent with managing a slightly increased amount of pain as opposed to severe pain.

RN Andresen's notes made at 7:50pm that evening noted Joshie was not keen to mobilise for long distances but that Jacqui was helping encourage him to take short and frequent walks. She documented the pain in his chest as improving.

Joshie's temperature settled briefly but spiked again after 7:00pm and remained above 38 for the rest of the night. Similarly his tachycardia, which hovered between 130-140 while awake and down to 120 when sleeping. He was noted to be warm and well perfused with no increased work of breathing.

Dr Horton and Dr Ward had discussed the situation that afternoon. In evidence they explained they were not certain of the cause of Joshie's ongoing fevers for which there were a number of potential sources, non-infective and infective. Differentials considered and managed prior to that weekend included pneumonia, actelectasis (a process of lung collapse without necessarily an infection in the lung), wound infection and physiological post-surgical response. The echocardiograms performed on 13 and 14 November ruled out an intra-cardiac source of infection. Dr Ward said they were concerned about an infective cause for the fevers. They weren't convinced it was a respiratory source, this explaining why they added the Vancomycin on the Saturday, but when the fevers had not settled with the Vancomycin on the Sunday, they reconsidered whether it might be respiratory. As there had been a previously diagnosed respiratory infection, they spoke to the respiratory team again on the Sunday and extended the antibiotic coverage by adding PipTaz. They discussed whether to involve the Infectious Diseases team at that time but decided to speak with the respiratory team in the first instance and then take up with the Infectious Diseases team the following day, Monday

16 November to “dig deeper”. Dr Ward confirmed the Infectious Diseases team was available over the weekend.

Dr Venugopal and Dr Rajanbabu also reviewed Joshie over the weekend. While Dr Venugopal recalled those attendances, Dr Rajanbabu did not. Dr Venugopal’s evidence was there was nothing unusual or unexpected over the weekend. They examined the VAC dressing noting there was a collection in the drain but not such that it raised any concern. This is consistent with references to the VAC dressing in nursing entries over the weekend which variously describe the dressing as intact, no redness or ooze, draining well and 100ml in the canister. It is also consistent with Jacqui and Mrs Dalton’s recollections of there being no significant increase in the volume in the drain.

Dr Ward, Dr Horton and RN Andresen all described Joshie as more interactive and looking better on Sunday than the day before. To them he seemed “quite well”. RN Andresen recalled he was singing along to music when she finished her shift that evening. From a clinical perspective, Joshie did not appear septic in the sense his clinical observations were not demonstrating cardiovascular compromise. While he had fevers and was tachycardic, he was not also concerningly hypotensive.

Jacqui and Mrs Dalton saw things differently. They both describe changes in Joshie that weekend including his reduced mobility and tachycardia on mobilising, there were dark circles under his eyes, he was more irritable and less friendly, he started needing a bed pan because he didn’t want to mobilise to the toilet, he was sleeping on and off during the day and not wanting to watch television or visit a baby on the ward who he liked to see every day. They recall him complaining about pain in his chest saying “*my heart hurts*” and them approaching the nursing staff for pain relief. Jacqui recalled talking to a junior doctor on the Sunday expressing her concern that while Joshie wasn’t getting any worse at that time, he certainly wasn’t getting any better. She was disheartened by not seeing improvement despite him being on three antibiotics. She really wanted to get him home.

Jacqui described Joshie’s chest pain complaints as more frequent after the VAC dressing was applied and they found themselves asking when he could have his next dose of pain relief. In evidence she had asked about Joshie’s pain during a ward round and was told it was quite reasonable for him to be saying “*my heart hurts here*” given his sternum had been opened four times, he’d had left lower lung collapse and there could even be a dragging, pulling sensation with the VAC dressing.

Jacqui recalled there was clear fluid with a fair bit of blood collecting in the VAC canister. Her Facebook post that day included the comment “*vacuum dressing still pumping gunk*”. Mrs Dalton recalled Dr Ward making a comment at some stage over the weekend about the contents of the canister to the effect “*gee, there’s still a lot of blood coming from that, isn’t there*.” Dr Ward did not specifically recall saying this but acknowledged he may have. In cross-examination by Counsel for the family, Dr Venugopal recalled there was 50-100ml of clear fluid in the canister over the weekend. He explained the VAC

canister contains a gel which swells when it contacts fluid, making an accurate volume assessment difficult.

None of the clinical witnesses involved in Joshie's care that weekend recall the family's specific observations about Joshie's behavioural changes or his complaints of pain (other than that documented by RN Andresen). None of them recall Jacqui or Mrs Dalton expressing any particular concerns.

Joshie's doctors were not unduly surprised by his decreasing mobility, pain, lethargy and ongoing fevers over the weekend of 14-15 November given he had undergone another general anaesthetic and debridement on 13 November. Dr Venugopal explained it is not unusual for a post-debridement patient to develop fevers and tachycardia as a physiological response to the release of cytokines following the disturbance of settled tissues by the debridement. He qualified this by saying if the fevers and tachycardia were persistent then they would look at it closely but at this stage Joshie was being taken to theatre on Monday for a VAC dressing change in any event.

It must be acknowledged that Joshie's family and his treating team were seeing his presentation over the course of the weekend from different perspectives. The clinical evidence and the family's observations of Joshie's behavioural changes demonstrate a change in his condition over that period. While his clinical signs were consistent with an expected post-operative physiological response, Dr Horton acknowledged that with the marked reduction in mobility with tachycardia on the Sunday and the ongoing fevers there was a deterioration in Joshie's overall picture that was "slightly greater" than he was expecting.

Was Joshie's condition over the weekend of 14-15 November managed appropriately?

I am satisfied the cardiology team was alert to the change in Joshie's condition and were investigating and managing it closely by commencing a septic screen, broadening his antibiotic therapy and consulting with the respiratory team with intention to involve the infectious diseases team the following day.

At some stage Dr Venugopal and Dr Ward were at the bedside together and had a discussion about how the VAC dressing worked as Dr Ward was not familiar with it. There is no evidence of any focussed discussion between them or other members of their respective teams about the fact of Joshie's fevers and potential causes, including whether it could be the wound or inside the chest. Indeed, Dr Venugopal was not aware the cardiology team were concerned about an infective cause and had commenced a septic screen. While the cardiology team were investigating a number of potential causes, active consideration of the wound in the overall picture was the responsibility of the cardiac surgical team, not theirs. On Dr Venugopal's evidence, the surgeons were not concerned about or actively considering the possibility of wound infection or mediastinitis over the course of the weekend. Even had he been made aware of the cardiology's concern about infection, he said he

would not have changed the plan to examine the wound again on Monday 16 November. On his evidence there was nothing to give him cause him to reconsider that plan.

Drs Horton, Ward, Venugopal and Alphonso were each asked to consider the possibility of the wound as a potential cause of the ongoing fevers and tachycardia:

- after being examined on Joshie's clinical observations and the progress notes, Dr Horton agreed it was theoretically possible to link them but difficult to be definitive. In expressing this opinion Dr Horton, like Dr Venugopal, acknowledged there was already a plan to return to theatre on 16 November to change the VAC dressing and reassess the wound;

- Dr Ward agreed that despite the negative blood cultures and wound swabs it was possible Joshie still had significant infection;

- Dr Alphonso accepted that if there was no source identified, it was possible the fevers were coming from the wound; and

- with the benefit of knowing the autopsy findings and the overall clinical picture, Dr Venugopal considered it was "very unlikely" Joshie had an early sepsis or a missed mediastinitis.

The experts' opinions about possible causes of the ongoing fevers and tachycardia can be summarised as follows:

- notwithstanding the autopsy findings, Drs Finucane and Konstantinov were not prepared to rule out the lungs as a possible cause of the fevers as it is possible for actelectasis to cause fever;

- in the context of negative blood cultures and the echocardiogram findings endocarditis was an unlikely cause;

- while it was not possible to rule out intravenous access as a potential source of infection, there is no indication in the medical record of any clinical suspicion or need for the access to be removed;

- while Dr Finucane thought the tachycardia might be due to a combination of fever and low haemoglobin, A/Professor Chard did not consider a haemoglobin of 8.6 to be low enough to cause significant tachycardia;

- A/Professor Chard considered an undiagnosed sepsis was a high probability for Joshie's tachycardia, particularly on Sunday 15 November. The other alternative was some sort of atrial arrhythmia but given the ECG report of sinus tachycardia he doubted this was an issue. He thought on the balance of probability the most likely cause of the fevers was the wound. Dr Finucane accepted that given Joshie's presentation on 15 November, a developing sepsis as result of the

wound was definitely high on the list of possibilities but by no means confirmed. Dr Finucane thought despite the debridement it was possible that infection was coming from the wound and that the surgeons had missed infection behind the sternum. Both Dr Finucane and Professor Konstantinov agreed it was more probable than not that the wound was the source of infection; and

- Dr Finucane advised that of patients who have a wound sample taken in the context of investigating mediastinitis, 75% would grow an organism and of the 25% who didn't most were on antibiotics.

Dr Finucane advised that you would expect post-wound exploration fevers to settle within 24-48 hours. After a couple of days of ongoing fevers she would be starting to investigate further with either a return to theatre to look behind the sternum or CT scan. She considered the plan to take Joshie back to theatre on Monday 16 November to review the wound was reasonable.

A/Professor Chard agreed with Dr Finucane that fever 24 hours after the exploration could be related to the disturbance from the surgery. However, with the prolonged fevers and tachycardia on 15 November (noting Joshie's normal resting heart rate was 80 beats per minute), he would have been deeply suspicious of an uncontrolled infection and it would have been worthwhile considering further exploration of the wound that day. His greatest concern was the development of bacteraemia which can be catastrophic and as such he would have been keen to control any septic focus.

It is important to assess the situation that was unfolding over the course of the weekend prospectively – fevers with associated tachycardia are not unexpected post-debridement; notwithstanding the ongoing fevers and tachycardia and some increased but not severe pain, Joshie was not presenting as acutely or systemically unwell; there was no redness or ooze from the wound nor any significant change in the contents of the VAC canister; nothing had grown on the blood cultures or wound swabs; there was nothing concerning on repeat echocardiogram on the Saturday; the repeat chest x-ray on Sunday showed resolving left lower lobe collapse; the cardiology team were actively considering infection as a possible cause and by Sunday afternoon Joshie was on triple intravenous broad spectrum antibiotics. While there appears to have been little or no discussion between the consultants and their teams about the possibility of infection per se or the wound being the cause, I accept the change in Joshie's condition wasn't so acute as to warrant bringing forward the planned return to theatre to reassess the wound the next day.

Events during the night shift 15-16 November

The 2:00am MET call

RN Alison Martin was rostered on the night shift and allocated to Joshie and one other patient. Unfortunately she was not able to be located to provide a statement or give evidence at the inquest.

The nursing handover identified Joshie as a patient of concern noting he had been febrile during the day and was on triple intravenous antibiotics. As such, he was seen at around 9:00pm by RN Jodie Murray in her capacity as Clinical Nurse Consultant Safety. She noted he was febrile at that time but his oxygen levels were good. There had been no change in his condition since the start of the night shift.

Mrs Dalton was staying with Joshie that night. At around 11:00pm, he woke for his usual cuppa. He said he was very thirsty so she offered him a glass of milk. He drank it and drifted off to sleep again. She did too.

Just before 2:00am Mrs Dalton was woken abruptly by the sound of Joshie's breathing which she described as "*changing and raspy*". She immediately activated the call buzzer. RN Martin was the first to arrive. Mrs Dalton recalls RN Martin checked Joshie's temperature. She then pulled down the sheet and they both saw fresh blood under the VAC dressing. Mrs Dalton described it as the size of an adult hand pooling under the intact clear dressing. RN Martin activated the nurse assist buzzer to which four nurses responded immediately - CN Cara Sizeland, RN Rachael Johnson, RN Yvette Canning and RN Lisa Doeblien.

RN Johnson recalled seeing Joshie in the bed and Mrs Dalton and RN Martin in the room. Joshie looked grey and cyanosed like he was not getting enough oxygen. RN Johnson applied an oxygen mask while RN Martin took a set of observations. Mrs Dalton told the nurses Joshie wasn't breathing right.

RN Johnson observed a circular pool of fresh blood under the clear dressing approximately at the centre of the wound nearly to the edge of the dressing and the VAC canister was full of blood. She could not estimate the volume of canister. We now know the canister held 300mL. CN Sizeland estimated at first the collection of blood was the size of a 20 cent piece. Both nurses described it as increasing in size over minutes. CN Sizeland recalled RN Martin telling her the canister had been empty an hour earlier when she had checked it. CN Sizeland had not seen the canister earlier that evening but felt what they were seeing was not consistent with Joshie having been bleeding for an hour; rather the bleeding increased very quickly over the short time they had been in the room.

This is consistent with RN Martin's description of the bleeding in her retrospective nursing entry made at 4:43am "*On initial assessment, VAC dressing observed to be intact with no sign of ooze. VAC pump also examined and appeared to be working well. RN Johnson also visualised VAC. Nil concerns raised…At 1000hrs, VAC dressing had nil ooze and VAC canister was empty…lights turned on and I immediately noticed blood pooling at VAC dressing site…Bleeding worsening within 1-2 minutes*."

The nurses present set about attaching Joshie to a portable monitor.

RN Doeblien arrived shortly after RN Johnson and said they needed to stop the bleeding. She and RN Johnson put on gloves and applied pressure to

Joshie's chest with their hands while other people were getting gauze packs. From this time on these two nurses did not remove pressure from Joshie's chest until they were asked to by Dr Venugopal once they were in theatre two hours later.

RN Johnson said they were having to apply quite a lot of pressure. They were standing either of the bed soaking up the blood that was now coming out each side of the clear dressing. They were using gauze squares (5cm x 5cm) and thicker, more absorbent combine dressings (10cm x 20cm) and having to change them very frequently. Mrs Dalton was helping the nurses by unpacking some of the gauze packs. Mrs Dalton said she was doing her best to stay calm as Joshie was looking up at her and she did not want to alarm him. RN Johnson was holding Joshie's hand on top of her hand on his chest, trying to calm and reassure him "*to make sure he knew he was safe*." Mrs Dalton told the court Joshie "just loved" RN Johnson.

In the meantime, CN Sizeland had left the room to phone Dr Rajanbabu from the nurses station. She recalled Joshie's telemetry monitoring was alarming at this time. She made the call at around 2:00am. She told him words to the effect *"there's an issue with the VAC, it's full of blood, he's bleeding from the chest*" and "*he's having trouble breathing*". He suggested they might need to repack the wound. At this point in the conversation RN Martin approached the nurses station saying Joshie was not looking well and asked whether they should call a Code. CN Sizeland agreed and told Dr Rajanbabu she was going to hang up in order to call a Code. She told him he needed to come in now.

CN Sizeland immediately called a Code Blue and RN Martin pressed the emergency buzzer in the room. She then took a resuscitation trolley into the room and commenced documenting Joshie's observations on the Medical Emergency Record. The first set were respiratory rate 52, oxygen saturation 95%, pulse 163, blood pressure 117/58 and temperature 38. Joshie was pale but conscious and able to speak. The nurses and Mrs Dalton were all reassuring him. Mrs Dalton contacted Joshie parents telling them to come in quickly. Jacqui was coming from Margate and Nick from Deception Bay.

The PICU MET team, comprising the PICU Junior Registrar and the PICU nurse, left the PICU immediately to attend the call. The PICU Fellow, Dr Sebastian Rimpau, accompanied them. The MET call came just as PICU consultant Dr Christian Stocker was preparing to leave for the night. He decided to stay in case his input was required.

The MET team comprised teams from PICU, the emergency department and the ward. The Medical Registrar, Dr McGrath was the first to arrive, followed by the emergency department team (a doctor and a nurse) and then the PICU team. The MET team was assembled at the bedside within minutes of the call being activated. RN Murray and Bed Manager, Jo Owen, arrived next.

CN Sizeland and RN Martin provided a handover to the team outside the room, including that Dr Rajanbabu had already been contacted and was on his way.

On entering the room Dr Rimpau observed Joshie was awake, responsive and orientated. He was able to speak to Joshie, get appropriate answers and reassure him. Joshie was on his back, semi-recumbent in the bed with multiple pillows behind his head. He was pale. He saw two ward nurses holding white dressings on to Joshie's chest. While unable to say whether the dressings were bloody, he did not think they were drenched. He did recall the clear dressing was bulging with dark blood pooling behind it but was not pulsating. He couldn't be sure if he saw at the time there was bleeding from the side. He too saw the VAC canister was filled with blood. He described the situation as both reassuring – because Joshie was awake, oriented, able to talk and he had good blood pressure – but alarming. His initial sense of relief slowly dwindled as it became apparent to him this was a quite serious situation.

Dr Rimpau led the resuscitation. He immediately asked Dr McGrath to call the Blood Bank to ask for a Group and Hold and packed red blood cells. She faxed a Request Form to the Blood Bank and followed up with a phone call to alert them the request was on its way and that the products were needed for a MET situation. Dr Rimpau recalled being told the requested blood products would not be available for 30 minutes because they didn't have an active cross-match. A nurse told him there were O-negative blood products in the operating theatre fridge on level 4 that had been reserved for another patient. Dr Rimpau instructed Dr McGrath to tell the Blood Bank they would use that O-negative blood while they waited for the blood products.

PICU nurses RN Mike Bingham and RN Samantha Tenison-Woods brought the Albumin and O-negative blood to the ward. They both stayed to assist in the resuscitation, including by collecting equipment and drawing up blood into syringes to administer to Joshie.

As Joshie only had a small PICC line, the MET team's next priority was obtaining intravenous access. Dr Rimpau recalls access was difficult but he was able to site a 22G cannula in the left hand. Intravenous fluids were commenced at 2:20am followed by four 60ml boluses of O-negative blood from 2:25am (equivalent to one unit of blood) and then two 60ml boluses of Albumin, the last of which was recorded as being given at 2:38am.

At some point the nurses started using towels instead of gauze and combine dressing to keep pressure on Joshie's chest. CN Sizeland explained this was because a towel being bigger was easier to use rather than opening up packets of combines. She could not say whether they ran out of dressings while Joshie was on the ward. She didn't think they had change the towels while he was there because she did not recall there being soaked towels when she cleaned up the room later.

Within ten minutes of the MET call, Joshie's heart rate had increased to 205 beats per minute. Apart from the elevated heart rate his observations remained stable. He was still awake and talking. When asked to consider Joshie's observations over the course of the resuscitation, Dr Rimpau thought his respiratory rate possibly reflected that Joshie was guarding but his oxygenation was fine; he attributed the significantly elevated heart rate to hypovolaemia and anaemia and he observed that Joshie's blood pressure remained quite reasonable up until around 2:35am, commenting that children can maintain their blood pressure for quite some time.

While the MET team were prepped to intubate on the ward, Joshie's condition at that time did not require it.

Dr Rimpau spoke briefly to Dr Stocker early in the resuscitation to ask him to stay as although he didn't have a full understanding of what was going on he knew he would need him.

In the meantime Dr Rajanbabu had run approximately one kilometre from his residence to the hospital. He said he left straight after the phone call from CN Sizeland, arriving at the hospital at around 2:16am. He was getting into the ground floor lift when he received another call on his mobile from the nurse asking where he was. He went straight up to Joshie's room. The MET team were all in attendance by this time.

Dr Rajanbabu came to the bedside and stood beside Dr Rimpau. Dr Rimpau recalled him looking at Joshie, the monitor and the wound from that position. CN Sizeland was standing on the other side of the room at this time holding the MET call record. She did not specifically remember telling him Joshie's observations but they were visible on the portable monitor.

Dr Rimpau and Dr Rajanbabu conferred briefly at the bedside. Dr Rimpau's recollection is Dr Rajanbabu was hopeful that it was oozing from the wound but when asked his opinion Dr Rimpau responded saying it could be but he didn't think so. He thought it was a surgical bleed. They also discussed whether to administer Prothrombinex to reverse the warfarin. Joshie's last recorded INR was 2.1, a level Dr Rimpau described as not particularly high. He said Dr Rajanbabu did not want to do this because of the mechanical aortic valve.

Dr Rajanbabu said he saw three things – how much blood was in the canister; there was an unusual amount of blood under the dressing and Joshie looked pale. He recalled seeing someone applying pressure to Joshie's chest to mop up blood that was coming out of the side of the clear dressing. He had never seen something like this before so he felt it important to get his consultant in to do the assessment.

At some point the suction on the VAC dressing was switched off.

The 2:19am phone call

Dr Rajanbabu then phoned Dr Venugopal. This call was made at 2:19am.

Neither doctor could recall the exact conversation.

The doctors agree the following information about Joshie's presentation was exchanged during the call:

- there was blood collected under the dressing;
- there was blood in the VAC canister; and
- Joshie was tachycardic.

There is conflict between their evidence about whether the following information was conveyed at this time:

- Joshie's vital signs - Dr Rajanbabu said Dr Venugopal asked him if Joshie was stable, this prompting him to ask the MET team about Joshie's blood pressure and then tell Dr Venugopal Joshie was pale and tachycardic but his blood pressure was stable. Dr Venugopal said he asked how Joshie was doing clinically but denies being told Joshie's vital signs, other than being told he was "slightly tachycardic" and sitting up and talking to his grandmother;

- Joshie's INR – Dr Rajanbabu said Dr Venugopal asked for the INR prompting him to ask a nurse and then tell Dr Venugopal. Dr Venugopal said he was not given the INR at this time but rather he asked Dr Rajanbabu to call him back with the INR and the vital signs;

- the description of the blood under the dressing – Dr Rajanbabu recalled seeing blood collected below the dressing with some blood leaking out the side. The two nurses were still applying pressure to the wound at the time. He could see they were using something to mop up the blood that was coming out. He said he told Dr Venugopal there was blood under the dressing. Dr Venugopal said he was told Joshie had significant ooze and soaked dressings;

- the amount of blood in the canister – Dr Rajanbabu said he thought Dr Venugopal asked how much blood was in the canister and he told him 200-300mls. Dr Venugopal did not recall being told this, saying he asked Dr Rajanbabu to call him back with the INR and amount of drainage in the canister. His evidence was had he been given this information during this phone call he would have come straight into the hospital rather that sit at home waiting for the next phone call. There is no evidence they discussed the appearance of the blood, for example, was it blood-stained fluid or frank blood? In cross-examination by Counsel for the family, Dr Venugopal said information suggesting the canister was full with red fluid "..*would be a concern, but it's not something which would alarm me, because it just means that the VAC dressing is sucking out the serous fluid from the wound, if it's haemoserous, and that's – that would be a normal presentation if you put somebody on a wound infection*"; and

- the MET team was in attendance – Dr Rajanbabu said he reported that that Joshie was being resuscitated with blood and fluids. Dr Venugopal denies being told a MET call had been made.

The doctors agree they discussed possible causes of the bleed being either the wound site or from inside the chest, with specific consideration of bleeding from the thin aorta (a catastrophic event).

Dr Rajanbabu explained a wound bleed in a warfaranised patient could be from the edges of the sternum, periosteal edges, skin edges where there are capillaries or from granulation tissue. He was aware it was an acute bleed. His preliminary thinking was it from the fragile aorta. His evidence is consistent with that of Dr Rimpau who described their shared impression at that time this was more than a "medical bleed" and needed surgical intervention.

But Dr Venugopal did not consider a bleed from the aorta as a "top priority" because a bleed of this kind so long after the initial surgery was unlikely. Further, had it been the aorta he would have expected a far more catastrophic bleed than he perceived there to be from the information he said he was given and for Joshie to be far more haemodynamically compromised than sitting up and talking. In evidence he explained "the more common possibility" for bleeding in a boy with an open wound with a VAC dressing with negative pressure suction and on anticoagulation was oozing from the granulation surface of the wound at a time post-operatively when new granulation tissue was forming, which was collecting in the VAC canister.

Dr Venugopal did not sense any urgency about the situation. Based on the information he says he was given at that time "*it looked unlikely that it was a more sinister bleeding*".

The doctors agree that Dr Venugopal asked that Joshie be taken to the PICU for the dressing to be taken down to inspect the wound and for Dr Rajanbabu to then update him further. In requesting the transfer to PICU, he was thinking about the potential for Joshie's INR to complicate things, him being on both anticoagulation and antibiotics. There is no evidence to suggest they discussed the possibility of Joshie needing to go to theatre even though Dr Rajanbabu was already aware the emergency/trauma team was being called in. He did not tell Dr Venugopal the call-in had been activated.

By the end of the phone call, Dr Rajanbabu understood the plan was to transfer Joshie to the PICU for further assessment including an echocardiogram and an inspection of wound in PICU. Although Dr Venugopal could not recall any discussion about an echocardiogram he conceded in cross-examination he might have ordered it because it would give some indication whether there was any collection behind the sternum.

By the end of the phone call, Dr Venugopal's expectation was that Dr Rajanbabu would arrange for the PICU team to attend the ward to transfer Joshie and then contact him again once Joshie was in the PICU, he had taken down the dressing and would have "more numbers" (the INR, haemoglobin,

blood pressure and pulse rate) to give him as well as where he thought the oozing was coming from.

Dr Rimpau said Dr Rajanbabu told him they thought it was the wound and would assess it further with a chest exploration or chest opening in PICU. He then asked Dr Rajanbabu to go to PICU to organise things there while he concentrated on managing Joshie. Dr Rajanbabu then left the ward.

Dr Rimpau explained they had done chest openings in the PICU previously to manage cardiac tamponade or for the surgeons to wash out and explore a bleeding source. In this situation he felt PICU was the safest place for Joshie and although theatre wasn't thought necessary at that time, he felt if the bleeding continued the way it was the cardiac surgical team would change their minds and take Joshie to theatre. The theatres are collocated with PICU.

Dr Rajanbabu contacted Dr Horton at around 2:26am just as he was getting into the lift on level 10. Dr Horton was asleep in the hospital at that time having come in earlier to review another patient.

Dr Rajanbabu then phoned the on-call theatre nurses. He spoke first with RN Jiby Matthew at around 2:32am. His rationale for contacting the nurses at this time was because he was almost sure they would need theatre support, or at least the theatre nurses, and he wanted to give them time to get ready. He explained that while he may not need them for a dressing change, he would need them for a chest opening in the PICU. At that time he was undecided about what he would do. RN Matthew said he told her there was a possibility she might be required for a VAC dressing change but he did not give her any other information about the patient. She then phoned the second theatre nurse, RN Diane Rejimon.

Dr Rajanbabu went from level 10 to the change rooms on level 5 to get into scrubs.

He then went to PICU on level 4. Joshie was already there when he arrived.

Dr Rajanbabu phoned RN Matthew again to tell her an echocardiogram was being performed and he would let her know the outcome. She updated RN Rejimon. Although they had not yet been told to come in to the hospital, both theatre nurses had already started getting ready.

Events on the ward after Dr Rajanbabu's departure

Joshie stayed conscious and alert throughout the resuscitation on the ward. He remained tachycardic (pulse rate above 190) with an elevated respiratory rate but good oxygenation and his blood pressure remained stable.

Dr Rimpau phoned Dr Stocker. Dr Stocker recalled this conversation occurring approximately 20 minutes after the MET call. Dr Rimpau told him the bleeding had stabilised, Joshie now had a good blood pressure and pulse but that it was significant bleeding and he thought theatre was required and someone was organising that.

Dr Horton arrived on the ward at around 2:28am. He did not specifically recall reviewing Joshie there. He was told Joshie was unstable and there was blood in the VAC dressing and they wanted an echocardiogram. Dr Horton then left the ward to set that up in PICU.

Dr Rimpau phoned the Senior PICU Registrar, Dr Andrew Hughes, to ask them to get ready for Joshie's arrival. RN Owen contacted the PICU Team Leader to ensure a bed space was set up to receive him.

When asked whether at that time there was any sense of urgency about getting Joshie to theatre, Dr Rimpau said he was hopeful that by the time they arrived in PICU the surgeons would have a plan in place given Dr Rajanbabu had left some 15-20 minutes earlier.

An on-call theatre team is activated

From the start, RN Murray assumed Joshie would be taken to theatre for repair of what she assumed was a deshisced wound. There were four on-call theatre teams at LCCH – emergency/trauma, liver and transplant, ECMO/cardiac surgical and cardiac catheter laboratory teams. She was looking for guidance about which team to call in.

Dr Rimpau had a brief discussion with RN Murray and RN Owen before he went into the room to assess Joshie. He recalled agreeing to a suggestion made at this time that the trauma team should be activated. He was inclined to accept the nurses' assessment that Joshie might need to go to theatre. His thinking was the trauma team could respond quickly and could always be stood down if it turned out they weren't needed. RN Murray's recollection is Dr Rimpau did not decide this until after he had assessed Joshie and when they were arranging additional intravenous access.

RN Murray and RN Owen had started calling the emergency/trauma team before Dr Rajanbabu left the ward. They did this from the nurses station with reference to the call-in lists in the Bed Manager's folder. They told the team members they thought it was a deshisced wound requiring surgical repair. Most of those RN Murray spoke to indicated they could be there within 15-20 minutes. However, RN Owen told her she was receiving calls from various trauma team members advising they do not come in for cardiac patients and the cardiac surgical team should be contacted instead.

RN Owen recalled waiting to speak to Dr Rajanbabu while he was on the phone with Dr Venugopal. Once he finished the call, she told him she had already called the trauma team and wanted to know if he wanted the cardiac theatre team to be called. On the evidence of RN Murray and RN Owen, Dr Rajanbabu indicated he did not as they were taking Joshie to PICU.

Shortly before Joshie left the ward for PICU, RN Owen sought further clarification from Dr Rimpau about the theatre team call-in. It was at this time he decided the cardiac surgical team should be called in. He felt this situation was more than something they could manage with just blood products. In

evidence he confirmed his thinking at this stage was not informed by any indication from Dr Rajanbabu about the need for that team to be mobilised. This is consistent with the evidence of RN Murray who said she and RN Owen had different instructions coming from each Fellow at that point. They decided to listen to Dr Rimpau given he was leading the resuscitation. RN Owen stood the trauma team down.

At that time there was no specific call-in list for the cardiac surgical team, but there was one for the ECMO team. The ECMO and cardiac surgical teams were the same, except for a perfusionist who was part of the ECMO team only. The decision to activate the cardiac surgical team lay with the Surgical Fellow or another member of that team.

CN Sizeland recalled seeing the two nurses at the nurses station at around 2:35am trying to figure out who to call. RN Murray contacted the hospital switchboard for assistance but they only had the same on-call lists. She and RN Owen then decided to start phoning everyone on the ECMO team. RN Murray phoned the first theatre nurse, RN Matthew who said she would be there in 20 minutes and would phone RN Rejimon. RN Matthew had already received the call from Dr Rajanbabu and knew this call was about the same patient. She could not recall whether RN Murray told her the patient was bleeding profusely. A short time later, RN Matthew received a third call from Dr Rajanbabu asking her to come in. She phoned RN Rejimon who by then was ready to drive in.

RN Murray next phoned the perfusionist, Carla Zazulak. Ms Zazulak explained it for unusual for her to be contacted by anyone other than the cardiac surgeon or cardiac Surgical Fellow. She was not given any information about the volume of bleeding. It was at this point RN Murray became aware they were getting ready to transfer Joshie so she returned to the room to help.

The transfer took approximately 10 minutes and was uneventful apart from intravenous access in Joshie's hand being lost. RN Johnson and RN Doeblin continued to apply pressure to his chest. Joshie remained conscious and alert. Mrs Dalton went with him.

The PICU observation recording commenced from 2:44am – the monitors record observations every minute as soon as they are connected to a patient. Using this as a benchmark, Joshie arrived in PICU sometime between 2:40am – 2:45am.

Joshie's arrival in PICU

Joshie was awake and able to talk when they arrived in PICU. The team was met by Dr Stocker, Dr Hughes, Dr Shane Gardiner (another Senior PICU Registrar), Dr Greg Nolan (the PICU retrieval registrar) and PICU nursing staff.

Mrs Dalton remained out by the nurses station as there was no room in the bed space with so many people around Joshie. RN Owen was supporting her.

Dr Stocker immediately assessed Joshie. He felt Dr Rimpau's earlier assessment was correct. From his inspection and patient assessment "*this was serious bleeding, not just superficially but coming from deep..*" - it was a serious situation. Joshie was still talking. He had a measurable blood pressure under a lot of effort with volume and adrenaline. At that time, Dr Stocker was under the impression the cardiac surgeon was on his way.

Within five minutes of Joshie's arrival, Dr Stocker initiated the Massive Transfusion Protocol (MTP). This activates the urgent delivery of packs of blood products from the Blood Bank. Dr Stocker explained he did this because he assessed Joshie as meeting the criteria of 'critical bleeding', meaning life threatening major haemorrhage. Dr Stocker described the situation as "*he already had several probably litres of fluid in him and still profuse bleeding from his chest wound, and we had to give volume ongoing. We had to give blood ongoing. We had to – had him on an adrenaline infusion and additional gave adrenaline [indistinct] so this bleeding was massive and would have met the criteria of critical bleeding*."

According to the MET record, Joshie had received 240ml of blood and 120ml Albumin in addition to normal saline running at 100ml per hour while on the ward. The fluid balance chart in PICU was not completed and no other documentation able to be located regarding fluid or drug administration so it is difficult to establish what fluids Joshie had had or was receiving when Dr Stocker assessed him.

Dr Stocker then assigned various PICU staff to different resuscitation roles. His aim was to stabilise Joshie haemodynamically. He described the PICU staff who were rostered on this shift to be some of the most experienced and highly qualified staff they had.

There is a paucity of clinical documentation for the period from around 3:00am until Joshie's death. Dr Stocker had appointed one of the PICU nurses to scribe once Joshie arrived in PICU. However, this nurse was called out to another patient in the PICU soon afterwards leaving no one else available to scribe – all other available staff were either assisting with Joshie or attending to other patient who they were unable to leave. It was not possible for those staff attending Joshie to maintain contemporaneous notes without the assistance of a scribe. This is why most of the clinical record for this period was documented retrospectively by the staff involved.

Dr Gardiner described the appearance of Joshie's dressing by now as a large bubble of blood under the clear plastic dressing which was 10-15cm and two nurses were mopping up the blood escaping from the sides of the dressing.

Dr Rajanbabu arrived in PICU after Joshie. He immediately spoke with the Dr Stocker. He did not recall being given an update or reviewing Joshie himself before this conversation. Dr Stocker said he asked how long it might be until the cardiac surgical team arrived and was advised they wanted to do the echocardiogram first. He recalled clearly expressing his opinion that regardless of the echocardiogram findings, Joshie needed to go to theatre

because the bleeding was not oozing but massive bleeding potentially from deeper down. Dr Rajanbabu could not recall being told about massive or catastrophic bleeding and did not think they discussed the echocardiogram. He agreed Dr Stocker indicated he was not happy for the wound to be inspected in PICU; that Joshie needed to be taken to theatre for investigation and the theatre needed to be activated. He estimated their discussion took several minutes because it canvassed two different plans – inspecting the wound in PICU or in theatre.

While Dr Stocker did not think the echocardiogram was necessary as the deep bleeding was obvious, he conceded if it had been ordered by a consultant, he as a consultant would expect the more junior doctor to carry out his order.

There is no evidence to suggest Dr Stocker told Dr Rajanbabu during this conversation that he had activated the MTP.

It happened that Dr Horton was performing the echocardiogram at around this time. He understood the echocardiogram was requested to investigate Joshie's heart function and whether there was pericardical effusion. He described performing the procedure in difficult emergency circumstances. Joshie was unstable, there were many resuscitation team members performing various tasks around him and it was complicated by the dressings on the chest, where the echo probe is usually placed. The nurses were still applying pressure to the chest. He did not remove or adjust any of the dressings because the "*ultimate importance was to tamponade the amount of bleeding."* His memory of the dressings was "*it was all soaked in blood. Certainly a very large amount of blood loss there*." This meant he was unable to obtain the standard views but did obtain windows from the lateral axilla and subcostal regions. The images were sufficient for him to determine quickly there was good hyperdynamic heart function and no pericardial effusion. Dr Horton reported these findings to Dr Rajanbabu, Dr Stocker and Dr Rimpau.

Dr Rajanbabu went over to see the echocardiogram before he phoned Dr Venugopal. He said he was standing in front of Joshie but said he did not have time to perform a formal assessment of him. In evidence he described the situation as "*it was difficult to assess, because the team was giving fluid, and I didn't have a chance to look at the canister or in the –thing*." After viewing the echocardiogram images, Dr Rajanbabu's priority was to start activating the theatre "on a priority basis" and he left the bed space to make phone calls from out near the nurses station.

It was not clear from his evidence whether he realised the MTP had been activated or that he understood what that was.

What Dr Rajanbabu did next

Dr Rajanbabu explained it takes approximately 45 minutes to an hour to assemble an on-call theatre team to be ready to operate at night. It was the Surgical Fellow's responsibility to initiate the call-in.

He contacted the theatre nurse first because they needed to set up the theatre. He phoned RN Matthew at 2:46am and told her to come in. She then phoned RN Rejimon who was by then ready to leave home.

Dr Rajanbabu was about to phone Dr Venugopal when he received a call from Ms Zazulak. According to Ms Zazulak's mobile phone log, this call was made at 2:47am. She was asking for more information about the patient and what was required of her. His evidence was he cut the call short in order to speak to Dr Venugopal first and then call her back. Ms Zazulak's evidence suggests a slightly longer conversation that left her with the impression she perhaps wouldn't be needed because it was going to be a dressing change with a theatre nurse. She conceded she couldn't be sure he didn't tell her this and instead needed to speak to the consultant to work out the plan first.

Dr Rajanbabu then phoned Dr Venugopal. In his initial statement made on 11 January 2016, he said this call was made at 2:49am. This is consistent with Dr Venugopal's recollection informed by reference to his mobile phone call log. However, in a subsequent statement made on 22 November 2017, Dr Rajanbabu said the phone call was made earlier at 2:47am. When this was put to Dr Venugopal, he maintained having received the call at 2:49am. Unfortunately phone records were unable to be retrieved to clarify this issue. Taking into account the timing of Joshie's arrival in PICU, Dr Rajanbabu's arrival, conversation with Dr Stocker, observation of the echocardiogram and prior phone calls with the theatre nurse and Ms Zazulak, I find the phone call was more likely to have been made closer to 2:49am.

Dr Rajanbabu estimated the call took 1-2 minutes.

The doctors agree they discussed the following information:

- Dr Stocker was not happy for the wound inspection to be done in PICU - Dr Rajanbabu described the purpose of this call as him conveying information between Dr Stocker and Dr Venugopal; and
- Dr Venugopal agreed to activate the theatre and was coming in to the hospital.

Dr Venugopal recalled being told the wound was still oozing. He said he did not get a sense of urgency from their conversation. Dr Rajanbabu couldn't recall much of the conversation including whether he explained why Dr Stocker held the view he did about where the inspection should be done. In evidence he acknowledged "*Obviously he told me that this patient is bleeding; "This patient needs to go to the theatre, and you need to get the theatre team*."

Dr Venugopal did not ask for any further information about the bleeding during this call. He said "*in retrospect, maybe I should've asked that. I didn't, because at that stage, I'd already made the plan that he's going to theatre anyway.*" In cross-examination he accepted he could have asked Dr Rajanbabu anything about Joshie's condition including vital signs and INR, and could have asked to speak with Dr Stocker. While he was surprised by

Dr Stocker's view he did not want to have a difficult conversation or get into an argument when he knew he knew he was going in to the hospital to inspect the wound anyway.

He said had he been given information such as the MTP having been activated and that Joshie was tachycardic and hypotensive it would have changed how he approached things – he would have been mentally prepared to come in as an emergency and would have immediately changed into scrubs before going to the PICU so he was prepared to shift the patient immediately. He would also have spoken to Dr Stocker. This would have given him a full picture and they would possibly have come up with a joint plan including the use of ECMO or opening the chest.

Dr Rajanbabu then contacted the on-call anaesthetist, Dr Mike Ranger, via the hospital switchboard. Dr Ranger said he told to come in as Joshie was draining blood into his VAC dressing. He was simply told it was urgent but not given any other information about the patient. He explained at that time in the morning that was all he needed to know. Dr Ranger advised he was an hour away. He left immediately to drive to the hospital.

Dr Rajanbabu then spoke to Dr Stocker about Dr Ranger's estimated time of arrival. Dr Stocker told him there was an anaesthetic registrar available in PICU would could manage the anaesthesia until Dr Ranger arrived. Dr Rajanbabu phoned Dr Ranger again to let him know and told him not to rush. RN Murray overheard this, later documenting in her contemporaneous note of the night's events as "*cardiac surg – told anae - don't rush not urgent*." Dr Ranger could not recall being told this; he was operating under the understanding he was required to attend urgently.

Dr Rajanbabu said he then phoned Dr Venugopal at 2:59am, he thinks to update him about Dr Ranger. Dr Venugopal did not recall this phone call. He was in his car at the time, and on checking his mobile phone since claimed there was no record of a call received at this time. In the absence of phone records, the fact of this call could not be verified.

Perceived delay in delivery of blood products to PICU

Joshie's resuscitation continued in the meantime. He remained awake, alert and quite calm.

On the first set of PICU observations recorded at 2:45am, Joshie's pulse was 188 and his non-invasive blood pressure was 88/45. Dr Rimpau recalled the blood pressure reading from the arterial line was much lower than had last been recorded by the cuff on the ward (100/43). It was not clear whether this represented a change in recording mechanism or a change in clinical condition.

Once the MTP was activated, the team's priority was to stabilise Joshie haemodynamically. On his arrival in PICU they took steps to enhance his vascular access with the addition of an intraosseous line (inserted by Dr Rimpau) and a central line and left femoral arterial line (sited by Dr Gardiner).

During the line insertion Joshie became briefly unresponsive with seizure-like activity lasting approximately 20 seconds. Joshie then regained consciousness. He was commenced on an adrenaline infusion.

Once Dr Stocker activated the MTP, staff were assigned to various roles – Dr McGrath was liaising with the Blood Bank; RNs Murray and Duncombe were allocated to receiving, safety checking and preparing the blood products for administration. This involved taking the blood products out of the pneumatic transport system (PTS) in the PICU, checking the product against the form sent with the product from the Blood Bank, signing and returning the form through the PTS, drawing up the blood product for use, labelling the syringe with Joshie's name and handing the syringe to the team for use. At some point, Dr McGrath was replaced by another doctor as she was called away to another patient.

A Medirest porter had been sent to the Blood Bank but returned without any blood products because they were being delivered to PICU by the PTS. There was a lamson located immediately outside Joshie's bed space. RN Duncombe said people were constantly asking for blood but it had not arrived. RN Johnson recalled Dr McGrath was periodically on the phone requesting more blood and becoming frustrated. Dr Gardiner recalled there was a problem with blood products arriving as the team was looking for platelets in particular (they needed to replace platelets to establish clotting). Dr Rimpau described sometimes finishing a syringe and wanting a new one but it wasn't available. That said, he and Dr Gardiner both confirmed in evidence they were always giving Joshie fluids including Albumin when blood products weren't available.

Dr Stocker did not recall any delay and thought blood conserves from the ward may still may have been running when Joshie arrived in PICU. There is no documentary evidence to support the administration of further blood products after the last 60ml bolus administered at 2:38am and the arrival of the first blood products under the MTP – two units PRBC and three units of cryoprecipitate – at 3:05am.

Joshie's family arrived in PICU at around 3:00am. Joshie was still awake and talking. RNs Johnson and Doeblien had put towels over him to try to make the scene less confronting for his parents when they arrived in PICU.

A blood gas was taken at 3:02am. It revealed a low haemoglobin (57; normal range 135-175) and Joshie was in metabolic acidosis. This was in the context of the whole unit of blood and Albumin already administered, suggesting there was ongoing significant bleeding.

When asked to consider whether Joshie's bleeding changed from the time he arrived in PICU to the time the arterial line was inserted and recording arterial blood pressure (3:07am), Dr Rimpau recalled *"..we had to give blood fluid volume [indistinct] blood faster and faster and more and more to maintain blood pressure and circulation. And also because of the bleeding – we changed the towels as some point. I think it became clear that the bleeding – more and more, I think, because of regulator speed up on resus*."

Dr Horton remained to assist at Dr Stocker's request. He recalled calling out four times for someone not involved in the resuscitation to update Dr Ward by phone. Dr Ward was not notified about Joshie's condition until around 3:55pm.

The 3:05am phone call

Dr Rajanbabu returned to the bed space for an update on Joshie's condition. He saw the blood was leaking much more than it had been previously – it was collecting on the bed sheet and staff were continuously giving fluids to maintain Joshie's blood pressure. He asked for the blood gas. To him, the combination of continuous blood loss, continuous need for fluid and blood products and the low haemoglobin led to him being *"..100 per cent sure that this is not something simple; we are dealing with something really bad*." It was at this time he thought things were out of control and he thought Joshie needed to be intubated. He immediately phoned Dr Venugopal who at this time was on Coronation Drive on his way in to the hospital.

Both doctors agree the following information was discussed:

- Joshie's haemoglobin was low – in cross-examination Dr Venugopal conceded Dr Rajanbabu may have told him the haemoglobin was 5;
- Dr Venugopal was on his way; and
- the dressing was not to be opened.

Dr Rajanbabu maintains he told Dr Venugopal words to the effect of "*I have a bad feeling about this bleeding. This is definitely from the mediastinal*". In contrast Dr Venugopal said he did not seek further information about the blood gas because Dr Rajanbabu told him the haemoglobin was low and everything else was fine. This made him think it was a significant ooze from the wound but that Joshie was relatively stable. Given he was almost at the hospital, this information did not make a material change to what he was going to do. He was not aware Joshie was receiving blood or the MTP had been activated.

When asked about his understanding of the instruction not to open the dressing, Dr Rajanbabu explained that the tamponade effect of the intact dressing was one of the factors keeping Joshie alive.

Joshie is intubated

At about this time, the resuscitation team decided to intubate Joshie – he was becoming more haemodynamically unstable and it would help save time when he was moved to theatre. He was awake and talking right up to being intubated and Jacqui, Nick and Mrs Dalton had the chance to give him a kiss goodbye. He was intubated successfully on the first attempt and remained cardiovascularly stable during the intubation.

The cardiac surgical theatre team assembles

After speaking to Dr Venugopal, Dr Rajanbabu phoned the Blood Bank to arrange bypass blood products. He then phoned Ms Zazulak. While there is

some discrepancy about the time this call was made I am satisfied it was after the 3:05am phone call to Dr Venugopal. He asked her to come in. She recalled being told about the blood gas haemoglobin level and that theatre was being arranged. She advised him she lived 14 minutes away and would come immediately.

Dr Rajanbabu then left PICU to collect a surgical consent form from his office on level 7. At this time he received a phone call from Dr Ranger asking him to phone the anaesthetic technician as he had been unable to make contact with her. He took this opportunity to ask about Joshie's progress and was told they were just about to or had just anaesthetised him for intubation and ventilation. Dr Ranger advised he was still 30 minutes away from the hospital. It was a short phone call.

Dr Rajanbabu returned to PICU to complete the consent with Jacqui. Joshie was intubated by this time. The consent was for emergency re-exploration of sternal wound +/- resternotomy +/- cardiopulmonary bypass +/- peripheral cannulation +/- intraoperative procedures as needed. Dr Rajanbabu explained that through peripheral cannulation, bypass can take over the function of the heart before the wound is opened allowing the heart to continue to beat but without blood flowing through it. Jacqui could not recall much of the conversation other than being told Joshie was being taken to theatre and Dr Venugopal was on his way.

Dr Gardiner recalled the team asking Dr Rajanbabu to go to the theatre and come back when it was ready. Dr Rajanbabu phoned the anaesthetic technician through the hospital switchboard. He phoned RN Matthew who advised they were already in the theatre. Dr Rajanbabu put this series of phone calls as occurring at around 3:21am. He then went to the theatre.

RNs Matthew and Rejimon had arrived at the hospital at around 3:11am, encountering each other in the lifts. They went to straight to PICU. They were met by Dr Rajanbabu who asked them to prepare the theatre immediately. He told them the rest of the cardiac surgical team were also coming. They could see Joshie surrounded by a team of people and although at that time they did not what procedure was being undertaken in theatre, they went to level 5 to change into scrubs and went straight to the theatre on level 4. This took several minutes. They entered the theatre via the scrub room via a corridor that was lit with a sensor dimmer light which activated as they walked along it. Upon entering the theatre, RN Rejimon turned on the light. They then attended to setting up the theatre which involved turning on the ambient lights (not the operating light) and monitors, checking the equipment, turning on the diathermy, collecting the sterile instruments from the sterile stock room and setting up the trays, disposables and equipment for the procedure. RN Matthew scrubbed for surgery.

On entering the theatre, Dr Rajanbabu told the nurses to get ready with an open heart tray and aortic grafts to prepare for a major procedure. He had asked them to check what prostheses they had in stock so RN Rejimon took him into the stock area to show him what was available.

Ms Zazulak was at the hospital and changed into her scrubs by around 3:25am. On entering the theatre room she saw the lights were on and the theatre nurses opening up theatre packs. She spoke to them to ask the patient's name so she could check the previous perfusion records in order to check what size bypass equipment was required. While in an adult operating theatre the perfusion circuit is set up awaiting any emergency surgery (because perfusion equipment for adults is often 'one size fits all' and there are more emergency surgeries associated with the adult cardiac population), this is not possible in the paediatric environment because the size of perfusion equipment depends on the size of the patient, there being significant variation in paediatric patients.

Ms Zazulak knew Joshie was bleeding so she went into to the collocated cardiac perfusion room to get the cell saver machine ready and moved up to the anaesthetic induction room. She had not yet been told they needed bypass.

Dr Venugopal had arrived in PICU while Dr Rajanbabu was in the theatre. On his evidence he had left home at around 2:50am and based on the call he received while on Coronation Drive at 3:05am, estimated he arrived at the hospital at around 3:10am – 3:20am. He went straight to the PICU.

Dr Venugopal arrived expecting to see a stable boy going to theatre in a relatively stable situation for a dressing removal and wound inspection. Instead he was presented with a child who was intubated and ventilated with lots of bleeding coming from his chest wound and with 2-3 nurses applying swabs to his chest wound to try and stop the bleeding.

He saw Joshie then spoke with Jacqui. He told her he was taking Joshie to theatre and hoped it was just a wound-edge bleed. He explained his assessment as being hopeful this was the case but he was prepared for the fact it could be something deeper. This is reflected in his later comment to Jacqui to the effect "*here's hoping it's not his aorta*". Jacqui described their conversation as having an air of complacency. She was disturbed by what she had seen and felt he wasn't taking it as seriously as all the other staff working on Joshie; a wound edge bleed did not equate to her perception of the seriousness of the situation.

Dr Venugopal had already spoken to Jacqui when Dr Rajanbabu returned to the PICU. He was there when Dr Venugopal asked for Joshie to be moved to the theatre straight away.

On Dr Rajanbabu's evidence he asked Dr Venugopal at around this time whether they should peripherally cannulate before they opened the dressing. He said Dr Venugopal was fairly confident it was a leak from the aorta; something they could control with a finger. Dr Venugopal could not remember this because there was so much happening. When asked about this possibility, Dr Rajanbabu also thought it was the aorta.

Dr Venugopal left PICU to change into scrubs and then went to the theatre. He expressed uncertainty about the situation, indicating they might need bypass and asked them to prepare a bypass tray. He also asked RN Matthew to prepare pledgeted sutures (specially designed to prevent tearing of tissues in bleeding cases).

Dr Rajanbabu acknowledged in evidence that he didn't know what was happening towards the end in PICU because he was busy with getting the theatre activated.

Joshie is moved to theatre

While the theatre was being made ready Joshie became more haemodynamically unstable with increasing tachycardia and hypotension.

The next packed red blood cells arrived at around 3:25am, together with two units of fresh frozen plasma but no platelets.

A blood gas taken at about this time returned a haemoglobin level of 55 and indications of hypovolaemia. This was despite four staff continuously pushing blood products through three access lines simultaneously and ongoing pressure on the chest wound. A calcium infusion was started to treat hypovalaemia. Joshie continued to receive fluids, blood products and escalating doses of adrenalin.

Dr Stocker described Joshie as having been deteriorating constantly since his arrival in PICU and the resuscitation team just barely managing to keep his blood pressure in a low-normal range. He said they realised they couldn't keep up with the blood loss. Various members of the resuscitation team were heard making statements to the effect of "*we can't hold on for much longer*", "*he's getting much worse*".

Witnesses described the situation by now as "*very hectic*". While there was some conflicting evidence about some brief discussion between the teams about whether to stabilise Joshie before he was moved into theatre, even if it did occur this does not appear to have delayed steps to get him moving. There was general agreement to get him into theatre even though the anaesthetic team were still on their way in.

Dr Gardiner recalled Dr Rajanbabu returning to the PICU and confirming the theatre was ready. The team quickly packed up what they needed and transferred Joshie to theatre. According to RN Matthew, this process started after 3:25am, this being the in-suite time recorded on the operation report which in practice reflects the time the doctor is told the patient is on their way. The "*in Anaesth. time*" on this report (3:35am) was when Joshie had arrived at the anaesthetic induction room beside the theatre.

Blood products continued to be administered by four staff and RNs Johnson and Doeblin continued applying pressure to Joshie's chest during the transfer. Jacqui described there being so many people they could barely all fit down the corridor.

Ms Zazulak happened to see Joshie being moved down the corridor. She had just received a phone from Dr Rajanbabu checking she was on her way to the hospital. She explained that the mere fact of the perfusionist being called in does not mean the patient will be going on bypass as the perfusionist can be required for a range of procedures including ECMO. The usual process is for the consultant or Surgical Fellow to communicate whether the plan involves bypass.

At this stage Ms Zazulak had not been told whether Joshie required bypass. However, on her own initiative informed by what she saw coming down the corridor she decided to start preparing the bypass machine. This is a two-stage process involving dry assembly and priming (to de-air the machine). It takes approximately 20 minutes in an emergency situation unnot less there are two perfusionists available to perform each stage. She explained you would normally be adding blood products during the priming stage but can get by without for a short time in an emergency situation. Ms Zazulak commenced the dry assembly stage. This was done in the perfusion room.

The last recorded PICU observations at 3:38am correspond with the operation report "*in OR time*" confirming this is when Joshie arrived into the theatre. While the perception of some members of the resuscitation team was the theatre was in darkness as they brought Joshie in, the evidence clearly shows the theatre was ready to receive him when he arrived via the anaesthetic induction room.

The events in theatre

Joshie had become more unstable during the transfer to theatre losing cardiac output and requiring CPR and multiple stat doses of adrenaline and an increased infusion rate.

Dr Gardiner immediately commenced Joshie on the anaesthetic machine. Joshie was put on the anaesthetic ventilator and the anaesthetic machine monitor. It was very quick and uneventful process. Dr Ranger and the anaesthetic technician both arrived in the theatre at 3:55am, just as Dr Gardiner was siting a neck access point. Joshie was anaesthetised by this time. Dr Ranger took over from Dr Gardiner.

While this was happening, Joshie was prepped and draped ready for the wound exploration. Dr Stocker was there, ensuring the supply of drugs, fluids and blood products to Joshie. The operating table had been moved as Joshie remained on the PICU bed for the procedure.

Shortly after Dr Ranger's arrival, Dr Venugopal asked him to attempt to place a central venous line via internal jugular vein to provide additional intravenous access. This was unsuccessful despite using ultrasound as the vein on the right side was completely collapsed due to hypovolaemia. Resuscitation continued from the already established access.

Dr Horton had accompanied Joshie to theatre, continuing to provide fluid resuscitation. Once Joshie was draped and prepped, he was no longer required. He immediately phoned Dr Ward. This call was made at around 3:55am.

It was not until the sterile draping was in place and preparation for the exploration of the chest had commenced that Dr Rajanbabu told Ms Zazulak she should get the bypass machine ready. The bypass machine was still in the perfusion room and she was yet to start the priming process. She sensed an urgency to get the machine ready. At around 4.02am, Ms Zazulak phoned the second on-call perfusionist to come in. She continued getting the bypass machine ready.

By now Joshie was extremely unstable with hypotension and bradycardia, requiring boluses of adrenaline to maintain cardiac output. Dr Venugopal could see there was massive bleeding. He said his desperate hope was that it was coming from a hole in the thin aorta, something he could quickly control by opening the chest and placing his finger on the aorta while they put Joshie on bypass and he could then close the hole.

RNs Johnson and Doeblin took their hands off the chest. As soon as the dressing was removed, effectively ceasing the tamponade effect, there was bleeding from the lower part of the sternal wound. At this point Joshie's blood pressure dropped significantly and he lost cardiac output. The sternum was quickly re-opened and Dr Venugopal undid the sternal wires. There was "torrential bleeding" coming from the heart. Dr Venugopal put his finger on what he presumed was the bleeding source. This is when he realised there was a large defect in the RVOT patch, which he later described in his operation report as easily admitting three fingers. Dr Venugopal was unable to suture the hole closed because the edges of the RVOT patch were extremely friable and would not hold any sutures. He tried several times but the tissue kept falling apart. RN Matthew recalled seeing him putting his fingers on the tissue in an attempt to control the bleeding and suture at the same time. Joshie was bleeding out rapidly.

Several of the witnesses described this as amongst the most extreme emergency situation they had even been involved in and the first time they had even seen a patient experiencing a bleed of this kind.

Dr Venugopal spoke with Dr Ranger and Dr Stocker who agreed it was not possible to save Joshie. Once the decision was made to cease active treatment, Joshie died quite quickly. He was declared deceased at 4:04am.

Dr Ward and Dr Horton examined the echocardiogram images again at around 5:00am. Dr Horton's retrospective entry in the medical record notes "*no signs/indications of pathology – extra-pericardial Would not expect to see on this ECHO the RVO patch dehiscence*." Dr Venugopal also examined the images, noting they did not show a collection behind the sternum.

Appropriateness of the emergency response to the acute bleed in the early hours of 16 November

Adequacy of the MET call response

I am satisfied the bleed was an unheralded event that occurred acutely not long before Mrs Dalton was woken at around 2:00am. The response of the Ward 10B nursing staff in contacting Dr Rajanbabu, activating a Code Call and applying pressure to the chest to contain the bleeding was immediate and clinically appropriate. It is a great credit to them collectively that they responded to a highly unusual situation with such presence of mind and team work, working to keep Joshie calm and most importantly putting in place measures that ultimately played a significant role in keeping him alive over the next two hours. Without detracting from the efforts of all the nursing staff involved from this point onwards, I wish to acknowledge in particular the extraordinary clinical focus and physical efforts of both RN Rachel Johnson and RN Lisa Doeblin who together maintained pressure on Joshie's chest from then until told to take their hands off him in theatre two hours later.

The MET call team responded swiftly and quickly recognised and responded appropriately to the potential seriousness of the situation pending the cardiac surgical team's assessment and plan.

Dr Rajanbabu responded immediately to advice that a Code was being called.

Was the cardiac surgical team's assessment of the bleed reasonable in the circumstances?

When Dr Rajanbabu first saw Joshie, the clinical picture was one of a boy on anticoagulation and antibiotics who had developed an unexpected, acute ongoing bleed that had filled the VAC canister, quickly collected under the dressing and had started to leak out the sides of that dressing. Two nurses were applying pressure to the by now soaked dressings on his chest while others supplied them with additional dressings and then towels to help mop up the blood. Joshie was febrile and tachycardic with an elevated respiratory rate but was maintaining his blood pressure and remained alert and responsive. He was being actively resuscitated with fluids and blood products.

Dr Rajanbabu had only a brief conversation with Dr Rimpau but did not undertake his own full assessment of Joshie before speaking with Dr Venugopal, a call made within several minutes of him arriving on the ward. His suggestion to Dr Rimpau that he was hopeful it was just a wound ooze indicates he did not immediately consider it to be a significant bleed even though Dr Rimpau indicated his view otherwise. Nonetheless, it was a situation Dr Rajanbabu had not encountered before, so he appropriately notified his consultant and did so within minutes of his arrival on the ward.

While the two surgeons did consider the possibility this was a deep bleed from the aorta, the key piece of information informing their initial assessment was that Joshie was awake and talking to his grandmother and was maintaining his blood pressure. Notwithstanding there was blood in the canister and collecting under the dressings which were described as being soaked, this

was reassuring to Dr Venugopal; that Joshie was apparently haemodynamically stable supported the "more common possibility" of significant wound ooze in an anticoagulated patient. Regardless of whether Dr Rajanbabu quantified the amount of blood in the VAC canister during that conversation or not, on Dr Venugopal's evidence under cross-examination, the fact of the VAC canister being full of red fluid was not of itself alarming to him in the context of Joshie's apparent haemodynamic stability.

Dr Venugopal maintained he was not told there had been a MET call. Counsel Assisting and Counsel for Dr Rajanbabu both submitted it was difficult to accept that that Dr Rajanbabu failed to convey that a resuscitation was underway. I am inclined to agree – a MET team was in attendance when he arrived, he had already spoken to the senior clinician leading the resuscitation being carried out in front of him and on his evidence, he was asking for information from that team during the phone call with Dr Venugopal. However regardless of whether he did give Dr Venugopal this context or not, I am not convinced it was information that did or would have impacted Dr Venugopal's initial impression that this was a wound bleed. At that time he did not consider Joshie was behaving clinically as though he had a catastrophic deep bleed.

The experts were asked to consider the adequacy of the communication between the two surgeons during the 2:19am phone call and its outcome.

A/Professor Chard said that on being called by a Surgical Fellow regarding wound bleeding, he would want to know the patient's overall haemodynamic and clinical condition. Dr Finucane acknowledged that as a consultant in that situation, receiving a call in the middle of the night, she has asked "is the child stable?" just as Dr Venugopal did, and if told yes, "*you tend to accept that*." Professor Konstantoniv explained it is common practice by consultants and consequently very appropriate for Dr Venugopal to ask an experienced Fellow whether the patient was stable.

Dr Finucane considered it would have been reassuring to Dr Venugopal to be told Joshie was sitting up in bed talking to his grandma. However, by the time of the 2:19am phone call, Joshie's pulse rate was above 200 (204 at 2:20am). Dr Finucane considered had Dr Venugopal been told what the heart rate was then and over the next half hour that would have indicated Joshie actually wasn't stable. Professor Konstantinov explained that when a consultant is told by an experienced Fellow who is at the bedside that the patient is stable, the questioning immediately de-escalates rather than seeking further information about specific vital signs.

Dr Finucane confirmed that the process of VAC dressing can create granulation in the wound which can cause surface bleeding. Blood drainage from superficial bleeders in the wound is well-reported in the clinical literature.

Professor Konstantinov confirmed that when a sealed VAC dressing is in place, anything coming from the wound, whether exudate or blood, will go into the VAC canister first and once that is filled, the only place for output to go is

to leak out the sides of the dressing. Once the vacuum is not applied anymore, it will leak outside the dressing.

The experts all agreed it was important to try to work out upfront the extent of the blood loss, particularly when given information about blood under the VAC dressing leaking out. As Dr Finucane expressed it *"the obvious thing to do is to actually ask what volume of blood loss do you think there has been*." It would be Professor Konstantinov's first question in this situation "*how much blood is there? How much blood loss has happened?"* They agreed that in the presence of a functioning VAC dressing it was reasonable to estimate what was happening with blood loss with that VAC drain. Professor Konstantinov confirmed that 200ml of blood in the canister would indicate massive bleeding but clarified that it is sometimes difficult to distinguish between blood and very blood-stained fluid such as that from a pericardial effusion. A/Professor Chard said he would be asking how much was in the canister and whether on observation there was evidence of active bleeding filling the wound. He clarified that while wound bleeding can come from granulating tissue, this tissue does not have a major blood supply connected to it. For this reason, if there was copious bleeding, this was concerning for bleeding from a larger structure such as the heart rather than simply the wound. He calculated 200ml blood loss to represent 8% of Joshie's blood volume, constituting copious bleeding. He would have expected to have been told a MET call was underway. He felt further interrogation was required at this stage.

Dr Finucane considered it was reasonable for Dr Venugopal to exclude bleeding from the aorta as it would have been extraordinarily unlikely for this vessel to have given way so long post-operatively. However, she agreed with A/Professor Chard that they needed to be working backwards from the worst case and there probably was an error in judgement in terms of deciding it was probably superficial rather than deep bleeding. That said, she acknowledged that what happened to Joshie is such a rare event for a child that their decision was an understandable one.

I accept it was not unreasonable at that time in the morning for Dr Venugopal to enquire whether Joshie was stable and be reassured by Dr Rajanbabu's advice that Joshie was awake, talking to his grandma and maintaining his blood pressure. It is understandable why these pieces of the overall clinical picture were falsely reassuring and led him to quickly discount the extraordinarily unlikely but potentially catastrophic possibility of a deep bleed in favour of the more common and less serious possibility of a superficial wound bleed exacerbated by anticoagulation. However, I accept the expert consensus that Dr Venugopal needed to have focussed more effort on exploring with Dr Rajanbabu the extent and nature of the blood loss before the call ended; that he didn't contributed to their collective underestimation of the seriousness of Joshie's condition at that time. Had he asked Dr Rajanbabu to describe the bleeding, information that the VAC canister was full of frank blood as opposed to blood-stained fluid would likely have brought him in to the hospital half an hour earlier to assess the situation himself and have

a consultant-consultant discussion with Dr Stocker about the management plan.

Was the decision to transfer Joshie to PICU reasonable in the circumstances?

The inquest heard it takes 45 minutes to one hour to assemble an on-call theatre team and have a theatre ready to commence a paediatric patient on cardiopulmonary bypass. Further, it is not possible to have a bypass machine ready on standby for paediatric patients given it needs to be assembled to accommodate the size of each patient.

There is consensus between medical, surgical and expert witnesses alike that the decision to move Joshie to PICU at that time was appropriate and reasonable in the circumstances.

I am not critical of the decision to move to Joshie from the ward to PICU in the first instance. I agree it was the place best equipped to deal with an evolving clinical situation and placed Joshie in a clinically appropriate environment where he could be further assessed and managed until the cardiac surgical team cemented their plan. It was a place where a chest opening, control of superficial bleeding and a VAC dressing change could all be undertaken safely. While the decision to transfer Joshie to PICU was in fact made to action the cardiac surgical team's plan for an echocardiogram and wound inspection with no expectation of emergency surgery, it was simply not possible at that time in the early hours of 16 November to take Joshie straight to theatre given the time required to assemble the on-call cardiac surgical team and have a theatre ready to receive him from the ward.

There is no evidence to suggest Dr Rajanbabu was anything other than reassured by Dr Venugopal's assessment at this time. This is reflected in his actions upon leaving the ward after informing the resuscitation team of the plan to move Joshie to PICU to explore the wound – he alerted the theatre nurses that they might be needed ostensibly for a chest reopening in PICU or maybe VAC dressing change.

Before leaving the ward, the resuscitation team had assessed the bleed as one requiring surgical management, meaning it was not something that could be managed medically with fluid and blood product resuscitation alone.

The resuscitation team moved swiftly to ready Joshie for transfer to PICU. He remained alert, responsive and still had adequate blood pressure albeit with ongoing resuscitation with fluids, Albumin and blood products. He remained stable during the transfer.

I am satisfied that the time taken from the activation of the MET call to Joshie's arrival in the PICU sometime between 2:40am – 2:45am was reasonable in the circumstances.

Should Joshie's chest have been opened sooner and would this have changed the outcome for him?

Dr Stocker immediately assessed Joshie's condition as critical and appropriately activated the MTP. While there were problems with the timely delivery of blood products, particularly platelets, I am satisfied Joshie was constantly receiving fluids, Albumin and blood products sufficient to keep him resuscitated. I do not consider the issues arising during the MTP activation to have impacted at all on the outcome for Joshie. Rather, the collective efforts of the team of doctors and nurses working together to support Joshie's ongoing resuscitation in spite of these problems deserve recognition. It is because of them, Joshie's parents had the opportunity to see and speak to him and kiss him goodbye before he was taken to theatre.

The experts agree that by the time Joshie arrived in PICU and the MTP had been activated, it was apparent the bleeding was extensive and there was no role for echocardiogram. However, Professor Konstantinov clarified that prior to the extent of the bleed being established it was reasonable to ask for an echocardiogram to exclude a large pericardial effusion that could be oozing from the wound. While an undiagnosed pericardial effusion was unlikely, it was something that could accumulate quickly and contain blood-stained fluid.

The echocardiogram result did not change the clinical assessment of a significant bleed requiring surgical management. It could not be relied on to exclude intrathoracic bleeding. However, I am satisfied that it was not an unreasonable investigation to order at a time when the extent of the bleed had not yet been fully appreciated by either the resuscitation or surgical teams. As Dr Horton was able to set it up in anticipation of Joshie's arrival in PICU and had it underway when Dr Rajanbabu came to the bedside, there was no time lost by proceeding with it.

While Dr Finucane considered Dr Horton should have called in Dr Ward, she did not appear to have been aware of Dr Horton's evidence that he had asked on four occasions during the resuscitation for Dr Ward to be contacted but this did not occur. As Dr Horton was fully engaged in assisting the resuscitation efforts immediately after the echocardiogram I am satisfied he made appropriate efforts to notify his consultant.

The experts considered the communication between Dr Rajanbabu and Dr Venugopal at 2:49am. Professor Konstantinov identified this as a missed opportunity for Dr Venugopal to have been told the MTP had been activated. To his mind, the key issue was not that Dr Stocker was not happy for the wound inspection to happen in PICU – this was irrelevant – but the fact the MTP had been initiated indicated there was massive bleeding. This should automatically trigger notification to the surgeon and escalate the situation immediately in their mind and the mind of the whole surgical team.

The evidence indicates Dr Rajanbabu had not appreciated the MTP was in place at this time. It must be acknowledged he was not present in PICU when Dr Stocker initiated the MTP as he had gone to change into scrubs first. Dr Stocker did not tell him this had happened, rather their exchange centred on where the wound exploration should be performed. Although Dr Rajanbabu was in the bed space looking at the echocardiogram and speaking with Dr

Horton, this was before the first blood packs from the Blood Bank arrived in PICU (the first not arriving until nearly 15 minutes after Dr Rajanbabu phoned Dr Venugopal).

While Dr Rajanbabu may not have seen or noticed activity indicating the MTP had been activated, I find it more likely than not that in discussion with him, Dr Stocker did express concern they were dealing with massive bleeding rather than a superficial wound bleed. While Dr Rajanbabu could not recall any reference to massive bleeding, on his evidence the conversation lasted several minutes as they canvassed two different plans.

Dr Rajanbabu acknowledged he did not reassess Joshie at this juncture. In his words, he had only had a ''s*ingle point assessment*" for two minutes on the ward prior to attending PICU. He described the process of surgical decision making as being based on how the bleeding progresses over an hour, considering the haemoglobin, lactate and how much fluid resuscitation the patient needs. His plan up to then was to see Joshie and see the echocardiogram and then decide the next step.

I consider Dr Rajanbabu should have taken a step back at this point to properly reassess the overall clinical picture in light of his discussion with Dr Stocker. At best, he may have recognised the seriousness of the situation unfolding in PICU with particular reference to the level of resuscitation Joshie was requiring; at the very least it would have positioned him to provide Dr Venugopal with more fulsome clinical context when relaying Dr Stocker's view about where the wound exploration should be done. Instead, knowing the echocardiogram results and the PICU consultant's views, Dr Rajanbabu was focussed on his priority to get the theatre activated, a process he commenced immediately by recontacting the theatre nurses before he phoned Dr Venugopal. Thereafter he was focussed on his consultant's instruction to get the theatre and the theatre team ready to receive Joshie, a process that took him away from the bedside during most of the rapidly evolving clinical situation.

Professor Konstantinov acknowledged the difficulty of Dr Rajanbabu's situation commenting *"this poor fellow found himself in extremely difficult situation when he had to communicate with 10 people at the..same time talk to the family and look after the patient…it's mission impossible*." He explained the process at the Royal Children's Hospital in Melbourne is for the hospital switchboard to manage the theatre team call-in once a MTP is activated by a MET team or a PICU consultant. A similar process operates at Dr Finucane's hospital in Auckland. I agree with their observation that relieving the Surgical Fellow of the call-in responsibility frees them up to care for their patient. I consider Dr Rajanbabu's focus on meeting these responsibilities distracted him from properly assessing and reassessing the clinical situation unfolding in PICU.

I agree with the experts that a consultant-to-consultant discussion would have been more beneficial at this time. It is a common practice when a patient is transferred to PICU, at which time the intensivist becomes the primary care

clinician under the shared care model operating at LCCH. Dr Finucane said she will often phone the consultant when she is in the car. She felt it would have been better for Dr Venugopal to call Dr Stocker given the major clinical demands of the resuscitation. She considered Dr Stocker did an extremely good job of managing Joshie's resuscitation. Given the criticality of the situation, it was reasonable for Dr Stocker to rely on Dr Rajanbabu to communicate with Dr Venugopal. Dr Stocker said he would have taken a call from Dr Venugopal during the resuscitation had Dr Venugopal wished to speak with him.

When questioned about this issue, it was clear Dr Venugopal wished he had spoken with Dr Stocker directly. It would have equipped him with a better informed assessment of the seriousness of the bleed and enabled a joint discussion about the management plan. It would have better prepared him and the theatre team mentally for the surgical situation they were to encounter. Although surprised when told Dr Stocker was not happy for the wound exploration to proceed in PICU, Dr Venugopal decided not to clarify the situation with Dr Stocker directly but to activate the theatre team and come in straight away. There is no evidence available to me to explain why Dr Venugopal was anticipating it would "a difficult conversation" with Dr Stocker. It is difficult to understand why, when his evidence was there was no information available to him at that time suggesting the urgency of the situation had changed, he did not take the opportunity to better understand Dr Stocker's position.

Dr Venugopal identified ECMO (extra-corporeal membrane oxygenation) as part of a joint management plan that could potentially have been developed had he and Dr Stocker spoken directly. ECMO is a procedure similar to bypass that re-routes the blood to bypass the heart, oxygenate the blood and pump that blood back into the body while the heart is operated on. The ECMO machine has a centrifugal pump that will not push blood out when there is significant amount of air in the circuit. There is also a need for a certain blood volume for the ECMO to be established.

Dr Venugopal explained that haemodynamically unstable patients can be placed on ECMO for an emergency chest re-opening in PICU – if the patient is extremely haemodynamically unstable, they do not shift them but rather bring all the facilities to that area if technically feasible.

Dr Stocker confirmed that had the cardiac surgical team decided they wanted to place Joshie on ECMO and open the chest in PICU this could have been done. When asked to consider whether this was a viable option for Joshie once he arrived in PICU, Dr Stocker said at the time he would have thought not given his assessment of the seriousness of the bleed and his understanding that the cardiac surgical team were already on their way; had he deemed ECMO to be a priority and initiated a ECMO call-in, it would have been the same team on the way in. However, because Joshie was still talking and had a measurable blood pressure albeit with a lot of volume and adrenaline support, his cardiorespiratory status did not trigger an ECMO call-

in. Dr Stocker was waiting for the cardiac surgical team to arrive so they could discuss whether ECMO was the way to go or theatre.

Dr Finucane explained that while ECMO is used routinely in most post-operative cardiac emergency arrest type situations, it will not work when there is major bleeding from the right side of the heart. Now knowing the RVOT patch had ruptured, the venous line that would have been inserted in the groin would suck air through from the hole in the right ventricle causing the ECMO circuit to shut down. Having regard to the management of adult patients with ventricular ruptures and bleeds, she considered peripheral bypass through the groin to be *"..the most successful way to salvage the situation if it ever is salvaged.*"

Despite there not having been any active consideration or discussion about the possible role of ECMO in the management plan, it would not have worked in any event.

Dr Finucane and Professor Konstantinov's joint report posited that once Joshie was intubated, the positive pressure ventilation probably exacerbated the bleeding. Dr Stocker disagreed, explaining that usually positive pressure ventilation keeps blood out of the heart and lowers the blood pressure meaning you'd expect less bleeding not more bleeding as a result of intubation. Both experts explained how the positive pressure ventilation will have increased the right ventricular pressure; this may well have stabilised the blood pressure if it was aortic bleeding but given it was actually right ventricle bleeding then it may have exacerbated that bleed. However, both experts clarified that in making this statement they were not critical of the decision to intubate Joshie - in a situation of massive bleeding the resuscitation team did not have the luxury of choice; the airway needed to be secured and it was all properly managed. They acknowledged the team had no way of knowing it was right ventricle bleeding and even had this been known, Joshie still needed to be intubated.

The next question is whether it was possible to have put Joshie on peripheral bypass sooner. The answer hinges on whether there was ever going to be enough time for the perfusionist to assemble and prime the bypass machine and cannulate him to establish bypass before they opened the chest.

Given it is not possible to have a bypass machine ready on standby for paediatric patients, it would have taken no less than 45 minutes to an hour to have the theatre ready to receive the Joshie and for the perfusionist to be able to commence bypass, noting even with the machine set up it takes anywhere between 6-15 minutes to cannulate the child and get onto bypass.

Dr Finucane and Professor Konstantinov identified the MTP activation as the point in time when the cardiac surgical team needed to have been called in for emergency surgery with bypass. Accepting Counsel Assisting's submission that Joshie arrived in PICU around 2:40am – 2:45am and that Dr Stocker had activated the MTP within five minutes of his arrival, the earliest opportunity for the full team call-in process to commence was around 2:45am – 2:50am. This

corresponds with Dr Rajanbabu's second phone call with Dr Venugopal at around 2:49am, the outcome of which was Dr Venugopal's instruction to activate the cardiac surgical team. In reality, the call-in process had already begun albeit in a haphazard fashion when Dr Rajanbabu first phoned RN Matthew at 2:32am and the perfusionist was phoned by RN Murray not too long after that.

Under cross-examination by Counsel for Dr Stocker, Professor Konstantinov accepted there was no missed opportunity to activate the cardiac surgical team simply because there was no direct communication between Dr Venugopal and Dr Stocker. Dr Finucane identified the "missed opportunity" as the perfusionist not knowing upfront that bypass was needed because the only way the bleeding problem was going to get fixed was with a bypass machine. Her concern was that consultant-to-consultant communication at this time about the seriousness of the bleed might have triggered Dr Venugopal to consider the need for bypass. In her experience discussion between senior clinicians helps trigger thought about what might be needed in an emergency situation.

Ms Zazulak was asked to come in by Dr Rajanbabu not long after the 3:05am phone call with Dr Venugopal and arrived in the operating suite not long after 3:25am. She was getting the cell saver machine ready when she saw them bringing Joshie to theatre and on her initiative, started assembling the bypass machine. By the time Joshie was prepped and draped in the theatre she had almost finished the dry assembly but needed another 10 minutes to prime the machine which was still in the perfusion room. Had Ms Zazulak been told at 2:50am she was required for surgery with bypass, she would have phoned a second perfusionist and then been at the hospital within 14 minutes to start that process by 3:05am - 3:10am. On her estimation, the two perfusionists may have had the bypass machine ready in under twenty minutes, so by around say 3:25am - 3:30am. It was at around this time Joshie was being readied to move to theatre arriving in theatre some eight minutes later, intubated and ventilated with an anaesthetic Registrar ready to commence the anaesthetic induction. Ms Zazulak would still have needed time to cannulate him and establish bypass.

Dr Venugopal was asked to consider whether having the bypass machine ready would have given them more time in theatre. He felt that while there may have been a very, very remote chance they could have achieved that state of readiness in time, from what he saw intraoperatively the die was cast from the minute Joshie started to bleed out. Even had the call-in been activated earlier, he felt they would have been "..*really pushing it. There's the – there would have been a very, very slim chance of making him survive*."

With the benefit of hindsight, Dr Rajanbabu felt it was a bad decision for them to have moved Joshie to theatre from PICU given Joshie decompensated during the transfer. Dr Venugopal did not think managing the surgical intervention in PICU rather than theatre would have made a difference to the outcome because they would have still encountered the same situation of such rapid exsanguination.

Both Dr Finucane and Professor Konstantinov concluded it was highly unlikely Joshie's life would have been saved even if the whole team had been mobilised an hour earlier and Joshie taken to theatre sooner with a bypass machine available. To paraphrase Dr Finucane, Joshie's only chance was if things had been expedited extremely quickly and fallen into place extremely smoothly, something very difficult to achieve in the middle of a weekend night. She considered it was possible Joshie could have been salvaged had the rupture occurred in daylight hours with the theatre team available and able to be mobilised quickly over that hour. Professor Konstantinov agreed; the only way to save Joshie's life was to emergently put him on cardiopulmonary bypass and repair the rupture. Noting the events occurred over two hours from the time the bleeding started in the middle of the night, he felt it would have been extremely difficult to save Joshie's life.

A/Professor Chard considered that even if the theatre was activated after Dr Rajanbabu's first phone call with Dr Venugopal at 2:19am, the chances of Joshie surviving were remote; emergency treatment of a situation like this would involve femoral bypass and reopening and repairing and unless there is a full team virtually standing by when the incident occurs, the chances of survival are not great. A/Professor Chard said that had Joshie's chest been opened on Sunday 15 November, it was possible the RVOT patch could have ruptured at that time. He could not say whether the bleeding could have been controlled at that time; it would depend on the degree of clinical suspicion for a serious problem with the heart and having a bypass machine ready *"..but it may well be that the reopening at that stage was greeted by the patch falling to bits, and that would have been that.*"

While I am satisfied Dr Venugopal's decision to activate the cardiac surgical team at 2:49am was timely, it was not made with an understanding that this was a surgical emergency requiring bypass. The 2:49am phone call was a missed opportunity to activate the perfusionist and have the bypass machine ready before they opened Joshie's chest. Dr Rajanbabu did not provide Dr Venugopal with the full clinical picture and Dr Venugopal did not question or seek to clarify the information he was given at that time. I agree with Dr Finucane that consultant-to-consultant communication at this juncture may have triggered consideration of the need for bypass and potentially bought Ms Zazulak an additional 20 minutes to prepare the bypass machine.

However, even had the bypass machine been ready when Joshie was brought into the theatre, Ms Zazulak still needed time to cannulate him and establish bypass. This was estimated to take anywhere between six to 10-15 minutes and Joshie was extremely hypovolaemic. Dr Venugopal acted immediately to try and control the massive bleeding which he assumed was coming from the aorta, rather than wait for bypass to be established. He could not possibly have anticipated the right ventricular bleed and rapid exsanguination that ensued, leaving no time or opportunity to get Joshie on to bypass. As such I consider that although there should have been earlier consideration of the need for bypass, even had it been ready and Joshie connected to it before his chest was opened, the catastrophic bleed he turned out to have was such that

it can not be said with any certainty that cardiopulmonary bypass would have changed the outcome for him. At best, it may have marginally increased an otherwise very remote chance of survival.

What caused the acute cardiac bleed? – mediastinitis versus the VAC dressing theory

Tissue specimens including from the RVOT patch sent for microbiology did not grow anything.

An operation report prepared by Dr Rajanbabu that morning noted "*intraoperative-picture suggestive of mediastinitis with possibly infected RVOT patch near totally disintegrated and given way with bleeding*". He explained he thought this because during the procedure the tissues were inflamed, red with some whitish flakes. He considered the inflammation could be secondary to many things, a common cause being infection. He explained that mediastinitis can be infective or non-infective – if infective, they would have seen abscess and pus pockets but all they saw was everything looking red with some whitish flakes. He said the reason he referred to a possible infective condition was because at that time everyone was assuming it was infection given Joshie was being treated for previous wound ooze.

Dr Rajanbabu considered the wound swab results showing leukocytes of 3+ with no organisms grown were indicative of inflammation but conceded given the wound ooze was described as "snotty looking exudate" on the morning of Friday 13 November that this would be consistent with infection.

Dr Venugopal's initial reaction was to question whether he had missed mediastinitis. This is because he saw lots of inflamed tissue, tissues were stuck together and the RVOT patch tissue wasn't holding any sutures. However, knowing the autopsy findings, he considered it very unlikely to be mediastinitis. There was no obvious collection of pus in the mediastinum; the surface of the heart looked normal; the swabs did not grow the usual organisms associated with immediate post-operative mediastinitis and only one, not all, of the patches showed evidence of excessive inflammation. He did not accept the proposition that it was possible to have a negative culture in a patient who has been treated with antibiotics but still have mediastinitis. In his opinion, if it was mediastinitis, the patch would normally deteriorate or rupture at high pressure points such as along the suture line, not in the middle. He could not find any description in the clinical literature of an acute rupture in the middle of the patch nor of a patch rupturing within three to four weeks of surgery without obvious evidence of infection. He explained that given mediastinitis affects the whole chest wall, not just one area, chances are the patch which is subject to the highest pressure will be the first to give way – the RVOT patch was subject to considerably less pressure, usually one-fourth or one-fifth the pressure to which the others were subjected. To his mind the post-mortem finding of inflammation in the RVOT patch meant something had been irritating it; possibly the patch was rubbing against a jagged edge in the sternum that gradually weakened the patch to cause chronic inflammation and then gave way.

None of the doctors involved in Joshie's care had ever seen an RVOT patch rupture in the same way.

After Joshie's death, Dr Alphonso reviewed all of their 500 CardioCel implants and all the literature published on this product and did not find any other case where the patch had ruptured in the centre. He said they have never had inflammatory cells in the CardioCel patch.

When asked to consider his own reference to infection in his report to the TGA, Dr Alphonso said the number one diagnosis and the first differential diagnosis in Joshie was always infection because he was being treated for a superficial wound infection. However, even considering the overall clinical picture and the absence of microbiology and post-mortem evidence of infection left him unable to conclude it was mediastinitis. Dr Alphonso agreed it was possible for there to have been some resolving infection to have caused the patch rupture in the context of a slight change in the integrity of the sternum as a result of the negative pressure of the VAC dressing. However, the location of the RVOT patch away from the undersurface of the sternum made this less convincing. Noting Joshie was a fourth-time redo sternotomy, he observed "*it doesn't require much to abrade these structures if you're rubbing against it constantly, you know, with each beat of the heart*."

Dr Forde confirmed in evidence that when forming her cause of death opinion she had reviewed the medical records and was aware of the history of a wound infection and ongoing fever and tachycardia on 14 and 15 November. This is why she considered *"..it's possible that there is potentially an infection there, or that this has been caused by an infection. But I haven't really found any clear objective evidence in my autopsy findings to be very firm about that*." She thought the VAC dressing theory put forward by Dr Finucane and Professor Konstantinov was plausible.

The VAC dressing theory was put forward following Dr Finucane's study of case reports. She explained for the theory to be accepted there needs to be some way in which the suction created by the VAC to apply to the heart – either there must be a channel through the sternum or over the top or underneath. She considered the most likely channel would be through a tiny breach in the area where the sternotomy was performed.

Dr Finucane was asked to consider Dr Alphonso's reservations about the applicability of this theory given the location of the RVOT patch away from the underside of the sternum. With reference to published data on right ventricle ruptures associated with VAC dressings, she explained there are probably a number of different ways this can happen:

- the bit that ruptures is right behind a sharp piece of sternal edge; or
- the negative pressure could cause the right ventricle to bulge forward just left of the sternotomy and as a thin walled low pressure structure be sucked up against the back of the chest wall creating friction.

Dr Finucane accepted the issue in applying this theory to Joshie is that reports of this happening in patients where the sternum hasn't been opened and the sternal wires haven't been taken out are extraordinarily difficult to find.

She accepted there could have been a low grade infection that may have changed the integrity of the sternum to create a small break which in combination with the VAC dressing caused the inflammation and in turn the breakdown of the RVOT patch; it could also have just been the negative pressure of the VAC itself.

Dr Finucane considered the finding of tissues being very stuck together and quite inflamed was more consistent with the normal healing process at that stage post-operatively, particularly given new materials were placed in the initial surgery, than with infection. She felt if there was still active infection, then probably more than 90% of the time it would grow something even with antibiotics present. She confirmed the expectation that an infected patch would usually "blow" through a suture line not the middle.

Professor Konstantinov felt it was inconsistent or extremely unusual to have such severe infection in the patch that it caused the rupture and yet grow nothing on cultures. Had there been such extensive mediastinitis, he would have expected to see pus on reopening and at least some bacteria as signs of severe ongoing infection.

Dr Finucane and Professor Konstantinov stood by their initial statement that while it was not possible to rule out low grade infection of the mediastinum completely, it did not explain the operative and post-mortem findings as completely as the VAC mechanism.

A/Professor Chard considered a VAC drain applying negative pressure to a wound that was truly superficial would put no negative pressure at all on the RVOT patch. The volume of blood that came from the heart behind the sternum into the VAC canister and the VAC dressing in front of the sternum could only come above, below or through the sternum, so there must have been a communication at that stage; had there not been the heart would have tamponaded in which case Joshie would have gone into cardiac arrest rather than bleed externally. In A/Professor Chard's opinion, if there is a communication behind the sternum from above, below or through, that is mediastinitis. The autopsy findings of very vigorous inflammation and a hole in the RVOT patch and no inflammation in the internal patch apart from a very light degree of response suggested to him an inflammatory process on the external patch which has probably caused the dehiscence. That inflammatory process has to be triggered by something and infection would be high on the list. He wasn't sure he knew of any other cause than infection.

The evidence is unequivocal that the cardiac bleed was caused by rupture of the RVOT patch which had become inflamed. The cause of that inflammation is much less clear. Clinically Joshie had signs of infection including high fevers and tachycardia over the weekend of 14-15 November which on the balance of probability were most likely due to wound infection. However, when

the sternum was reopened emergently in the early hours of 16 November, there were no overt signs of infection such as pus and widespread inflammation of the chest wall and internal structures that are usually seen in mediastinitis; rather the state and appearance of the tissues were more consistent with the normal post-operative healing process. The confounding issue is the absence of evidence of infection on post-mortem cultures or at autopsy. A/Professor Chard's opinion that there must have been a communication from under the sternum in order for Joshie to have bled externally rather than go into cardiac arrest due to cardiac tamponade is compelling. However the absence of evidence of infection, even accounting for the fact Joshie had been receiving extensive antibiotic coverage which may have acted to suppress wound infection, the fact that only one of the CardioCel patches was significantly inflamed and the unusual location of the rupture mitigate against mediastinitis as the underlying cause. On the available evidence, I am most regrettably unable to make a definitive finding about what caused the RVOT patch to become inflamed and disintegrate – low grade infection or trauma caused by the effect of the VAC drain or a combination of both are all possibilities and there is not sufficient evidence to displace one in favour of another on the balance of probabilities.

Mycobacterium chimaera

Joshie's family was concerned he may have been exposed to Mycobacterium chimaera given he received bypass during his initial surgery. This is an organism which most commonly lives in water and soil and can cause low grade infections. In 2016 it was recognised internationally as contaminating cardiac bypass machines. This prompted LCCH to issue an advisory to families whose children had received treatment on contaminated machines to alert them to the possibility of acquired infection. Dr Hallahan explained this organism causes an endocarditis, an infection of the lining of the heart. This is a low grade infection which the clinical literature suggests takes at least six months and typically several years from exposure to become symptomatic. It will typically affect a mechanical valve with visible vegetation on the valve.

Dr Forde explained she performed special stains on the post-mortem tissues to look for bacteria and did not see anything. Mycobacterium can be quite difficult to grow and culture so she did not specifically request it at the time of the autopsy. She subsequently sought advice from a microbiologist in relation to it but her testing had already been sent off by that stage. While she could not exclude it, she considered it to be a very low possibility in Joshie's case.

There is no compelling evidence to suggest this organism played a role in Joshie's death.

Changes implemented by Children's Health Queensland Hospital & Health Service following Joshie's death

It is clear from the outset Children's Health Queensland has taken steps to carefully consider and genuinely reflect on the events leading up to Joshie's death. The inquest heard evidence about their progress in implementing the

RCA recommendations and other changes made to address issues identified during the coronial investigation.

Interaction between Surgical Services and Infectious Diseases Team

The cardiology, cardiac surgical and infectious diseases teams worked together throughout 2016 to finalise a statement of best practice for consultation with the infectious diseases team. There are regular infectious diseases ward rounds in PICU to discuss all patients, the team is available for consultation any time and there is active management/liaison with treating teams regarding positive sterile cultures.

Massive Transfusion Protocol

I am reassured by the extensive review of the hospital's MTP culminating in a revised MTP incorporating a flow chart outlining the respective responsibilities of the resuscitation team and the Blood Bank; general principles and indications for MTP; clear guidelines on when to activate the MTP; transportation and storage of blood throughout the MTP; roles and communication during patient transfer during the MTP; deactivation decision-making and processes; role cards for PICU, emergency department and operating theatre environments; role cards for medical, nursing and porter personnel (medical team leader, nursing team leader, transfusion doctor, transfusion nurse and porter) and use of the Blood Bank Liaison role as the single communication point.

The revised MTP has been informed by simulations to test the activation process in the emergency department, operating suite and PICU. There is provision for alternate porter arrangements in the event porters are not available for the MTP (a minimum of two porters are available across the hospital at all times). Blood products delivered by the PTS are now accompanied by a form which if not returned to the Blood Bank within ten minutes triggers contact by the Blood Bank for follow up. By the time of the inquest, simulated scenarios, education and training in the revised MTP had been undertaken. Dr Hallahan advised it has been used multiple times and represents a significant improvement for the health service.

Review of need for 24/7 onsite theatre team

Children's Health Queensland undertook a benchmarking exercise with reference to comparable Australian and international paediatric facilities which found that 24 hour cover on site is not warranted for surgical teams but that on-call within an acceptable response time is adequate to meet demand. It has been agreed that on-call clinicians are to be in attendance at the hospital within 30 minutes, with nearby accommodation made available to those who live in areas exceeding a 30 minute response time.

After consideration, Children's Health Queensland Division of Surgery has not instituted 24-hour nursing and anaesthetic registrar cover because any urgent procedures require consultant surgeon attendance which will still take 30 minutes. The potential time saving of 15 minutes was not considered clinically significant.

Processes for after hours call-in of theatre teams
The hospital now has a process by which the call-in lists for on-call theatre staff are updated daily prior to being emailed to the Nurse Manager Patient Flow and Staffing Unit at 3:00pm every day.

Dr Hallahan said the Divisional Director of Surgery now considers the hospital to have a prompt and reliable system for activating an operating theatre after hours.

The ECMO call now automatically alerts team members through a call to the hospital switchboard – the team includes the cardiac surgeon on-call, the perfusionist and nursing theatre staff. This call does not automatically call in the anaesthetist on-call, leaving this step to the cardiac surgical team once they determine whether an anaesthetist is required.

The cardiac surgical team call-in process now operates as follows:

1. the Surgical Fellow in consultation with the consultant, or the consultant alone, deciding to stand up theatre;
2. the Surgical Fellow or consultant contacting and requesting call in from the on-call anaesthetist, perfusionist and cardiac theatre scrub nurse; and
3. the scrub nurse then notifying the Nurse Manager Operations that a cardiac surgery call-in is underway.

I discuss this particular call-in process further below.

Consultant-to-consultant communication
Dr Hallahan agreed that consultant-to-consultant communication is critical in emergency situations and advised there has been improved collaboration, communication and transparency between PICU, cardiology and the cardiac surgical teams since Joshie's death. He said communication between PICU and cardiac surgical team is considered to be working well.

Dr Alphonso advised that since Joshie's death it has become protocol for the PICU consultant to phone the on-call cardiac surgeon whenever an ECMO call-in is made or a cardiac surgical patient in PICU becomes critically unwell. I consider this to be an appropriate response to address aspects of the communication issues examined by this inquest.

Protocol for measuring and recording pain
In acknowledging the family's concern that Joshie's pain was not well managed, Dr Hallahan explained the health service has been specifically assessing the effectiveness of pain management across the hospital and is committed to improvement in that space.

NUM Larkin explained that on Ward 10B a pain assessment forms part of the fourth-hourly observations. It was his expectation nurses would ask Joshie about his pain. Jacqui did not recall nurses enquiring about Joshie's pain with this frequency. Both she and Mrs Dalton would tell nursing staff if Joshie was in pain and would ask for pain relief. Jacqui could not recall any occasion

when requested pain relief was not given though there were some occasions when he would have to wait a short period before his next dose was due. Joshie was not requesting Oxycodone on as frequent a basis as it was ordered; sometimes he would only have 1-2 doses in a 24 hour period. While Joshie did have some wound pain associated with the wound infection and after the debridement, it was not of the severity that signposts mediastinitis.

At the time of Joshie's admission, the cardiac/respiratory observations form in use on the ward did not easily allow for the recording of pain. There was no recording of a pain assessment using a pain scale (0-10) or visual cue symbols for Joshie. While nursing staff could then, and still can record pain scores in the progress notes, this information was not previously recorded routinely by all staff as part of each set of observations.

Dr Finucane considered that while the absence of a pain scale for pain assessments was not a deficiency per se it was something that could be addressed as a service improvement. NUM Larkin advised the cardiac/respiratory observations form has since been revised to include a pain score field.

Paediatric deterioration detection system for cardiac patients

The hospital uses a paediatric early warning and response observation tool known as the Children's Early Warning Tool (CEWT). This instrument records the child's vital signs (heart, rate, respiratory rate, oxygen saturation, blood pressure) and other clinical information (oxygen requirement, conscious state and capillary refill) to produce a score which compares the child's clinical condition to the normal range for that age group; scores outside the normal range trigger escalation with measures including more frequent observations and urgent medical review and management. NUM Larkin explained this tool is not used on Ward 10B because it is not suited to these particular patients as the symptoms of their cardiac conditions would generally trigger a high CEWT score even when there was in fact no clinical deterioration. Instead, if there are different parameters for an individual patient meaning their normal baseline is higher than generally expected, the treating team indicate acceptable parameters for that patient which are documented in the patient record. NUM Larkin acknowledged this was not documented for Joshie, though NUM Larkin recalled his tachycardia was verbally discussed. At the time of the inquest, the hospital was undertaking a project to investigate whether the CEWT scoring system can be adapted to the paediatric cardiac patient population.

Findings required by s.45 of the Coroners Act 2003

I am required to find, as far as possible, the matters set out under section 45(2) of the *Coroners Act 2003*. Having considered all of the evidence, including the material contained in the exhibits, I am able to make the following findings:

Identity of the deceased: The deceased person is Joshua Ryan Statis.

How he died:	Joshua died 18 days after a fourth time sternotomy and redo Konno procedure to upgrade his mechanical aortic valve, enlarge a patch to cover a ventricular septal defect and to enlarge the right ventricular outflow tract with a CardioCel patch. He had been returned to theatre on day 16 post-operatively for exploration and surgical debridement of a superficial infection of the sternotomy wound which had started to ooze on day 9 post-operatively. A VAC dressing was applied at this time with a plan to return him to theatre on day 18 post-operatively to reassess the wound and change the dressing. Joshua was actively investigated and treated for persisting fevers and tachycardia over the next two days, most likely caused by wound infection. In the early hours of day 18 post-operatively, Joshua developed an acute bleed through the sternotomy wound which filled the VAC canister and was collecting under the VAC dressing. He died in theatre approximately two hours later undergoing an emergency chest reopening which revealed the right ventricular outflow tract CardioCel patch had ruptured. Unfortunately surgeons were unable to fix the defect or control the catastrophic bleeding from the right ventricle. The Cardiocel patch ruptured because it had become inflamed but the cause of the inflammation remains uncertain.
Place of death:	Joshua died at the Lady Cilento Children's Hospital, Brisbane in the State of Queensland.
Date of death:	Joshua died on 16 November 2015.
Cause of death:	Joshua died from cardiac haemorrhage due to or as a consequence of congenital aortic stenos (surgically repaired).

Comments and recommendations

Section 46 of the *Coroners Act 2003* provides that a coroner may comment on anything connected with a death that relates to public health or safety, the administration of justice or ways to prevent deaths from happening in similar circumstances in the future.

The inquest identified some shortcomings in clinical documentation practices within the Queensland Paediatric Cardiac Service and a missed opportunity for the cardiac surgical team to have properly understood the seriousness of the acute bleed sooner. While I am satisfied these issues were not outcome changing for Joshie, they represent opportunities for systems improvements.

Clinical communication and documentation within the Queensland Paediatric Cardiac Service

At the outset, the absence of any documentation by the cardiac surgical team (other than operation reports and consent forms) was very concerning to me. However, the evidence given by witnesses from the cardiology and cardiac surgical teams involved in Joshie's care has clarified that while a dearth of written communication by the surgeons was the accepted culture and practice within the paediatric cardiac service at that time, there was ongoing and effective oral communication between the teams throughout Joshie's admission.

Dr Ward described the working relationship in the following terms "*I mean, the communication with the surgeons is extremely free, and contact with the cardiologist us frequent. So I would see the surgeons a number of times during the day, whether I was on call or not, and I'd also see the fellows many times during the day. And so the communication has always been extraordinarily good with our surgical team at the moment, and that's historically probably the best I've ever worked with. So whenever you've got a question, it's very easy to approach our surgeons or the fellows to see what the plan is, and – and so on. So I guess that we do a lot of verbal communication rather than anything else. It's much easier to get – get thing from the horse's mouth than something that's sort of written in the notes, and often a bit stilted, and so we communicate verbally…I can appreciate what you're saying, but I'm not sure that writing it down had made that any better; I thought it was good to begin with."*

Evidence from the experts provided broader context for this practice by confirming the prevalence of little if any daily documentation by the surgical team in other cardiac surgical services operating under a similar shared care model. A/Professor Chard explained there is an expectation at his hospital that consultant surgeons and Surgical Fellows will document if there is a surgical issue such as significant wound change. Dr Finucane conceded it would be reasonable practice for a member of the cardiac surgical team to regularly document a description of the wound and document the amount and appearance of any discharge given wound changes can be very subtle. None of the expert witnesses work with wound care nurses but they variously described the use of wound protocols though none of these incorporate photographing the wound.

Dr Alphonso acknowledged the cardiac surgical team were remiss in not documenting Joshie's wound infection and accepted they should be documenting when there is a serious wound infection. He accepted that while there was good oral communication between the teams it was poorly documented with no record of what was discussed "*This is a bit different. In this case, I absolutely agree it would have been very helpful for us to document because this is not common, and then that record would have helped, you know, in the event that some – something like this happens, you can go back and accurately assess what the correct state of the wound is. So I accept that. But that's just the reasoning. That's just how we work."*

In evidence Dr Alphonso confirmed that since Joshie's death the cardiac surgical team has started making entries in the patient notes, though he indicated a view this practice does not seem to add value. NUM Larkin explained the cardiac service has since developed and uses a template that auto-populates the previous surgical team entry into the patient's electronic record and this is added to by the cardiac surgical team for all ward rounds on all patients each day. He described this change as helpful for nursing staff in that it now makes clear the surgical team's management plan for each patient.

Dr Alphonso described the rationale for this change in practice as "*I think it's more to serve, you know, as a record that we're actually seeing the patient even though if we came to the hospital, everyone would tell you that we see the patient several times a day. But even now, the note, in my opinion, is incomplete because, you know, you assess a patient, and you have to write a plan down. And we don't write a plan. We write "as per cardiology." So in a way, it's just a record of what – the only things that we've changed is, yes, if there's a wound, I don't think actually a wound description is, really, very accurate because a different person seeing the wound would describe it differently. It's very subjective*." Drs Alphonso and Venugopal explained they were implementing a process for photographing wounds as a more objective record for wound management. This is a sensible enhancement of the team's wound management strategies. I am sure the legal issues of privacy and consent for this component of post-operative care can be easily managed in the broader context of consenting families for life-saving and life-extending complex surgery.

Notwithstanding Dr Alphonso's attitude to clinical documentation, Dr Hallahan appropriately acknowledged the importance of contemporaneous, clear, useful documentation, observing *"At its heart, what this is about is communication, both in present and future moment*". His enquires of other surgical colleagues and the hospital's other surgical services indicate they do document in the patient chart on a daily basis. In evidence he confirmed the cardiac surgical service has given its commitment to do so and now document "at a satisfactory level".

Joshie's family sought formal recommendations to cement improvement in the documentation, communication and planning practices within the cardiac surgical service through auditing the cardiac surgical team's documentation practices; developing specific documentation requirements for surgical ward rounds and implementing a documentation system that requires treating teams to both record their own patient review notes and confirm they have reviewed notes entered by other clinicians. Much of the detail of these proposed recommendations represents basic good clinical practice.

While I am satisfied the lack of documentation by the cardiac surgical team did not compromise Joshie's care, the somewhat dismissive attitude expressed by the Director of Queensland's only paediatric cardiac surgical service to clinical documentation as a compliance exercise and aide for retrospective chart review is disappointing. I reiterate Counsel Assisting's

submission that the cardiac surgical team should be documenting clinical information and management of a patient specific to their specialty and scope of involvement in the patient's care, particularly in relation to wound management, as a meaningful part of the overall communication between teams in a shared care model. If it can be achieved by all other surgical specialties within Children's Health Queensland as part of their daily patient management, I see no reason why the cardiac surgical team can not do the same. I urge Dr Alphonso to reflect on his attitude to this important element of clinical care and encourage him and Dr Venugopal to instil in their Surgical Fellows the importance of good clinical documentation practices.

In evidence, Dr Alphonso emphasised repeatedly the importance of vigilance for wound infection in post-surgical cardiac patients given the potentially serious consequences of deep infection. In his words "*That's our constant worry. Almost every patient of ours has foreign material, so the risk is very real for us, and in the presence of foreign material, infection is very hard to eradicate. So in this situation, prevention's better than cure, so ---".* Given the significance of this complication for the service's patients, I consider it important for those caring for these children to have a shared understanding of the minimum standards expected for documenting wound inspections. **To this end, I recommend that Children's Health Queensland consider developing a wound inspection guideline for the cardiac surgical service to ensure consistency in documenting wound features that may be indicative of infection, such as the nature and extent of any wound ooze, whether it is odorous, whether there is redness or swelling or hot areas and the location of affected areas, and consistency in documenting the wound management plan and its implementation. The service's efforts to incorporate the use of wound photographs can be incorporated in this exercise.**

At the time of Joshie's death and as at the inquest, there was no ward protocol or observation sheet for measuring and recording the contents of a VAC canister. There was no communication, entry or indication about the VAC drain on the surgical pathway. As was heard in evidence, the volume in the canister is difficult to measure as there is a gel pack within the canister that solidifies any liquid. NUM Larkin said nurses were to check the VAC canister hourly to ensure the suction is on and the machine is functioning properly though RN Andresen could not recall a directive to this effect, suggesting it was at the nurses' discretion. There are some references in the nursing notes which indicate the VAC canister was being checked and noted to be functioning. At the inquest, Dr Hallahan observed there was room for the hospital have a better guideline and observation mechanism for VAC dressings and advised he has tasked the wound care team to consider this further. I encourage Children's Health Queensland to continue this work as an adjunct to my recommendation regarding the development of a wound inspection guideline for the cardiac surgical service.

Process for after hours call-in of cardiac surgical theatre team

Dr Hallahan's statement outlined the usual call-in process for urgent theatre cases, outside of cardiac theatre, is for the relevant Surgical Fellow, after

consultation with the consultant surgeon, or the consultant who telephones the on-call anaesthetist and then contacts the Nurse Manager Operations to call in from the relevant list.

However, the cardiac surgical team operates a different call-in process because Drs Alphonso and Venugopal believe the surgical Fellows' personal phone calls to the team allow communication of important clinical information about the child's condition, the anticipated procedure and the equipment required and as such, allows the team to plan for the emergency procedure and be mentally prepared when they arrive at the hospital and in theatre.

Dr Hallahan advised that emergency bypass is performed rarely at LCCH with there having been fewer than five instances of this since the hospital opened in November 2014.

Dr Hallahan's statement refers to assurances given by Drs Alphonso and Venugopal to the hospital executive that very close attention is paid to the call-in process during the orientation of Fellows to the cardiac surgical service and about what is expected in relation to communication between team members. Dr Alphonso advised that all cardiac Surgical Fellows "*are expected to be detailed in their assessment and communication of findings when discussing patients with either of the consultants*". Just what this entails in practice was not explored further in evidence.

I remain concerned that the cardiac surgery theatre call-in process does nothing to address the Surgical Fellow-to-consultant communication issues arising in this matter which I consider to have been compromised in part by the call-in responsibilities Dr Rajanbabu was expected to manage and which impacted his ability to assess and reassess the rapidly evolving clinical situation in PICU. There is no evidence before me to explain or justify the clinical need, as opposed to individual consultant preference, for a different call-in process for cardiac surgery patients than for any other urgent theatre cases including emergency trauma. Noting the shared opinion of the hospital's own experts about the benefit of relieving Surgical Fellows of onerous call-in responsibilities, **I recommend that Children's Health Queensland formally review the cardiac surgery theatre team call-in process with a view to assessing the reasonableness and relative clinical merit of the Surgical Fellow call-in responsibilities with reference to call-in processes operating in comparable paediatric cardiac surgical centres.**

Exercise of discretion under s.48 *Coroners Act 2003* Reporting offices or misconduct

Section 48(4) of the Act gives a coroner discretion to refer information about a person's professional conduct to the relevant professional disciplinary body if the coroner reasonably believes the information might cause that entity to inquire into or take steps in relation to the conduct. The disciplinary body for a health practitioner in Queensland is the Health Ombudsman.

The *Health Ombudsman Act 2013* empowers the Health Ombudsman to assess, investigate and take disciplinary action in response to notifications about conduct by a health practitioner that may constitute unsatisfactory professional performance, unprofessional conduct or professional misconduct. These concepts are defined by the *Health Practitioners Regulation National Law (Queensland) 2009* to encompass knowledge, skill or judgement possessed, or care exercised by the practitioner below the standard reasonably expected by a practitioner of equivalent level of training or experience; conduct of a lesser standard than that which might reasonably be expected of the practitioner by their professional peers or the public; and conduct falling substantially below the standard expected by a practitioner of equivalent training or experience.

The regulatory regime for health practitioners practising in Queensland is designed to protect public health and safety by ensuring health services are provided by health practitioners who are suitably trained, qualified and competent; it is not punitive in focus.

The clinicians involved in Joshie's care during the early hours of 16 November 2015 were confronted with a rapidly evolving clinical situation now known not to have been reported previously in the clinical literature. It was an extraordinarily rare and unheralded complication that unfolded over a two hour period in the early hours of a Sunday night.

I have found that Drs Venugopal and Rajanbabu collectively underestimated the seriousness of the bleed and made an error of judgement in assessing it as superficial rather than deep bleeding. This occurred in the context of the communication between them at 2:19am and again at 2:49am which with the benefit of hindsight was less effective than it could have been on both their parts – Dr Venugopal needed to have focussed more effort on exploring with Dr Rajanbabu the nature and extent of the bleeding during the initial phone call; Dr Rajanbabu needed to have reassessed the situation himself after speaking with Dr Stocker in PICU and before he spoke with Dr Venugopal again at 2:49am. However, that is not to say either doctor failed to take the situation seriously; there is certainly no evidence to suggest either adopted a cavalier approach to the situation.

It is evident both doctors have since reflected carefully on what might have been done differently that night and each made appropriate concessions around these issues at inquest.

It is important to consider their communication shortcomings in the broader context of whether earlier activation of the cardiac surgical theatre team and emergency bypass would have changed the outcome for Joshie. The expert consensus is that even had the whole theatre team been activated immediately and Joshie taken to theatre sooner with a bypass machine ready, the chances of saving his life were remote given the particular nature of this catastrophic bleed; something that could not reasonably have been anticipated by any of the clinicians caring for Joshie that night. It is in this context that I consider the conduct of Drs Venugopal and Rajanbabu does not

raise professional conduct issues warranting referral to the Health Ombudsman for further examination from a regulatory perspective.

I offer sincere condolences to Joshie's family.

I close the inquest.

Ainslie Kirkegaard
Acting Coroner
BRISBANE
24 October 2018