

THE MEETING OF THE ANAESTHETISTS ON OCTOBER 19

The anaesthetists were still concerned about the surgical results. At their October 19 meeting, (Exhibit 19, Document 262) they agreed on the need for the Wiseman Committee to look at cardiac deaths.

At this meeting, there was also discussion about the length of time it was taking both the Standards and Audit Committee and the Pediatric Surgical Standards Committee to review the deaths in the pediatric cardiac program. Anaesthetic representatives to the committees were to write to those committees to encourage them to expedite their reviews of the cases.

THE DEPARTMENT HEADS MEETING OF OCTOBER 28

On October 28, Blanchard, Postl, Craig and Wiseman met. At this meeting, Postl summarized the discussions he had conducted with the individuals involved in the Pediatric Cardiac Surgery Program.

According to notes taken by Blanchard at the time, Craig said that pediatric cardiac anaesthesia was “remarkably naïve & feel besieged. Reluctantly [sic] to see selves as a major part of problems.” (Exhibit 66, HSC 68) Craig said he did not recall making these comments. He did say that he believed the department was to a measure insulated from the larger politics of the HSC. He also testified that he did recognize that, as a result of their actions in May, the pediatric cardiac anaesthetists did feel as if they were being portrayed as villains.

Blanchard said that it was at this meeting that he realized that “there were serious concerns in the nursing realm as well.” (Evidence, page 36,625) Blanchard explained that he knew in May that the nurses had concerns, but he believed they were largely “in the realm of compassion, of caring, of grief, you know, that sort of thing.” (Evidence, page 36,625) Despite this evidence of discord, Blanchard testified that he believed at the time that it was proper to allow the program to continue at full activity.

At the end of the meeting, he distributed copies of Odim’s letter to the two other department heads and to Wiseman, with instructions that they not distribute it further. Craig testified that, when he read the letter, he was disappointed and wondered if the Wiseman Committee’s efforts at team building were not doomed to failure.

In his testimony, Wiseman said that the letter was disturbing in a number of respects. He was now open to Odim’s recommendation of an external review.

But an external review, because of the need for—my sense was that there was still a need for cardiac surgical expertise in the perspective of a review, which I didn’t, I couldn’t offer. And as you know, in terms of a genuine peer, there wasn’t one in the city. (Evidence, page 40,712)

In his testimony, Postl commented that the letter disturbed him as well.

I remember reading it and being surprised at the intensity of the comment, some of the negativity that was expressed. I think that’s my memory. I was a little surprised at that. (Evidence, page 35,488)

During the autumn, Postl began reviewing the surgical results from the Pediatric Cardiac Surgery Program and concluded that the numbers were not satisfactory. He testified that he raised the issue with

Giddins. In their discussion, Giddins pointed to the small number of cases that were under review and suggested that the surgical results were consistent with the results during the period when Duncan was the surgeon. Giddins told Postl that some very difficult cases had actually gone very well. Giddins said that an improvement could be expected over time, as in Duncan's case.

This suggests that Giddins believed that Odim was progressing along a learning curve, and that events in the operating room needed to be looked at from that perspective. This was not the first time that Giddins and others had used this approach to rationalize the results that the program was exhibiting.

To repeat what has been said elsewhere in this report, it is simply not appropriate to allow patient care to be compromised while a surgeon gains experience. If it was felt results would not be as good as they ought to have been because Odim was progressing along a learning curve, greater care ought to have been taken in case selection to ensure that he did not take on cases that were beyond his level of skill and experience. That was never done.

THE CASE OF ASHTON FEAKES

ISSUES

Ashton Feakes died on November 11, 1994, after undergoing cardiac surgery on November 1, 1994.

The issues to which Ashton's case gives rise are:

- Were his parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should Ashton have been referred out of the province during the summer of 1994?
- Should consideration have been given to performing a mitral valve replacement before November 10?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Ashton Feakes was born in St. Boniface General Hospital on July 15, 1993. The first child of John and Linde Feakes, Ashton was delivered by Caesarean section at 36 weeks gestation. At birth, he was diagnosed with Trisomy-21 (Down's Syndrome). At that time a heart murmur was also detected and he was diagnosed with congestive heart failure. He was treated with digoxin and a diuretic (aldactazide). On July 17 when Linde Feakes met with Giddins, he left her with the impression that Ashton needed surgery within the following six months and that the operation would likely take place in Toronto, Edmonton or Saskatoon. Ashton was discharged on August 10.

When Giddins re-examined Ashton on August 11, 1993, Ashton was in no apparent distress. His respiratory rate was 50 breaths per minute, while his heart rate was regular at 140 beats a minute. All his peripheral pulses were palpable, and the size of his liver was normal.

An echocardiogram showed:

- a right aortic arch (which means that the arch curved to the right rather than to the left)

- a complete atrioventricular canal defect
- mild atrioventricular valve regurgitation
- bilateral ventricular hypertrophy. (Both his ventricles were enlarged.)

In this defect, the tricuspid and mitral valves (the atrioventricular valves) that normally separate the heart's upper and lower chambers are not formed as individual valves. In Ashton's case, these valves were abnormal and disrupted.

An additional septal defect was identified post-operatively. Before surgery, it would have been difficult to determine if this defect was separate or a part of the atrioventricular canal defect.

His right aortic arch and his left ventricular outflow tract were unobstructed; however, he had a moderate amount of muscular obstruction of his right ventricular outflow tract as well. His pulmonary valve annulus appeared to be mildly stenotic or narrowed. His ductus arteriosus was long and narrow, but still patent.

In a subsequent letter to the family doctor, Dr. Laura Hawkins, Giddins wrote that it appeared that Ashton was developing increasing muscular obstruction of the right ventricular outflow tract. This was leading to bi-directional shunting in the canal. He also indicated there was a plan for a heart catheterization. Giddins suggested that there was no reason for Ashton to continue to take digoxin, and that the dose of the diuretic could also be reduced.

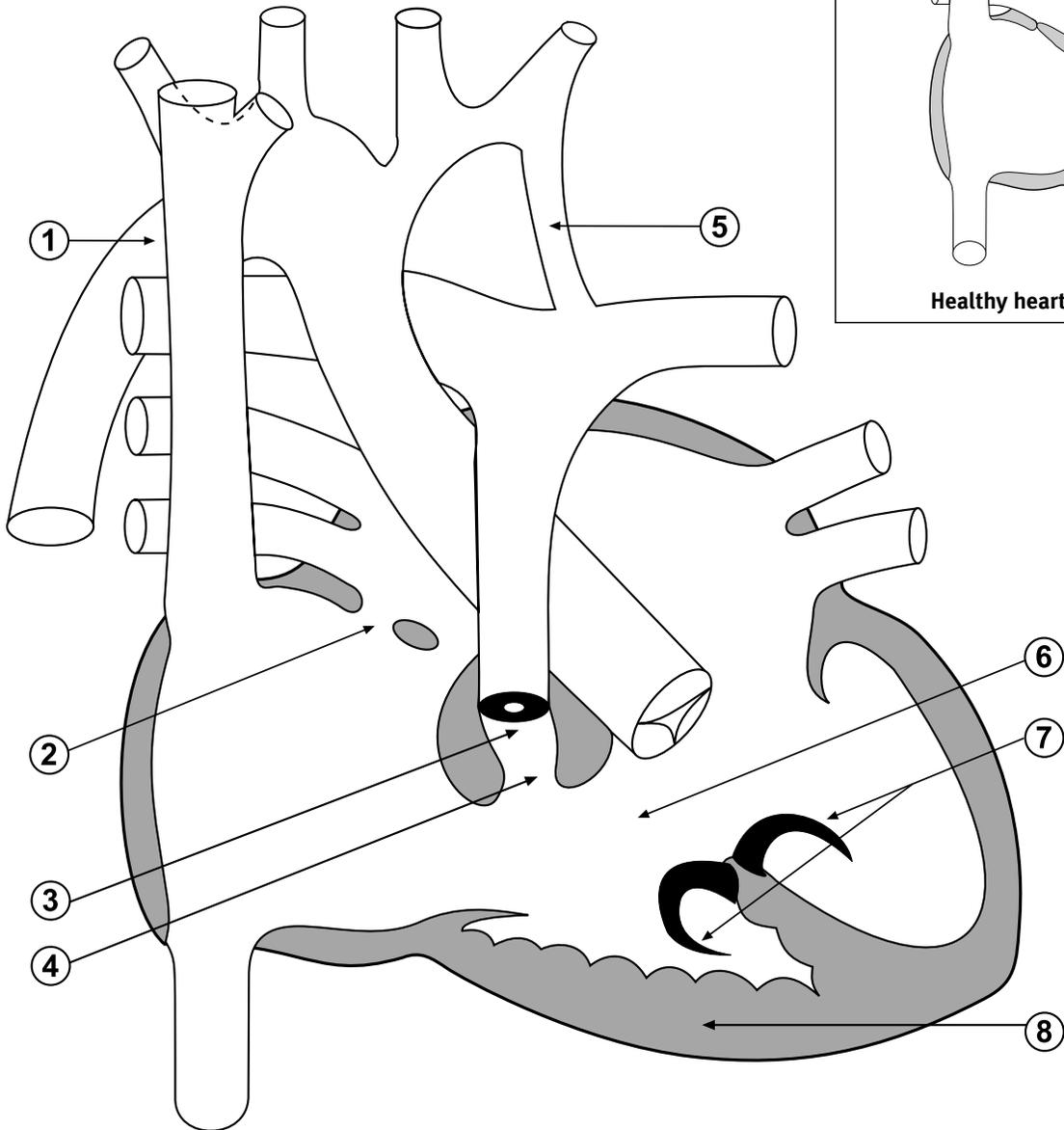
A heart catheterization on September 7, 1993, led Giddins to conclude that Ashton suffered from a condition reminiscent of Tetralogy of Fallot, complicated by an atrioventricular canal defect. The catheterization also showed that Ashton had moderate atrioventricular valve regurgitation from the left ventricle to both atria.

There was a considerable degree of risk involved in repairing the combination of defects that Ashton had. For that reason, and because he felt that Ashton's condition did not make an operation urgent, Giddins decided that it would be more appropriate to undertake a surgical repair when Ashton was older and stronger. One of the reasons why a repair could be delayed was that the significant right ventricular muscular obstruction was protecting the pulmonary arteries from high pressures. Giddins said that he anticipated that Ashton's condition would evolve in one of two ways: either Ashton would develop lung congestion and difficulty breathing or the muscle obstruction would increase, causing less than normal blood flow to the lungs. Giddins decided to reassess Ashton in three months and that, in the meantime, he would not need any medication. In the end, surgery did not take place until November 1, 1994. Before then, Ashton experienced a number of serious respiratory problems.

On December 10, 1993, he was taken to the HSC suffering from rapid breathing and in-drawing of the skin between his ribs and under the breastbone, a sign of his breathing difficulties. A chest X-ray showed that he had an enlarged heart, increased pulmonary flow, and possible mild pulmonary edema. The X-ray report concluded that Ashton had bilateral pneumonia. He was restarted on aldactazide for treatment of the mild congestive heart failure and was sent home at 0155 hours on December 11.

When Giddins saw Ashton on December 13, his chest was clear and his respiratory rate was 60 to 70 breaths per minute, with mild subcostal in-drawing. In his testimony, Giddins commented that, despite the interpretation of the X-ray taken when Ashton was in the HSC two days earlier, there was no evidence of any

Diagram 8.5 Ashton Feakes – pre-operative heart



- 1 – Right aortic arch
- 2 – Atrial septal defect (identified post-operatively)
- 3 – Stenotic pulmonary valve
- 4 – Right ventricular outlet narrowing

- 5 – Patent ductus arteriosus
- 6 – Atrioventricular canal defect
- 7 – Anterior bridging leaflets
- 8 – Dysplastic right ventricle

infection. He also said that Ashton did not have an elevated temperature and that the X-ray showed only a slight enlargement of the heart.

Giddins concluded that Ashton was having respiratory symptoms due to the degree of left to right shunting, and should continue to be given the diuretic. He suggested a follow-up appointment in three months. In a December 14 letter to Ashton's referring doctor, Giddins wrote that his case would be taken to a CVT conference in 1994 once Odum arrived. Giddins thought that the best course of action would involve surgery in the coming year.

However, Ashton's respiratory problems were not over. On December 30, 1993, he was once again admitted to the HSC and was diagnosed with pneumonia. Ashton was treated with an antibiotic given intravenously. It would appear that his condition on December 13 was more serious than Giddins had originally thought. Ashton was discharged on January 5, 1994, on antibiotics.

THE DECISION TO OPERATE

By the spring of 1994, Giddins was giving active consideration to scheduling Ashton's heart repair. A March 30 echocardiogram showed increased right ventricular outflow tract obstruction. While the muscular right ventricular outflow tract obstruction had been giving Ashton a measure of relief from increased pulmonary blood flow, over time the obstruction itself was increasing and coming to represent a threat to adequate blood flow. Ashton continued to be given a diuretic to treat his pulmonary congestion. Giddins wrote to Hawkins that while Ashton was old enough and large enough to undergo a repair, he had no short-term concerns about his health.

On April 11, Ashton's case was presented at the CVT conference. Following this meeting, Odum arranged to discuss surgery with Ashton's parents. The Feakes testified that, based on that conversation, they expected surgery to take place in the spring of 1994.

On May 2, Ashton was admitted to the Children's Hospital with a cough, an elevated temperature and decreased oxygen saturation. After a chest X-ray showed that he had bronchopneumonia, he was given intravenous antibiotics. Ashton also had a rash on his buttocks, trunk, arms, and back. He was discharged in stable condition, still taking the diuretic, on May 17.

Odum met with Ashton's parents on May 30, 1994. In testimony, Odum was unable to explain why there had been a seven-week delay between the CVT of April 11 and the meeting with the Feakes. By the date of this meeting, the PCS program was in hiatus, as a result of the action taken by the anaesthetists. The very serious lesion that had put Ashton in the high-risk category was one that could not be repaired in Winnipeg during this period. Odum testified that he did not inform the parents of the slowdown in the Winnipeg program; nor did he suggest that they consider having the operation performed out of province.

I guess it did not cross my mind. My sense was that was really the territory of the cardiologist and it didn't really cross my mind. They were having discussions with cardiology, cardiology refers me a patient, I see the patient in clinic. (Evidence, page 25,731)

In a letter to Ashton's doctor, Odum wrote:

The planned definitive repair and attendant risks were discussed with the parents in detail. The natural history of medical therapy versus operative intervention was explained to the family. The higher risk in this particular subset of patients with Tetralogy of Fallot and AV canal lesions was explained to the family in detail. In view of his torrential pulmonary blood flow despite his right ventricular outflow tract obstruction and his pulmonary hypertension, which responds to oxygen therapy, I think Ashton is a candidate for definitive repair. (Exhibit 6, page FEA 5)

He also wrote, “In the interest of improving his quality of life and extending his longevity the parents are willing to take the substantial operative risk and consent to surgery.” (Exhibit 6, page FEA 5)

CONSENT

In her testimony, Linde Feakes said that Odim’s assessment of the risks Ashton was facing came as a surprise to her. She said from her earlier meetings with Giddins she had been left with the impression that there was 99 per cent success rate for the sort of surgery that Ashton was to undergo.

It was just run of the mill. All of these kids, whatever, a lot of kids with Down’s have heart surgery and come through no problem. Basically, when we talked to Odim, it was like he basically dropped a bomb or something.

I don’t know, we came in there with—okay, we are going to meet the surgeon, no problem, and we left like totally in tears and everything. He told us that the repair Ashton had to have done, in the worldwide centres, like in the world renown centres or something like that, they had an 80 per cent success rate with that surgery. And in Winnipeg in the last 10 years, they hadn’t saved one with that surgeon—I mean with that surgery.

We didn’t know why it was so—why all of a sudden the big change. His answer was because it was rare for a kid to have all of those defects in the same heart, because there is kids that have the different parts and those are easier to fix, but Ashton had so many things wrong with his heart.

And he told us he was from Boston. He just came from Boston, and that was one of the major world centres that he named. So we were assuming that this would mean that he would have an 80 per cent survival rate also, if Boston did.

And we asked him how many of these surgeries [he] had done. He told us he did one under supervision, on his own, and he had assisted with some, I don’t know how many, and he did all of these other parts individually, but it’s rare to find them all together. So, that’s why he hadn’t done it often, all together in one kid. (Evidence, pages 2,891–2,892)

Linde Feakes also testified that Odim said the operation should be done right away. He also suggested that it should have been done by that time. John Feakes said that at first he thought Ashton should be sent out of province, but concluded that because Odim was from Boston, it would be appropriate to have him treated in Winnipeg.

The Feakes expected to hear back from Odim by the end of the first week in June. However, no date was set during this period. Linde Feakes indicated that the family had been expecting that surgery would take place during the summer, before Ashton’s July 15 birthday. She said that the reason given to them about delay was that there was a backlog, not that the program had slowed down. She said that during the summer, no one raised the possibility of sending Ashton out of province, even though other children were being referred to other centres during this time.

Following a July 6 VCHC visit, Giddins wrote to Dr. Hawkins that it was likely that a date would be arranged for September or October. However, he said that this could not be finalized until the end of August. He also wrote that the family understood that there would be a delay. In his testimony, Giddins was asked on what basis he had made the prediction that it would be possible to undertake the surgery in September or October. He replied:

My belief that the issues that were resulting in the hiatus at the time were going to be and, in fact, were being addressed, and the program was developing appropriately. (Evidence, page 4,108)

When Giddins was asked if he had told the family of the slowdown in the program, he said he did not believe he had, since “It had no pertinence to Ashton’s surgical care in the future.” (Evidence, page 4,109) Giddins did acknowledge that the operation was deferred until the re-establishment of the program and that he had not informed the parents of this fact.

Linde Feakes testified that following the July 6 meeting with Giddins, the family again thought that surgery would take place soon. When she pointed out that Odium thought the operation should have taken place immediately, she said that Giddins told her that there was no danger in delay. In his testimony, Dr. Walter Duncan said that Ashton was still an acceptable candidate for surgery in late October, despite the delay.

It was only after the program resumed full operation in September 1994 that a final decision was made to perform surgery in Winnipeg. The initial decision was to schedule the operation for October 18. It is apparent that if it had not been for the program slowdown, Ashton would have undergone surgery in the late spring or summer of 1994.

It should be noted that this was an extremely high-risk procedure. Giddins testified that he would describe this repair as relatively high-risk, having a risk factor of 25 per cent. While Cornel and Dr. Walter Duncan agreed that the surgical approach that Odium employed was appropriate, they noted in their report that:

this is one of the more difficult types of repair to do well. Statistics are not favourable. Estimated Canadian risk for surgery in this condition may be as high as 10–20%. (Exhibit 354, page 13)

Soder gave this description of difficulties involved in this surgery.

We often refer to mitral valve surgery and AV canal surgery as an art. It is like sewing wet tissue paper is how our surgeons describe it. It takes a degree of creativity and artistry that I don’t understand to make those filmy leaflets somehow line up and function in a reasonable fashion, because the canal is such a gross malformation of normal anatomy, and this isn’t sewing firm tissues together in a sort of predictable mechanistic fashion. So it involves the highest level of skill, and in my opinion a great deal of intuition to get it right. (Evidence, pages 44,195–44,196)

As difficult as it sounds, this approach is preferable to putting in a prosthetic valve. Such valves require that the child take medication to ensure that there is no clotting around the valve. Furthermore, as the child grows, there must be further operations to replace the valve as the heart becomes bigger.

It is reasonable to ask if, in undertaking this operation, the team was not once more—to use the words of the Wiseman Committee interim report—taking on a case ‘of an order of complexity that exceeded the program maturity.’

The operation was set for October 18, but was postponed when Ashton was found to have petechiae. These are minute reddish or purplish spots caused by hemorrhaging in the skin or mucous membrane. In

some patients, the presence of petechiae means that there are not enough platelets. In other patients, petechiae are associated with a platelet dysfunction. (Platelets normally assist in blood clotting.) On October 5, Dr. Rachelle Yanofsky, an HSC hematologist, examined Ashton and concluded he had very mild petechiae and mild polycythemia (an increase in the total number of red cells of the blood). She recommended that Ashton not be treated with aspirin or antihistamines pre-operatively.

The results of an October 17 heart catheterization were essentially unchanged from the previous catheterization, except that the muscle bundles causing the right ventricular outflow tract obstruction were noted to be increasing in size and significance. The consulting witnesses agreed that Ashton had been diagnosed correctly. His parents gave formal consent for his operation.

PRE-OPERATIVE STATUS

Ashton was scheduled for surgery on November 1 and was admitted on Monday October 31, 1994. On admission to the HSC, Ashton was breathing rapidly, with his ribs clearly showing each time he took a breath. However, his chest was clear and in his testimony, Giddins said he believed that Ashton was fit for surgery. The report from the anaesthesia consultation indicated that Ashton was seen to be high risk, but that a decision had been made to proceed with the operation.

THE OPERATION—NOVEMBER 1

On Tuesday November 1, Ashton underwent:

- a single-patch repair of the complete atrioventricular canal defect;
- division of the anterior bridging leaflets, with re-suspension, of the mitral and tricuspid components, to the pericardial patch (or refashioning of the existing components of the mitral and tricuspid valves, using material from the pericardium);
- Reed annuloplasty of the mitral valve (or repair of the opening of the mitral valve);
- closure of the mitral valve cleft;
- pulmonary valvotomy (or enlargement of the pulmonary valve opening);
- excision of the extensive parietal muscle bundles within the right ventricle; and
- ligation of the patent ductus arteriosus.

The operating team is set out in the accompanying chart.

TABLE 8.5: Persons involved in the operation on Ashton Feakes, November 1, 1994

<i>OR team member</i>	<i>Persons involved</i>
Surgeon	J. Odim
Surgical assistant	B.J. Hancock
Anaesthetists	H. Reimer, J. Doer (resident)
Scrub nurses	C. Youngson, C. McGilton
Circulating nurses	B. Zulak, C. Weber, K. Cox
Perfusionists	M. Maas, D. Smith

The myocardial protection used was moderate hypothermia and intermittent cold blood cardioplegia.

TABLE 8.6: Length of phases of the operation on Ashton Feakes, November 1, 1994

<i>Phase of the operation</i>	<i>Time taken</i>
Induction	1 hour 47 minutes
Bypass	3 hours 21 minutes
Aortic cross-clamp	1 hour 57 minutes
Total surgical time	6 hours 20 minutes
Total operating-room time	8 hours 22 minutes

Odim testified that in his opinion, the repair in Ashton's case went very well. The other participants in the operation raised no issues about this procedure. However, Soder said that a procedure of this length would give him some anxiety.

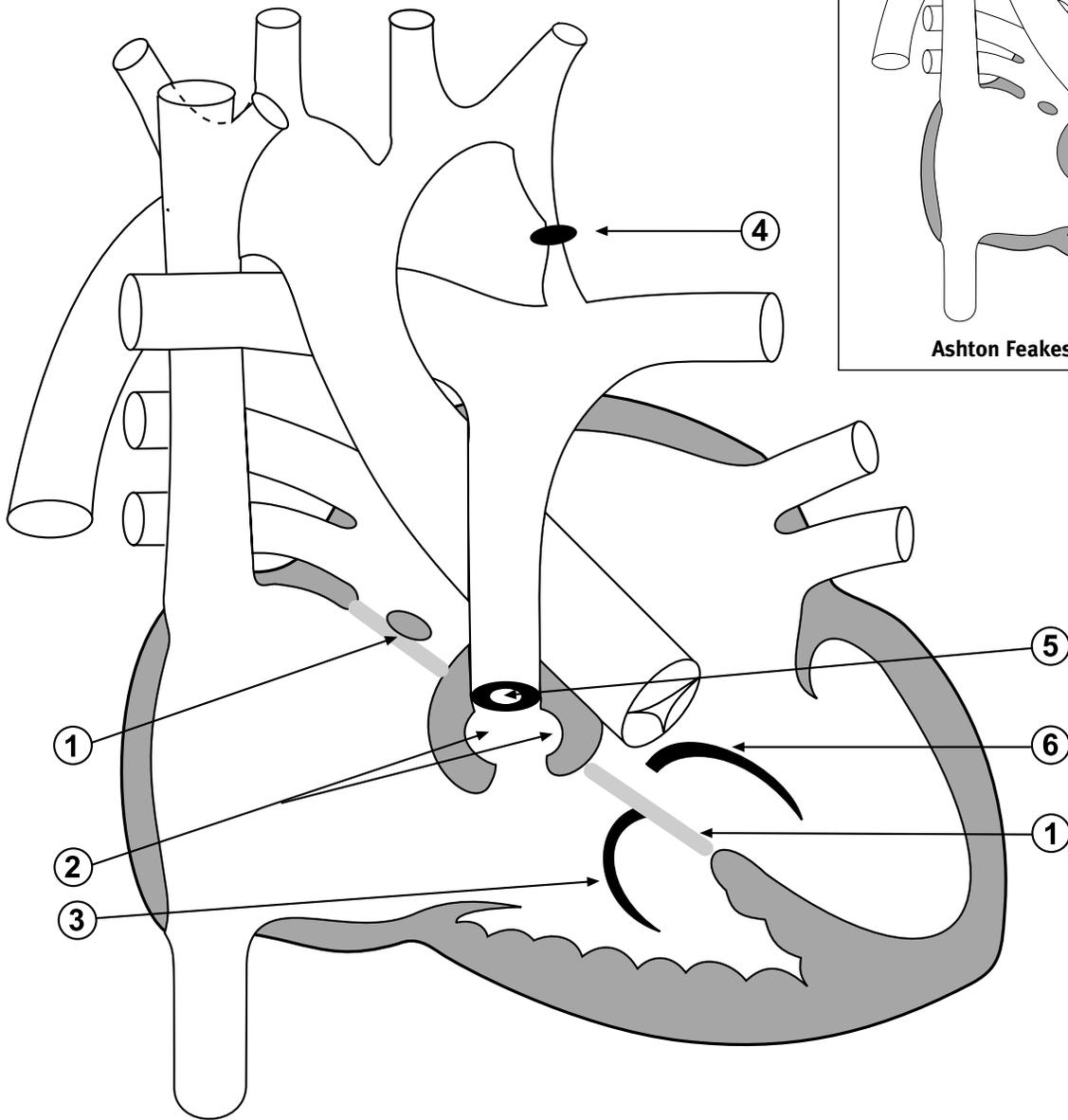
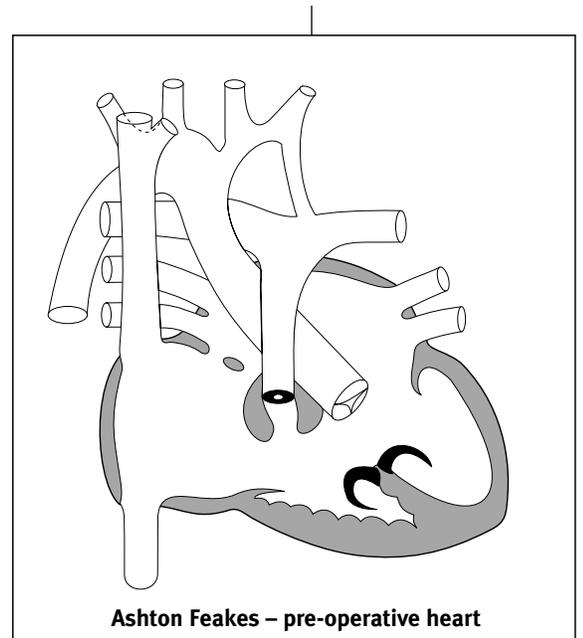
During surgery Ashton experienced problems with heart block that continued during his post-operative treatment. He had third-degree heart block during the closure of his chest, which required cardiac pacing.

Aside from the fact that withdrawal from bypass required substantial doses of inotropes, Cornel concluded that the "surgery appears to have been otherwise uneventful. Intraoperative pressure recordings were consistent with a satisfactory repair. The pulmonary artery pressure was elevated but the left atrial pressure and central venous pressure were within expected range." (Exhibit 353, page 59) In their joint report, Cornel and Duncan noted that the patches appeared to be intact and appropriately placed. In his testimony, Dr. Walter Duncan said, "I think it was well done. This is a difficult repair, I think his patches were intact, his valves looked okay, his pressures were perfect." (Evidence, page 41,451)

POST-OPERATIVE COURSE

The operation that Ashton underwent placed a tremendous strain on his system. It was not expected that he would return to the PICU in anything other than critical condition. However, the expectation was that after 24 hours, he would begin to improve. Initially, Ashton followed this course. However, on November 5, four days after surgery, his condition began to deteriorate. From that point on, he never recovered.

Diagram 8.6 Ashton Feakes – post-operative heart



- 1 – Single pericardial patch of atrioventricular canal defect
- 2 – Partial excision of the extensive parietal muscle bundles within the right ventricle
- 3 – Resuspended tricuspid valve

- 4 – Ligated ductus arteriosus
- 5 – Pulmonary valvotomy (or enlargement of the pulmonary valve opening)
- 6 – Resuspended mitral valve (with subsequent dehiscence)

Recurring issues during his post-operative care were an increase in regurgitation through his mitral valve, problems with his heart rhythm and concerns that he may have been suffering from a lung infection.

On November 10, it was discovered that his reconstructed mitral valve was no longer functioning. In light of this finding, one of the central debates over his post-operative care was at what point should the team caring for him have considered performing a valve replacement. One of the signs of mitral valve failure is regurgitation through the mitral valve. However, regurgitation is common following surgery of this nature—the challenge is to determine if the level of regurgitation is excessive and indicates a need to re-operate.

Doyle admitted Ashton to the PICU following his operation. At the time, she noted that he had low blood sugar, low blood pressure, metabolic acidosis, an elevated temperature and a decreased number of platelets in his blood. Except for his left upper lung, he had good air entry to his lungs. She concluded that Ashton's heart was unstable, with poor contractility and residual regurgitation through an atrioventricular valve, and with low blood pressure. Doyle testified that this was not unexpected, given Ashton's condition before surgery. Ashton was treated for the conditions Doyle had identified and his condition stabilized. However, Doyle testified that as efforts were made to reduce those treatments, Ashton's condition deteriorated.

An echocardiogram performed immediately after surgery showed abnormalities in the function of the left ventricle and mild tricuspid regurgitation. The possibility of mitral valve stenosis was also questioned. However, there was no mitral valve regurgitation. Giddins testified:

I was perhaps surprised by that because that was surprisingly good, I would have expected some leak. (Evidence, page 4,342)

Based on the results of that echocardiogram, Giddins said he thought that the operation had gone very well.

For the first eight hours following surgery, Ashton's left and right atrial pressures were both elevated, but were approximately the same. After eight hours, however, the left atrial pressure increased and remained higher than the right atrial pressure. According to Cornel, this was a possible indication of dysfunction on the left side of the heart and, in particular, of a problem with the atrioventricular valve repair (that is, the mitral valve).

Throughout his stay in the PICU, Ashton experienced heart block. Odum said that Ashton had sinus (or normal) rhythm when he came off bypass, so he thought the block was not a technical issue. Odum said he thought it might have had a metabolic source or might have been related to swelling in the tissues of the heart.

On November 2, Ashton's metabolic acidosis improved, but he still needed pacing. Giddins wrote that Ashton had complete atrioventricular heart block with a paced ventricular rate of approximately 120–130 beats per minute. He said there was “very little ‘coordinated atrial kick’ but when pacer placed in backup mode, every 2nd vent [ventricular] impulse preceded by atrial kick therefore this seems optimal for now. Other aspects of of [sic] status all look satisfactory.” (Exhibit 6, page FEA 80)

What Giddins was describing was a way of pacing the heart by stimulating only the bottom part of the heart – the ventricle (or “paced ventricular rate”). When Ashton's heart was paced at a rate of 120–130 beats per minute, there was no spontaneous activity from the atrial or top part of his heart. However, when the

pacer was put in the backup mode (and not actively pacing), then Ashton's heart would produce a small beat from the top of the heart, in the form of an 'atrial kick'. This 'kick' represents a small amount of blood that is ejected and helps with the overall output of blood from the heart. Giddins believed that this situation was the best for the time being.

In his report, Cornel wrote, "The rhythm management was questionable. AV sequential rhythm would probably have produced a significant improvement in cardiac output. AV sequential rhythm might have been achieved by administering digoxin combined with AV pacing at a faster rate than the atrial rate." (Exhibit 353, pages 61–62)

Cornel was suggesting that a better way of managing Ashton would have been to use AV sequential pacing, in which the atrium was stimulated electrically, followed by electrical stimulation of the ventricle. Cornel indicated that the technique would involve two components. First, Ashton would have to be given digoxin, a drug that can be used to slow electrical conduction between the atrium and the ventricle. Second, the pacemaker would have to be set at a rate faster than the rate at which Ashton's heart was attempting to beat on its own. By doing these two things, Ashton's heart would be able to contract in a way that most closely resembled normal, with the result that Ashton would have had improved output of blood flow from his heart.

On November 3, Ashton had an elevated temperature and was treated with diuretics to address his low urine output. While Ashton still had heart block, Giddins said, he was satisfied with his heart rhythm.

Increase in mitral regurgitation

On November 4, Ashton's chest was clear and the process of weaning Ashton from mechanical ventilation was started. Giddins testified that he was not concerned by Ashton's continued heart block. He said it was his practice to wait at least a week to determine if a child then needed a permanent pacemaker.

Ashton was still being given inotropes. An echocardiogram showed that he had good ventricular function, right atrial enlargement, right ventricular hypertrophy, mild mitral stenosis, moderate mitral regurgitation and mild right ventricular output obstruction. Giddins said these results indicated that Ashton's condition was continuing to improve.

The consulting witnesses to this Inquest raised questions about the mitral valve regurgitation. According to Cornel, the leakage could have been due to the components of the valve becoming pulled apart or because the valve was becoming detached from the suture line. Cornel said the regurgitation likely became significant following the increase in the left atrial pressure. He thought it would have been appropriate for the post-operative care team to have considered whether or not mitral valve replacement was required at that time.

Cornel acknowledged that such a replacement was a difficult procedure. However, he said:

... the outcome of doing nothing with a severely regurgitant valve, where the heart is not managing to cope with the regurgitation, the outcome of that is terrible. (Evidence, page 44,894)

Soder testified:

In general, our approach has been to let the general clinical condition of the patient guide us. If the patient appears to be on the mend, we tolerate up to moderate degrees of mitral valve regurgitation

or tricuspid regurgitation. If the patient appears to be deteriorating and getting into trouble, then we re-investigate and possibly re-operate. (Evidence, pages 44,183–44,184)

Odim was asked if there was any consideration of a re-operation on November 4. He said there was nothing to suggest that the repair had broken down.

Furthermore, we—the child was being ventricularly paced and we know that ventricular pacing will make mitral regurg worse because what happens is you are pacing the ventricle at a rate that is not congruous with the atrial, the atrial rate in the patient, and many a times, this impulse comes down through the tissue and it bombards this area and you get what is called a V-wave, so he was being ventricularly paced which we know exacerbates mitral regurg and there were issues of this being a functional problem because of the loading conditions on the pump. (Evidence, page 25,758)

Thus, as well as ventricular pacing producing less than optimal cardiac output, there was a possible second problem in the effect on the mitral valve. With artificial pacing of the ventricle only, there is no co-ordination with any spontaneous activity from the heart's normal atrial pacemaker. Then, if the atrial pacemaker does cause the atrium to contract, the result is what is known as a 'V-wave' that exacerbates mitral regurgitation.

A chest X-ray on November 4 showed slightly increased but unidentified spots in the left upper lobe and a new right pleural effusion. (This is the term for the fluid that fills the space between the chest wall and the lung. Pleural effusions can occur as a result of congestive heart failure.)

On November 5, there was no improvement. Giddins said this lack of progress actually indicated a significant change for the worse, since he had expected that Ashton would have been improving by this time.

A chest X-ray taken early in the morning of November 6 showed pulmonary edema, with increased pleural effusions on both sides of the chest. Ashton's platelets began to drop in number and remained low despite transfusions. Tests were done to see if he had a viral infection, which could have been associated with a decline in his oxygen saturation. However, Giddins testified, the results of those tests took a while to come back and little could be done about such viruses in any event. It does not appear that any requests were made to have the performance of the tests expedited. From this point on, the post-operative care team checked for a variety of infections, although none were identified during this period.

Over the next 24 hours, Ashton's oxygen saturation decreased, and he required more oxygen and manual ventilation. He retained fluid and his weight consequently increased, for which he was treated with diuretics. A chest X-ray showed that he had a collapse of his right upper lobe and pulmonary edema. An echocardiogram showed that the mitral valve now had moderately severe regurgitation. The tricuspid valve also showed an increased volume of regurgitation.

November 7—the mitral regurgitation worsens

By November 7, Ashton was again given doses of muscle relaxants to completely weaken his muscles. The aim of this treatment was to reduce oxygen use by the muscles, thereby reducing his heart's workload.

An echocardiogram showed that Ashton had moderate to severe left atrioventricular (mitral) valve regurgitation. Giddins said this was the first clear evidence that the valve was failing. Soder said he would then have called his team together to discuss the possibility of repair of the mitral valve. Soder would also have liked to have seen another heart catheterization done at that time.

However, Giddins said, there was no cause for a re-operation at that point.

Knowing, though, that in these cases moderate to severe valve regurgitation isn't an impediment in some cases to them leaving the ICU, we maintain a philosophy that, if at all possible, we should improve everything else that we can do in the intensive care unit before thinking of something like more surgery to address a failing valve.

Q: Would this have been the first day that the thought of a redo, or going back into surgery occurred to you?

A: Before going back into surgery, we would want pretty solid documentation that there was no alternative. (Evidence, pages 4,366–4,367)

Giddins also said he did not believe that Ashton was in any condition for surgery on November 7. Given the fact that Ashton was becoming more edematous, Giddins decided not to perform a heart catheterization until his condition improved. Catheterization itself, he felt, would put considerable stress on a child in Ashton's condition. The dilemma that Giddins faced was whether Ashton's problems were the result of a viral infection or from a failed mitral valve repair. Because a re-operation entailed significant risk, Giddins wanted to rule out all other possibilities, before considering valve replacement.

November 8—a small improvement

Giddins thought that Ashton's condition was improving on November 8. His oxygen saturation was increasing, his fluid overload was resolving and his platelet count had not decreased further. However, he was still in heart block and still needed the pacemaker.

The same day, a hematologist was consulted to look at persistent thrombocytopenia (or low numbers of platelets in the blood). The hematologist suggested treating the condition with platelet transfusions until the surgical site healed. The opinion of the hematologist was that the number of platelets was low because they were being used to form clots around the wounds.

November 9 – a turn for the worse

Ashton's condition started to deteriorate once more on November 9. His oxygen saturation fell when staff attempted to keep his lungs clear of secretions, through what is termed chest physiotherapy. His platelet count, however, was stable. Giddins thought that Ashton's condition was not as bad as on November 7 but not as good as on November 8.

November 10—the opportunity for mitral valve replacement passes

On November 10, Ashton suffered a hemorrhage from his lungs that left his system so weakened that it was no longer possible to consider valve replacement. It was also on November 10 that the results of a heart catheterization showed that such a replacement was necessary.

At 0445 hours that day, Ashton's oxygen saturation decreased. Pink frothy sputum was suctioned from his lungs. This is often a sign of pulmonary edema and its increased presence was confirmed on a chest X-ray. Over the course of the day, subsequent chest X-rays also showed a large left pleural effusion, the fact that

both lungs appeared more dense in patches, and there was the possibility of a pneumothorax on both sides of Ashton's chest. (A pneumothorax is the abnormal presence of air in the space between the lung and the chest wall.) Ashton was not responding to aggressive treatment.

By this point, he had developed what Soder called frank pulmonary edema.

By frank pulmonary edema we mean that the pulmonary edema fluid is now actually bubbling up through the endotracheal tube and is externally visible, as opposed to just X-ray findings of pulmonary edema. (Evidence, page 44,191)

The pink froth was an indication that Ashton was hemorrhaging into his lungs. The development of pulmonary hemorrhage was a turning point in his post-operative deterioration.

An echocardiogram showed a small VSD leak, two forceful leaks (or jets) from the left ventricle to the right ventricle and severe mitral regurgitation, with shunts from the left ventricle to the right atrium.

Giddins and Soni performed a cardiac catheterization in the PICU, using a special portable X-ray machine. The procedure was complicated by Ashton developing a marked slowing of his heart rate and a drop in his blood pressure that required chest compressions for about five minutes. The catheterization showed severe mitral valve regurgitation, passive pulmonary hypertension and severe left ventricular function. Giddins wrote:

It is clear to Drs. Ward, Odum and I that no [underlining in original] further specific operative intervention would be tolerated; even if it were, prosthetic mitral valve management is extremely difficult (both short and long term) @ this age + size....prognosis nearly hopeless, and I would hope comfort is maintained as a priority. Family informed of above. (Exhibit 6, page FEA 101)

Swartz, who was the intensivist, also agreed that, following his lung hemorrhage, Ashton would not tolerate being placed on bypass, which would be required if his mitral valve was to be replaced.

Soder testified that from his perspective, the pulmonary hemorrhage was the terminal event in Ashton's case.

In my opinion the kind of the last chance to really do surgery was somewhere before he developed pulmonary hemorrhage on November 10. I think reoperating on his mitral valve up until that point still had a significant chance of success. Once you are into the situation of frank pulmonary hemorrhage, the likelihood of surviving surgery becomes very, very minimal. (Evidence, pages 44,193–44,194)

Dr. J. Embree of Infectious Diseases examined Ashton on November 10 and concluded that she did not believe an infection was playing a significant role in Ashton's problems. He had tested positive for coagulase negative staphylococci. However, she said that these bacteria could not have caused the problems that Ashton was experiencing.

Her notes indicated that she wondered if it was too early in Ashton's case to see signs of cytomegalovirus (CMV). This was a virus that was more common in adults than in children. However, Embree said that it was a virus present in all humans at all ages, but that the body's natural immune system is usually able to control it. In infants and immune-compromised persons, however, it has serious, permanent consequences. CMV infections can cause an opportunistic, severe pneumonia that may be life-threatening. She said that at the time of Ashton's surgery, there was no effective treatment for CMV infection.

After seeing Ashton, Embree recommended a fine-tuning of his antibiotic treatment, ongoing surveillance for further infections, and that samples be sent to be tested for various viruses (including CMV) and bacteria. Unfortunately, due to an error in the transmission of this request, no test for CMV was performed.

Linde Feakes testified that on November 10, Giddins told the family it was unlikely that Ashton would survive the night. John Feakes testified that it was made clear to them that it was not possible to repair or replace the mitral valve, given Ashton's weakened condition.

Throughout the evening, Ashton's condition continued to deteriorate. At 2400 hours Swartz wrote that Ashton was being given large doses of inotropes and maximum artificial ventilation, with no significant improvement.

November 11

On Friday, November 11, Ashton's condition continued to deteriorate. He had significant elevation of his pulmonary arterial pressure as a result of the mitral valve regurgitation. He was suffering from a progressive lack of oxygen in his blood and his kidneys had stopped making urine. Artificial kidney dialysis was successfully carried out that afternoon.

Linde Feakes testified that on that morning Odum informed her that it was still possible for Ashton to pull through. That statement proved to be more hopeful than accurate. Ashton was given comfort care to reduce his pain and died at 2027 hours on November 11, in the presence of his parents.

POST-MORTEM FINDINGS

The debate over whether Ashton's deterioration was driven primarily by a failing mitral valve or by an infection appeared to have been firmly settled in the autopsy report.

The autopsy was performed on November 13, 1994, by Dr. Joseph de Nanassy, and was restricted to an examination of the heart and lungs. While a preliminary report was issued on December 13, 1994, the final report was not completed until February 20, 1995. In the preliminary report, there was no mention of a finding of evidence of a viral infection in the lungs.

In the final report, de Nanassy determined there was extensive recent hemorrhage in both lungs and that there was pulmonary necrosis related to cytomegalovirus infection (CMV). He also noted marked bilateral myocardial hypertrophy. He concluded the most likely cause of death was the pulmonary hemorrhage. The implication from this was that the CMV attacked tissue in Ashton's lungs, leading to pulmonary necrosis. The weakening generated by this necrosis in turn could have led to the hemorrhaging and to Ashton's death.

As noted above, CMV is a very serious viral threat to children in Ashton's condition. While Embree had raised it as a possibility, no one involved in Ashton's treatment had thought it likely that he suffered from such an infection. Giddins testified that he was surprised at the results of the autopsy.

Consulting witnesses to this Inquest have come to a different conclusion about the cause of Ashton's death. Soder, Duncan, Cornel and Taylor each concluded that the problem lay with the dysfunctional mitral valve and not with CMV. Taylor testified, in fact, that he did not believe that Ashton had a CMV infection.

When Cornel examined the heart, he said that the degree of disruption of the AV valve was very severe.

The leaflet was almost completely detached. So that the degree of competence of the valve would have been minimal. It is an extremely severe lesion. (Evidence, pages 44,891-44,892)

When asked how this could happen, Cornel testified that the suture line bears the entire stress of left ventricular contraction and pressure.

If there is a tiny defect anywhere in that suture line, there is going to be added stress at that point and it may start to tear. Once a tear has begun, it becomes a progressive weakness, like tearing a stamp along the perforation. So the tear may very well be progressive. It is one of the reasons I don't do this type of repair anymore. There is a higher incidence of leaflet dehiscence in the one patch repair than some other types of repair. (Evidence, page 44,892)

Dehiscence means the coming apart of the surgical incision or suture line. It was Cornel's view that the leaflet tissue remaining on the mitral valve that had been sutured to the patch had come away from the suture line. When asked about his positive assessment of the surgery and the mitral valve regurgitation, Duncan testified:

It doesn't matter which surgeon where does an AV septal defect repair, the left-sided inlet valve will always leak after surgery, some more, some less. It depends how much tissue you have to work with.

This valve was behaving satisfactorily at the completion of the surgery, but I presume either the sutures pulled out or maybe became infected and pulled through, I don't know. But for whatever reason, the valve began to perform much worse in a relatively short period of time and just became progressively more so. (Evidence, pages 41,452–41,453)

De Nanassy disagreed that there was valve dehiscence, because, he said, there was no valve tissue to dehiscence in the first place. Taylor, however, said that if that had been the case, Ashton would have been in trouble immediately after surgery.

So in my opinion the leaflet valve tissue was attached to that patch. The suture line was there, although part of those sutures are for the other side, the tricuspid valve. And the leaflet pulled away from the patch, apart from the suture line, dehisced over the course of the clinical events leading up to the child's death. (Evidence, page 43,260)

Odim said that he was surprised to read Taylor's conclusion about dehiscence.

Certainly when I saw this I was a little bit surprised because certainly when Ashton was alive we were looking for evidence of this on his studies, echos and cath. So I was a little surprised by that finding.

I was also surprised because I think I recall looking at the specimen and I certainly don't remember picking this up and we may have looked at it as a group, I don't remember whether this was done in the setting of the M & M round. (Evidence, pages 25,771–25,772)

Taylor said there were three potential explanations for the suture line coming apart. They can be summarized as follows:

- There could have been an infection that undermined the repair. If the wound had become infected, the suture line would have 'softened', allowing the sutures to loosen and pull away.
- Technique: the sutures needed to be placed deep enough to have a sufficient grasp on the tissue being sutured. If not, they could have easily pulled out.
- Ashton could have had an inherent problem in the mitral valve tissue that prevented it from holding the suture.

As was mentioned, Taylor disagreed with the conclusion that the child had a CMV infection that caused the necrosis. He noted that the child had been checked for infection numerous times before death and no one had noted any infection. He said that CMV grows fairly easily and therefore would have been easily detectable. Embree confirmed this. It should be noted that de Nanassy did not actually test for the presence of CMV, but reached his conclusion based on observation.

Tests conducted by Taylor on sections of the lung were negative for the presence of CMV. He did feel that Ashton had bronchitis and pneumonia (both bacterial, rather than viral, infections) and that these bacterial infections led to the necrosis. He pointed to the fact that samples of endotracheal secretions that were taken from Ashton on November 7 tested positive for bacterial infection. It is not known when the results of these laboratory tests of November 7 were available to the team caring for Ashton.

Taylor thought that the mitral valve regurgitation could have led to a backup of fluid in the lungs that would have led to an infection in the lungs. This would then have led to the pulmonary hemorrhaging that eventually led to Ashton's death.

Taylor also thought that the infection could have moved along the suture line, causing the valve to dehiscence. This would also have led to regurgitation of the mitral valve and the resultant backup of fluid in the lungs, leading to pulmonary hemorrhaging. As a result, Taylor concluded that the two key factors in Ashton's death were the mitral valve regurgitation and the necrotizing pneumonia.

In his report, Taylor wrote:

The clinical history of the post-operative period indicates progressive development of mitral regurgitation. Initial echocardiogram showed no regurgitation while the last echocardiograms showed moderate to severe regurgitation. On the last day of this child's life it was clinically appreciated that he needed mitral valve replacement. My examination of the post-mortem heart specimen showed the anteromedial leaflet of the mitral valve to be separated from the suture line to which it was suspended from the atrial ventricular septal defect patch. This was also reported on the initial autopsy examination of the heart. Progressive dehiscence of this leaflet from the patch would cause the clinical findings recorded in the postoperative days. The finding of massive pulmonary haemorrhage is in keeping with fulminant mitral valve regurgitation. (Exhibit 336, page 10.1)

FINDINGS

As noted at the outset, the following issues arise in this case:

- Were Ashton's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should Ashton have been referred out of the province during the summer of 1994?
- Should consideration have been given to performing a mitral valve replacement before November 10?
- What was the cause of death and was it preventable?

Were Ashton's parents provided with sufficient information to allow them to give informed consent to the procedure?

■ Finding

As in the other cases dealt with by this Inquest, the evidence suggests that the parents did not receive sufficient information to give informed consent. They were never informed about the state of the team during the summer months while they were waiting for the operation to be performed. While Odim and Giddins were probably accurate in their assessment of the degree of risk that the operation presented, the evidence would suggest that they did not seem to have factored into their thinking the relative inexperience of the surgeon and of the team in dealing with this type of surgery. This information is something that would probably have been a factor in the thinking and granting of consent by any reasonable person, and should have been provided to the Feakes. This evidence tends to suggest that Ashton's parents were not provided with sufficient information to allow them to give informed consent to the procedure.

Should Ashton have been referred out of the province during the summer of 1994?

■ Findings

Given the seriousness of Ashton's condition, it would have been appropriate for the VCHC to have referred Ashton out of province for surgery in the summer of 1994. It was clear that Ashton was not an appropriate patient for the surgical team to undertake care of, during the summer of 1994, when the program was in hiatus and performing only low-risk procedures.

During the summer months, the review team was considering the question of whether or not to allow the program to proceed to high-risk cases. At that time, Giddins, in consultation with the Wiseman Committee, made the decision to defer high-risk cases until the program could do them. No consideration was given to transferring such patients unless the parents demanded that the child be transferred or unless the patient could not wait for surgery.

The Feakes were not given the option of considering a referral to another centre. They should have been. More importantly, however, was the fact that Ashton could not have benefited from waiting additional time for his surgery. There is evidence that Odim thought the operation should have been done sooner, rather than later. While the program waited for the hiatus to end, Ashton's condition was becoming worse. His muscle bundles, for example, became more and more problematic as time passed.

The evidence suggests that the team and its surgeon were not in a position, even in November, to be able to provide the best possible care for this child. While the operation was judged a success, it was a very high-risk process. It may be that the valve dehisced as a result of a problem with surgical technique, although this is only a possibility. However, it would have been appropriate for the team to have referred this child out of province, even after the PCS program had gone back to full service.

Should consideration have been given to performing a mitral valve replacement before November 10?

■ Findings

The treatment team came to the conclusion on November 10 that the surgical repair had failed and that the mitral valve needed to be replaced. However, by that time, Ashton had deteriorated to such a condition that it was not possible to consider another surgical procedure.

There is evidence to suggest that the team had sufficient information before November 10 to enable it to consider performing a mitral valve replacement. Cornel was of that view. He thought the echocardiogram on November 4 showed that the regurgitation was at the point of indicating a valve repair failure. Soder's view was the same. He said that so long as the patient was improving, regurgitation was tolerated, but the evidence suggests that Ashton did not improve to any degree after November 4. Giddins felt that Ashton's failure to improve on November 5 was actually a sign that he was getting worse.

By November 7, Ashton was showing evidence of an inability to tolerate another surgical procedure. That should have caused the team to consider a valve replacement if Ashton rallied, which he did on November 8. However, despite interpreting that as a sign of overall improvement—which seems more like wishful thinking, in hindsight—no steps were taken to replace Ashton's mitral valve. He quickly deteriorated thereafter.

What was the cause of death and was it preventable?

■ Findings

It seems clear that Ashton died from pulmonary hemorrhage. The question is: what caused the hemorrhage? The consulting witnesses believe that the dehiscence of the mitral valve repair led to the mitral valve regurgitation that ultimately led to Ashton's lungs becoming congested and hemorrhaging. No firm conclusion can be reached as to what caused this dehiscence.

The evidence also suggests that with a different approach to post-operative care, a decision would have been made earlier on to repair the dehisced mitral valve, although this would have been a high-risk venture.

Both the dehiscence and the failure to attempt to repair the mitral valve do lead to one very significant conclusion: this death could have been prevented if the case had been referred to a larger medical centre in the summer of 1994, rather than being deferred until November 1994.

EARLY WINTER

On November 2, Postl, partly at Blanchard's prompting, met with Odum over lunch. At that meeting, Odum told Postl that he felt that a number of team members had not given him a fair chance. He also indicated that there was a poor turnout for M & M Rounds. Finally, Odum restated his belief that fewer anaes-

thetists should provide anaesthetic care to pediatric cardiac surgery patients. After this meeting, Postl attempted to attend a pediatric cardiac M & M Round, only to discover that it had been cancelled.

At some point in late autumn or early winter, Postl received a phone call from Ward, who said that he had met McNeill by chance at a public skating rink. Postl testified that Ward told him about his conversation with McNeill. She had said to Ward that the only problem with the Pediatric Cardiac Surgery Program was Odim. If he was removed from the program, then it would be fine. Ward told Postl that this was evidence that the anaesthetists were not giving Odim a chance. Postl spoke to Craig about the encounter, who in turn, passed the information on to McNeill. In her testimony, McNeill gave this account of her meeting with Ward.

So he and I skated together for a little while; and during that time I expressed my concerns with some of the recent events in the operating room, that perhaps some of our concerns that we had had earlier in the spring were recurring. I guess I was partially informing, partially ventilating, and partially asking what he thought of what had occurred, because he knew some of the patients involved.

At the time, I didn't really think much of the conversation, it was shop-talk type of a thing. He was one of the cardiologists in the program, and I thought it was a reasonable thing to talk to him about events that were occurring in the program. (Evidence, page 13,530)

McNeill testified that Craig told her he thought her comments would serve to undermine the program. McNeill arranged to meet with Postl. She testified that she:

... explained to him, you know, that I really hadn't meant to be malicious or had no intent to undermine the program, and it was really, I thought, a relatively innocent conversation between people that were involved in the same work. (Evidence, page 13,532)

Postl said that he did not view the encounter as a major issue, but recommended that she not be indiscreet in public places.

Postl testified that as November progressed, he became troubled that the numbers of concerns about the program were increasing. Also, he said, people seemed to be, in his words, simply handing off their concerns when they reported them to someone else. The problem appeared to be, however, that those to whom the concerns were being reported were not resolving the issue.

On November 7, Craig wrote to Blanchard, stating that he had read Odim's letter and saw it as a warning. He recommended that there be an external review of the program (Exhibit 19, Document 265).

Odim testified that some time after he sent his letter to Blanchard, Craig spoke to him about Odim's concerns with anaesthesia. Odim recalled that Craig told him that he would ask Reimer if he was prepared to do the majority of Odim's cases. Odim said that Craig also told him about the possibility of having Dr. Heather Tulloch work with Odim. Tulloch was an anaesthetist who had trained at the Children's Hospital of Pennsylvania and was working in adult anaesthesia at the HSC. Odim said that he was agreeable to those proposals, but that he never heard back from Craig.

In contrast to Odim's testimony, Craig testified that he never met with Odim at that time, stating that their one meeting had been in June 1994.

Craig did testify that Tulloch had contacted him to inform him that Giddins had sounded her out about the possibility of her working in pediatric cardiac surgery. Craig testified that he pointed out that Giddins was neither the section head of pediatric anaesthesia nor the department head of anaesthesia. Craig also said Tulloch was aware that the situation was highly charged and therefore she was hesitant about entering

into it. Craig also said that he recalled that her name had been put forward at another meeting, possibly by Wiseman or Blanchard. At the time, Craig said that, before he agreed to her working in the PCS program, he would have to check on her knowledge and skills in anaesthesia for pediatric cardiac surgery. Because there was no further discussion of the prospect of Tulloch providing anaesthetic care for pediatric cardiac surgery, Craig did not pursue the option.

Craig also testified that at some point after the program had resumed full service in September, Blanchard had suggested that Swartz take a three or four-month break from the PCS program. Craig discussed this proposal with McNeill, who said that it would be a loss to the service since she regarded Swartz as one of its most capable members. During this same period, the anaesthetists decided that, whenever possible, two anaesthetists would participate in each case.

NOVEMBER 8—THE CASE OF KF

On November 8, 1994, KF, a five-month-old boy, underwent surgery to repair a complete atrioventricular canal defect. In addition, he underwent closure of an atrial septal defect, ligation of a patent ductus arteriosus and repair of his mitral valve.

Witnesses gave differing accounts and differing interpretations of events that took place shortly before the team went on bypass. The controversy revolved around the administration of heparin. In order to conduct bypass, the patient's blood must be treated with heparin to prevent it from clotting. If blood is passed through the heart-lung machine without heparinization, it will begin to clot immediately, with potentially fatal results.

The heparin was measured in advance and kept in a sterile area in the operating room. Generally, a scrub nurse handed the heparin to Odim or his assistant, who would then inject it into a small part of the right atrium, known as the right atrial appendage. From there, the heparin would enter and mix with the blood in the rest of the heart.

About five minutes after the heparin was given, the perfusionists normally measured what was referred to as the activated clotting time (ACT), to ensure that the patient was fully heparinized. A blood sample was injected into what is called an ACT machine. The machine had a timer that measured how long the blood took to clot. Preparation for cannulation generally took place while the ACT was being measured.

According to Wong, in the KF case he noted that Odim was inserting the aortic cannula without having asked for the ACT. Concerned about this, Wong asked Odim if he had already injected in the heparin into the heart. According to Wong's testimony, Odim said that he had not done so and then proceeded to inject the heparin. After waiting until the ACT was measured, Odim finished inserting the cannula. Wong said that it was normal to administer the heparin before inserting the aortic cannula. He also said that while this incident was not as disturbing to him as were the KZ and JB cases, he was left feeling more uncomfortable.

In the notes that she was keeping on problematic incidents during this period, Youngson made the following entry regarding this operation:

Cannulae in and circuit divided and hooked up all before the HEPARIN given. Usually given by assistant through the R.A. APPENDAGE. Surgeon did not ask for the Activated Clotting Time before he cannulated, de-aired and hooked up the aortic cannula. (Exhibit 20, Document 278 D)

Youngson testified that, during cannulation, she noted that the ACT timer was not ticking. However, she said nothing right away. She was asked who drew it to Odim's attention that the heparin had not been administered.

I think the perfusionists picked it up. To be honest, I can't remember. I was standing there watching it and thinking, should I say something? I was thinking, well, I will just wait a little longer.

First of all, I couldn't believe that we hadn't done this because it's so routine, it's just one of the things that you sort of do as you go along. I thought maybe I missed it, maybe somehow, maybe I was writing in the chart or something and I just didn't see this. So I didn't want to say anything at that point in time until I was sure that this was actually what was going on. So I just sort of hung back for a minute or two and sort of watched.

But nothing was happening with this machine, it wasn't ticking off the seconds. So, finally, I don't remember who it was that said, hey, we haven't given the heparin. And everybody said whoa, stop. (Evidence, page 8,620)

While Odim did not connect the event with the KF case, he did recall this incident. He gave the following account.

I do remember an incident in which we had cannulated and the heparin was sort of lying on the nursing tray, and I had indicated to the perfusionist to go on pump, and the nurse mentioned that, oh, we had not given the heparin yet. And so we gave the heparin and then we went on pump.

Q: Had you gone on pump without giving the heparin, what are the potential consequences?

A: Hopefully, we wouldn't have done that, because the perfusionist's job, before he turns on the pump, is to be sure there is an ACT, and an ACT had not been measured. One of the checks and balances in the system is the perfusionist's responsibility is to be sure that the ACT is greater than 400 seconds before going on pump.

At any rate, if you were to go on pump without heparinizing, you run the risk of clotting the system, pump and cannulas. (Evidence, page 25,805)

Odim said that the standard procedure was for him to give the heparin in the right atrial appendage, except in repeat operations, when the anaesthetist would administer the heparin. He said that, in this case, one of the perfusionists apologized to him. For his part, Odim said, he thanked the nurse for bringing it to his attention and the operation went forward.

While it appeared that the incident with the heparin had no long-term impact on KF's health, it served to further erode relations among team members and confidence within the team.

NOVEMBER 10—THE CASE OF ID

ID was born on November 4, 1994, at the Victoria General Hospital. He was found to be cyanotic at birth and was transferred to the HSC on November 5, 1994. Cardiac catheterization showed transposition of the great arteries, a sizable patent ductus arteriosus with bi-directional shunting and a very small atrial septal defect.

The repair of transposition of the great arteries is a very complex, high-risk operation. At one point, consideration was given to having Dr. Roxanne MacKay come from Saskatoon to assist with the procedure. However, she was unable to do so, for personal and professional reasons.

On November 10, 1994, the day before Ashton Feakes died, ID underwent an arterial switch operation, repair of an atrial septal defect, and ligation and division of the patent ductus arteriosus. Closure of the sternum was delayed because of post-operative bleeding. Odim performed the operation and was assisted by Hamilton. Both McNeill and Reimer provided anaesthetic care. There was a bypass time of three hours and forty-three minutes, an aortic cross-clamp time of one hour and thirty minutes and a circulatory arrest time of ten minutes. Aside from an episode of bleeding at the end of the operation, the procedure went largely as anticipated.

McNeill testified that, during ID's operation, Hamilton played an effective role in helping to control bleeding sites. She said she felt that he had made a positive contribution to all of the operations in which he participated, particularly those of ML and ID.

It was beneficial. He was another cardiac surgeon who obviously had the expertise of a cardiac surgeon and could form independent judgments. And, you know, had skill in doing specific procedures, as compared to Dr. Hancock who was definitely in an assistant position, being, you know, sort of told—directed, if you will, by the surgeon. I think it is sort of reasonable or is understandable that it would be helpful to have two surgeons in the room who are both trained in the procedures.

Q: Okay. That specific expertise, are you able to say if he made any contribution to sort of the atmosphere in the operating room in terms of—I'm not sure we have had this evidence from you, can you comment on that?

A: Yes, I would say it was in some ways reassuring. And he, by his nature, is sort of a calm individual, so his response to difficulties is calm and measured, which is always helpful when there is difficulties. (Evidence, pages 13,483–13,484)

In his testimony, Reimer indicated that Hamilton played a very positive role in helping to distinguish between surgical and non-surgical bleeding and addressing them appropriately. Celine Weber, the circulating nurse for the procedure, commented that she thought that Hamilton was able to reduce the stress level that had been common in previous pediatric cardiac operations. She said it appeared at one point that he had actually taken over the case from Odim.

When ID's bleeding was controlled, he was taken to the NICU. On November 16, Hancock and Hamilton closed his chest. Hamilton was surprised to discover that the pediatric cardiac cases were spread between the NICU and the PICU. He told the nurses that he thought it was a foolish policy. He testified that Odim warned him not to say those things because they put people's noses out of joint.

Through his early period of recovery from surgery, ID was given drugs to completely relax his muscles. This medication was stopped and its effects allowed to wear off. On November 23, 13 days after surgery, a nurse noticed that ID was moving his arms, but not his legs. Dr. Oscar Casiro was called to examine ID, who was discovered to have damage to his spinal cord due to what is termed a hemorrhagic infarction. The blood supply to an area of the spinal cord had been diminished. In addition, a hemorrhage had occurred in that area. As a result, ID's lower body was paralyzed and he was paraplegic.

Casiro testified that there were a number of possible causes for the infarction. The area of the spinal cord where the damage occurred normally receives its blood supply from an artery that travels from the aorta. Casiro said that circulation to that area of the spinal cord could have been reduced during the operation, when the aorta was cross-clamped and sutured.

Another possibility involved the umbilical arterial line or catheter that was inserted in ID on November 5 and remained until November 7. The catheter was inserted into the umbilical artery and passed up into the aorta. A clot could have formed in the umbilical artery and then traveled to the smaller artery that supplied the spinal cord, producing the damage. At the time, spinal cord complications associated with umbilical artery catheters had been reported in the medical literature. Casiro testified that ID needed other lines that could have also generated clots of this nature.

The cause of ID's paralysis became controversial in the HSC, when a number of the doctors and a nurse involved in ID's care wrote a brief academic article on the complication. The paper was titled "Spinal Cord Infarct After Arterial Switch Associated with an Umbilical Artery Catheter" and was written by Robert P. Lemke MD, Nnanake Idiong MD, Saad Al-Saedi MD, Niels G. Giddins MD, Cameron Ward MD, Andrew Hamilton MD, Lois Hawkins MN, Betty J. Hancock MD, and Jonah N.K. Odum MD PhD. The article was published in the *Annals of Thoracic Surgery* in 1996, volume 62, pages 1532–1534.

The paper generated comment in the hospital because it appeared to conclude that the umbilical arterial catheter (UAC) caused the paraplegia. The final two paragraphs of the two-page article read:

On the other hand, the use of UACs has a known, albeit rare association with neonatal spinal cord ischemia. The proposed mechanism of cord ischemia appears related to thromboembolism of the segmental artery supplying the thoracolumbar spinal cord. Clinically silent thromboses have been demonstrated using aortography in 95% of infants with UACs. Furthermore, there are reports of infarction of other major organs such as the intestine and kidneys associated with the position of the UAC catheter tips in sick newborns. Despite widespread use of UACs, cord infarction is presumably rare because of variable collateral blood supply. Indeed, there is a great deal of variability in the patterns and degrees of cord infarction in experimental animals when selected vessels are ligated under tightly controlled conditions. We surmise that this cord was predisposed to a localized hemorrhagic infarction during the surgical repairs because of an unrecognized preoperative ischemic insult related to the use of umbilical vessel catheters [UVC]. We further speculate that the combination of an indwelling UAC and UVC in the inflow and outflow vascular territories subserving the midthoracic spinal cord may have compromised blood flow and increased the potential for thromboembolic occlusion of the blood supply to the anterior spinal artery. The diagnosis of cord infarction and paraplegia in this case was delayed because of a period of postoperative muscle relaxation due to an open chest.

With the widespread use of umbilical vessel catheters in newborns and the increasing trend toward earlier definitive repair of complex congenital heart defects in neonates, the use of peripheral arterial lines may prevent this rare but devastating complication of local spinal cord hemorrhagic infarction. (*Annals of Thoracic Surgery*, 1996;62,1532–4)

Casiro was consulted on the article, which was meant as a case report to be shared with other doctors. The intent was to include Casiro as one of the authors. While he had initially considered participating, he eventually withdrew his name from the article because he did not agree with the conclusions, which he found to be too speculative.

I had some difficulty with the conclusions in that I thought that the cause of the paralysis, in my view, as I expressed before, was not clear, and that I wasn't so convinced that the umbilical artery catheter in this case could be seen as the major cause, given the fact that the child had surgery on the heart and the aorta afterwards.

So I felt that the conclusions were a bit too skewed towards blaming the umbilical artery, and I would have favored a more balanced view in the speculation part of the article. (Evidence, page 37945)

Casiro said that if the cause had been the umbilical catheter, one would have expected to see some signs of the damage between November 7, when the catheter was removed, and November 10, the day when ID underwent surgery. Casiro noted that other experts also suggested that the catheter could decrease the blood supply but not sufficiently to cause paralysis. There could, however, have been a second event that might have triggered the paralysis. In his testimony, Casiro pointed out that ID was still moving his lower limbs after the line was taken out, on November 7, three days before the operation. The paralysis followed the operation and the insertion of the left atrial catheter. Casiro said he was not sure which event caused the problem.

Seshia also testified that she believed the proposition put forward in the article on ID was speculative:

We know [ID] had an umbilical catheter in place. We know that the catheter was above the diaphragm. We know that the catheter came out on day three, okay, of his life. We know that he had his surgery, I think on day five. So the catheter had been removed two days prior to the surgery, and during that period of time he was moving his lower limbs quite all right.

I think the hypothesis in the paper is that perhaps there was some thrombosis developing around the catheter which somehow impaired the blood supply to the artery supplying the spinal cord.

Q: Thrombosis, is that clotting?

A: Clot, yes, such that at the time of the surgery, then perhaps there was decreased blood flow going to the spinal cord; and had there been no thrombosis around the catheter, no thrombosis around the site where the catheter had been, then the blood supply to the spinal cord would have been okay. But what we don't know, or what I don't know is, was there a thrombosis? I have no idea if there was a thrombosis. (Evidence, pages 33,559–33,560)

In his testimony Odum explained the origin of the article.

Actually, during this period, [ID] actually was slowly sort of gaining back some recovery. However, the neonatology staff I guess have a M & M or a weekly conference where they present the goings on in the neonatology unit, and a couple of the fellows had done a literature search on this problem, and they approached me to sort of get my input, because they had discovered in the literature that this finding has been seen in neonates who have had umbilical artery catheters in place, particularly if these catheter tips were not placed below the level of L3 and L4.

So they came up with four or five papers in the literature describing paraplegia in cardiac surgical babies following UAC line placements. They thought that that was what might have happened in [ID's] case, and it really hadn't crossed my mind.

Initially, my thoughts were that perhaps the line placement in the groin, there may have been some bleeding which bled into the retro peritoneum around the spine and the problem was a mass effect. However, the scan suggested that wasn't the issue, it was within the cord and not outside of the cord, and I really could not explain it until the neonatology fellows had done this search. (Evidence, pages 25,798–25,799)

Odum testified that the neonatologists then looked at the X-rays done after ID's birth. They found that the catheter had been placed in the same area as in the papers they had reviewed.

So, once they went back and tried to review [ID's] background, and discovered that indeed the UAC catheter was not in an optimal position, they felt that this contributed to the findings. They basically wanted to discuss, from my perspective as a surgeon, whether I had ever seen paralysis in a neonate after open heart surgery, and issues of what happens when you cross-clamp the aorta, issues of what happens in neonatal coarctations, operations that we do all the time. And they were basically trying to find out, from the surgical perspective, what was in the surgical literature with regards neonatal paralysis after open heart.

Q: What was in the surgical literature?

A: Basically what they identified. When associated with this cath—there is certainly a report in Edmonton, in fact, from the surgical team there, in which a patient essentially thrombosed a small artery going to the spinal cord, and shortly after heparin, in an open heart procedure, the child had developed paraplegia. They had hypothesized the same rationale.

It was the presence of the catheter causing this thrombosis and infarction in the cord, which probably may not have amounted to much except that when someone gets heparinized, there is a tendency to bleed into these areas.

It's sort of like having a stroke in the brain and the decision, do you put that patient on a blood thinner? And many times if you put a patient that has had a stroke, you can convert it into a hemorrhagic region. And that's the sort of pathophysiology of this area in the spinal cord. (Evidence, pages 25,801–25,802)

The case of ID marked yet another milestone in the collapse of the Pediatric Cardiac Surgery Program. The operation had been conducted without significant incident, yet the final result was tragic. It is beyond the scope of this Inquest to comment on whether or not the hypothesis of the article that was written about ID's complication was too speculative. However, it should be noted that the article did not mention the fact that the catheter had been removed three days before surgery.

By this time, most of the anaesthetists and nurses were inclined to put the darkest interpretations on Odim's actions. The same cannot be said for Seshia and Casiro. Up to this point, they had not voiced any complaints about the Pediatric Cardiac Surgery Program. The case of ID was followed by three more difficult neonatal cases, two of which ended in death. By then, Casiro and Seshia had become very apprehensive of the program and its results.

THE NOVEMBER MEETING WITH MARIETESS TENA CAPILI'S FAMILY

Ben Capili attempted to organize a meeting with HSC representatives following Marietess's death but was initially told to wait until the autopsy report had been prepared. However, the meeting was held in November and by the time of that meeting the autopsy report was not available. The family did not receive the autopsy report until February 1995.

Teresida Tena (Marietess's grandmother) accompanied Ben Capili to this meeting. Sarah Tena declined to attend. Capili said Giddins told them that Marietess's heart was the most complex he had ever seen. Teresida testified that Giddins told them that Marietess had died from fluid in the lungs. She was disappointed that Odim was not at the meeting. Capili said he raised concerns about Odim's ability, to which Giddins responded that he had studied in Boston and Montreal.

THE CASE OF JESSE MAGUIRE

ISSUES

Jesse Maguire was born November 25, 1994, and was immediately diagnosed as suffering from an interrupted aortic arch, ventricular septal defect and an atrial septal defect. He underwent surgery on November 27, 1994, and died while on the operating table.

The issues to which this case gives rise are:

- Should the operation have been performed in Winnipeg or should Jesse have been referred out of province?
- Were Jesse's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should Dr. Andrew Hamilton have assisted in this operation?
- Was a cannula inadvertently dislodged during the operation?
- Were all the repairs intact?
- What was the cause of the poor perfusion following the initial repair?
- Were Jesse's parents fully informed about the circumstances surrounding his death?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Jesse Maguire was born at the HSC Women's Centre on Friday, November 25, 1994, at 0829 hours. The child of Laurie Maguire and Richard Shumila, Jesse was delivered at 38 weeks gestation by caesarean section.

On his admission to the nursery at 1100 hours, Jesse was slightly cyanosed and pale. The neonatal resident, Dr. Carr, examined him and found that his pulses and perfusion were good. His chest was clear, with good air entry. Jesse had a heart murmur and an irregular heart rhythm. The heartbeat would occasionally accelerate to a rate faster than two hundred beats per minute. Carr ordered diagnostic tests and consulted with Ward.

An echocardiogram showed Jesse had a number of heart defects:

- an interrupted aortic arch (In this condition, the aorta does not develop completely in the area of the arch. As a result, the aorta is divided into two parts that are not connected to each other, and there is no blood flow through the aorta.)
- a large ventricular septal defect with misalignment (The septum bulged into the outflow tract of the left ventricle.)
- a patent foramen ovale (During surgery, Odum identified this PFO as an atrial septal defect.)
- a bicuspid aortic valve
- an enlarged left atrium
- a restrictive patent ductus arteriosus (PDA).

It was the natural closing of this PDA that caused Jesse's initial problems. As a result, he was treated with prostaglandin to keep his PDA open. Ward concluded that Jesse needed surgery in the immediate future.

In his testimony, Ward said there were three different ways that a heart condition such as this could be approached. He noted that all three approaches were difficult and carried a significant degree of risk. The two approaches with which Ward was most familiar both involved entering the heart from the side and repairing the interruption in the aortic arch. One of these methods involved placing a band on the pulmonary artery to restrict the flow from the VSD, while the other involved simply repairing the arch and then, at a future date, repairing the VSD. Both of these methods required a second repair.

A third approach involved entering the heart from the front and repairing both the VSD and the aortic arch. The difference in this third approach was that to perform the repair from the front, it is necessary to put the patient on bypass.

In his testimony, Ward explained that it was difficult to make clear-cut statements about the comparative risk of these approaches.

If you do it from the side and you do it with an interposition graft, then it's relatively low risk surgery but you encounter other risks down the track that then increase your risk down the track, in your morbidity and mortality down the track. So you may not play all your cards up front but you're placing yourself at risk down the track.

Whereas to do it all in one procedure puts basically all your eggs in one basket and it puts all your risks up front. You can argue it in numerous ways and it is argued in numerous ways in the medical literature. (Evidence of Dr. Ward, pages 148–149)

Ward recommended that Jesse undergo a two-stage repair.

Jesse was transferred to the NICU at 2100 hours on November 25. While his chest was clear, his tongue and lips were becoming more pale and his fingers and toes were becoming cyanotic. During the night, his breathing became increasingly shallow, rapid and irregular. His breathing eventually stabilized; however, he had bouts of irritability.

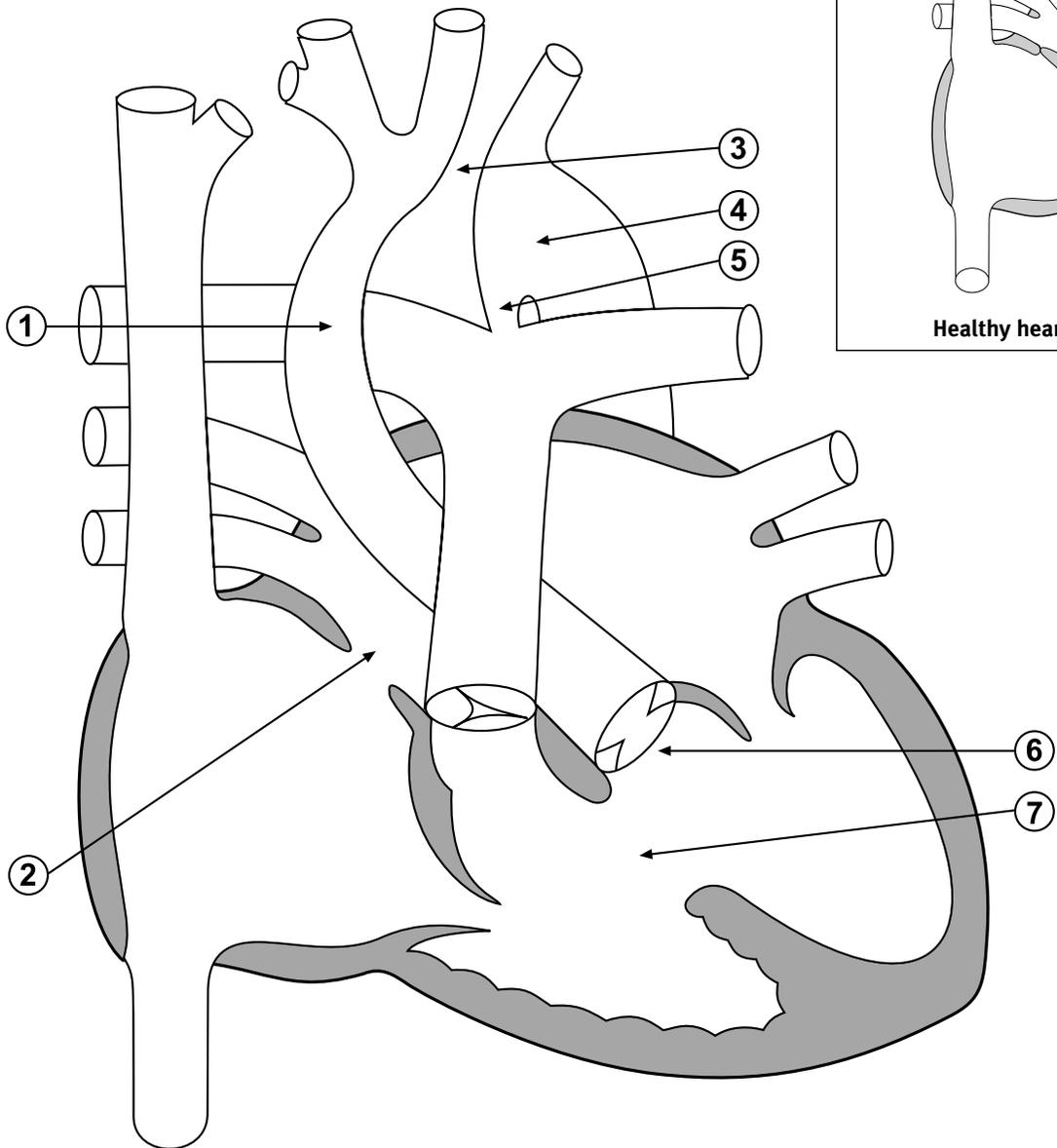
Casiro and Ward spoke with Jesse's parents that evening. Ward testified that in that conversation he did not suggest referring Jesse out of province. According to Laurie Maguire, Ward told her and Jesse's father that the success rate for these operations was approximately 85 per cent. She also testified that Ward explained the options and indicated that he believed Odum would probably opt for the one-stage approach.

THE DECISION TO OPERATE

On November 26, at 1600 hours, Odum assessed Jesse. At the time, he thought Jesse had a good blood pressure, good pulses and good urine output. While he concurred with Ward's diagnosis, he felt that a one-stage repair would be appropriate. He said he reached this conclusion because he felt that the overall risks in a two-stage repair were greater than the initial risks of a one-stage repair.

With the one stage there is a risk with the procedure, but successful procedure enables one to have the hook-up of the descending aorta with the proximal part using biological tissue that can grow with the child and obviate the necessity for additional procedures at that region. (Evidence, pages 25,816–25,817)

Diagram 8.7 Jesse Maguire – pre-operative heart



- 1 – Hypoplasia of ascending aorta
- 2 – Atrial septal defect
- 3 – Interrupted aortic arch
- 4 – Descending aorta

- 5 – Patent ductus arteriosus
- 6 – Bicuspid valve (identified at post-mortem)
- 7 – Ventricular septal defect

Odim then discussed his intention with Casiro and Ward. Casiro testified that he had reservations about this approach.

Well, I asked him why he was choosing that, and I asked him why wouldn't he go for a staged repair, because the first procedure will be low risk, or lower risk than doing both at the same time, and why wouldn't he wait for the child to grow up, be bigger, before attempting the second procedure? So we had a discussion about that.

But he was very adamant that doing it in two stages would involve two, perhaps three operations, timing and so on and so on, and the combined risk was higher than doing it all at once. And I guess my concern arose from the fact that that wasn't what I was used to with the previous surgeon, in general. (Evidence, pages 37,958–37,959)

According to Casiro, Ward expressed the same concerns that he did. Casiro said that Odim's reasoning seemed valid. Casiro said that while he knew of the slow-down in the PCS program, he assumed that because the program had come back to full speed, whatever problems had existed had been addressed.

Odim then spoke to Swartz, who was the anaesthetist on call, and arranged for the operation to be performed the following day, which was a Sunday.

CONSENT

Odim then consulted with Jesse's parents. He testified that he explained the need for surgery, and the nature and risk of the procedure. He said he explained that there were different approaches to the operation. However, he did not ask Laurie Maguire to select the one that she preferred.

What I did was essentially discuss the risks involved with either approach, and at the end of it, told her what I thought was best, and she accepted it. (Evidence, page 25,836)

In his testimony, Odim said that he had been involved as a first assistant in approximately six such cases over a three to four-year period before coming to Winnipeg. He testified that he did not tell Jesse's parents that this was the first time he had performed this operation as the "main or primary or attending surgeon." (Evidence, page 25,837)

I felt that the team was competent and could provide an acceptable level of care, ... and the issue of my being an attending for the first time when I came to Winnipeg did not cross my mind. (Evidence, pages 25,837–25,838)

According to his notes, Odim told the family that the mortality rate for this procedure was 10 to 15 per cent. He also testified that he told them the procedure would take between six to eight hours.

Odim was asked if he considered sending Jesse out of province.

No, that really didn't come to my mind. I knew that interrupted aortic arch lesions are quite rare, and even at the centres that have been in existence for many years, a man 20 years, or a surgeon 20 years out in practice may only come into contact with five cases, just based on the frequency of this type of lesion.

My practice and training was relatively contemporary, and I had seen and worked with a number of surgeons and seen this lesion. So, I was comfortable with the approach to the lesion and the various components of the operation. (Evidence, pages 25,823–25,824)

Laurie Maguire testified that Odum explained the nature of the lesions, the repair and the need for surgery. She said that they did not ask him about his experience with these lesions. Both Jesse's mother and father confirmed that Odum quoted them a 10–15 percent mortality rate for the operation. Richard Shumila testified that Odum indicated that he had not performed this repair before, but he explained that pediatric cardiac surgery was his area of expertise.

NOTIFYING THE OR NURSES

Youngson testified that she received a telephone call from a nurse named Cindy Davidson on the afternoon of November 26. She gave this description of the conversation:

It was kind of odd. Cindy called me and said, you know, we are doing an open heart, we need the cardiac team to come in. But she said, when Dr. Odum came to book it or phoned to book this case, I asked him if he wanted me to call you, and he said, no, that we would be able to manage.

I went, oh, really. Well, I am coming. You know, we will come. She said, well, she was kind of laughing about it, like this was the most ridiculous thing she had ever heard. Because these were two junior nurses. They have had no experience in cardiac surgery. This was like a neonate.

I am sure they didn't realize how difficult or high risk this particular baby was because they weren't experienced, but they realized that they needed a cardiac nurse. And, in fact, we called in another cardiac nurse as well. Helen Skomorowski came as well. There were two of us that went in for this particular case on a Sunday. (Evidence, pages 8,632–8,633)

Odum testified that he did not think that he ever gave the instructions referred to in Youngson's comment. He testified:

It's possible that I was asked if Ms. Youngson should be called, and I said, oh, no, that's not necessary. She's one of several cardiac nurses. So I don't think I—if I am understanding this, that I bluntly stated that I didn't want cardiac nurses present. (Evidence, pages 25,849–25,850)

In this testimony, however, Odum indicated that he did not give any special instructions to any members of the team with whom he would be working, in preparation for this operation.

These two pieces of testimony are open to numerous interpretations. The harshest is that Odum did not care if experienced cardiac nurses were present or not for a difficult operation. The most innocent is that Odum felt that, since other operating-room nurses could handle the case, it was not necessary to call Youngson in on her day off. It was, in all likelihood, an innocent, perhaps even a considerate remark. However, it is clear that the nurses did not view it in that fashion. That they did so is not a sign of poor judgment on their part as much as a clear indication of the near-complete lack of respect and trust between the members of the team. This was a legacy of the treatment that the nurses had been accorded from the beginning of February 1994 onwards. By the end of this operation, both the nurses and anaesthetists had even less inclination to give Odum the benefit of the doubt.

HAMILTON NOT CALLED IN

One of the people who should have been called to participate in this operation, but was not, was Hamilton. He testified that this procedure fit the category of operations in which he was expected to assist. He told this Inquest that when he heard about the operation and Jesse's death, he was extremely surprised that he had not been called to assist, although he said he did not speak with anyone about why he had not been asked to do so. In his testimony, Blanchard said he also was surprised that Hamilton had not been brought in to assist. Blanchard testified that he made inquiries after the operation and concluded that Hamilton would have been available to assist, if he had been contacted.

PRE-OPERATIVE STATUS

Swartz conducted a pre-operative assessment that evening. She observed that Jesse's extremities were cool, his heartbeat was irregular and his chest was clear. She assessed him as ASA IV and indicated that he was at risk for arrhythmias, heart block, coagulopathy, paralysis and other neurological injuries. The morning of surgery, Jesse's condition remained relatively unchanged.

There was no evidence presented to this Inquest to suggest that there were any errors in the diagnosis, the pre-operative care or the surgical plan. Several consulting witnesses indicated that the one-stage repair that Odum chose is increasingly common, for the reasons that Odum advanced.

THE OPERATION — NOVEMBER 27

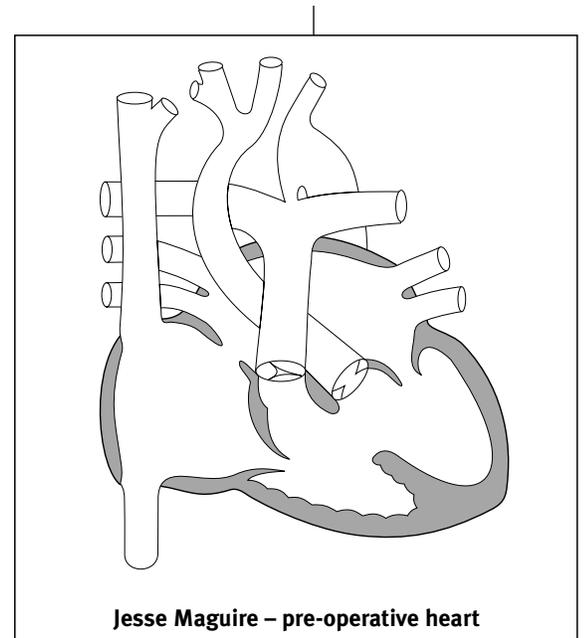
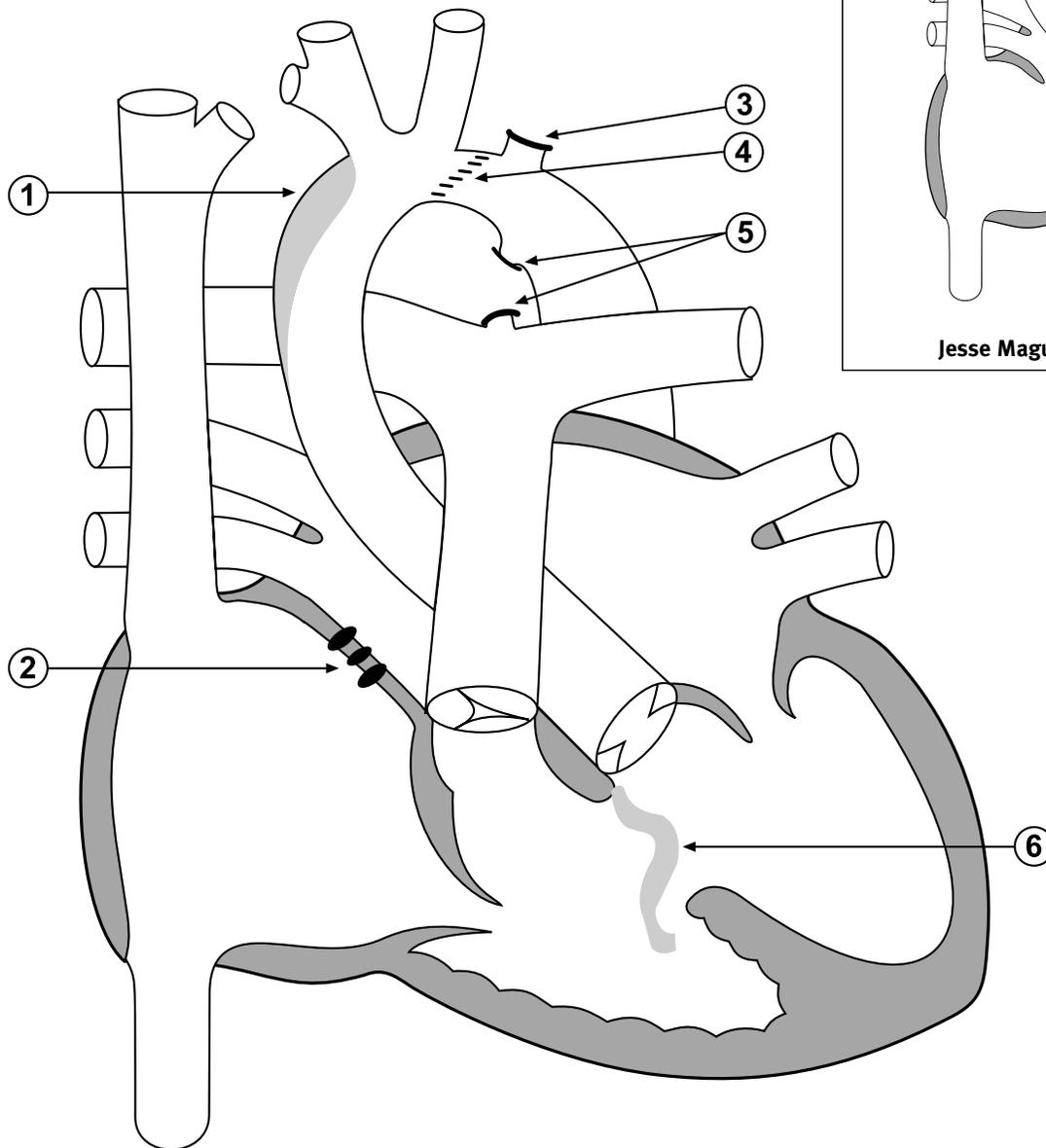
On Sunday morning, November 27, Jesse underwent emergency surgery for expansion of his ascending aorta, repair of his interrupted aortic arch, closure of a ventricular septal defect with a dacron patch, suture closure of an atrial septal defect and closure of a patent ductus arteriosus. Myocardial protection was to be provided by both bypass and profound or deep hypothermic cardiac arrest.

The operating team is set out in the accompanying chart.

TABLE 8.7: Persons involved in the operation on Jesse Maguire, November 27, 1994

<i>OR team member</i>	<i>Persons involved</i>
Surgeon	J. Odum
Surgical assistants	B.J. Hancock, D. Miltenburg (resident)
Anaesthetists	J. Swartz (relief provided by R. Graham and L. Patel), L. Stanko (resident)
Scrub nurse	C. Youngson, M.J. Wasney
Circulating nurses	H. Skomorowski, C. Davidson
Perfusionists	M. Maas, D. Smith

Diagram 8.8 Jesse Maguire – post-operative heart



- 1 – Patch expansion of ascending aorta
- 2 – Suture closure of atrial septal defect
- 3 – Ligated and divided left subclavian artery
- 4 – End-to-end repair of interrupted aortic arch

- 5 – Ligation and division of ductus arteriosus
- 6 – Buckled ventricular septal defect patch

TABLE 8.8: Length of phases of the operation on Jesse Maguire, November 27, 1994

<i>Phase of the operation</i>	<i>Time taken</i>
Induction	2 hours 29 minutes
Bypass	6 hours 12 minutes
Total circulatory arrest	2 hours 49 minutes
Total surgical time	11 hours 7 minutes
Total operating-room time	13 hours 59 minutes

To undertake the repair, the team inserted cannulas into Jesse’s blood vessels, using double-arterial cannulas (one in the ascending aorta Y-connected to one in the pulmonary trunk) and a single venous cannula (in the SVC). Intermittent cold blood cardioplegia and deep, hypothermic, total circulatory arrest were to be used for myocardial protection. At 1247 hours, the anaesthetist applied ice to Jesse’s head to protect his brain. Bypass was then started. Solumedrol was given intravenously at 1300 hours, conceivably to decrease swelling of the brain, or cerebral edema, and total circulatory arrest (TCA) was then instituted. At that point, the cannulas were removed to give the surgeon a relatively clear operative field. While cannulation is always a significant factor in any open-heart procedure, it is particularly significant in the repair of an interrupted aortic arch, since the aortic cannula is being inserted into the very vessel that is to be repaired.

Repairing the VSD while on TCA

After repairing the aortic arch and ligating the left subclavian artery to improve the mobility of the descending aorta, Odum went on to repair the VSD and ASD while Jesse was still on TCA. Swartz testified that she was surprised by the decision to repair the VSD on TCA, since she thought that the team would return to what is termed low-flow bypass for this repair. Low-flow bypass differs from regular bypass, in that there is a lower flow of blood through the patient and the low temperatures of circulatory arrest are maintained. Low-flow bypass does provide some perfusion of the body, in contrast with TCA when there is no blood flow.

Swartz testified that she spoke to Odum about this decision not to return to low-flow bypass for the VSD repair.

After Jesse had been on circulatory arrest for 45 minutes, I said to Dr. Odum—I can’t remember the exact words that I said, but I basically said, aren’t we going back on low flow? And he said no. And I said, well, we have been on, you know, deep hypothermia for 45 minutes. And he said to me, are you worried? And I said yes. And he said me too. And that was it. So, he didn’t go back on low flow and we continued on deep hypothermic circulatory arrest for the duration of the repair. (Evidence, pages 16,250–16,251)

Swartz was afraid that there was increasing danger of neurological damage as a result of the length of TCA. Youngson confirmed the exchange between Odum and Swartz. According to Youngson, Swartz asked Odum if he was repairing the VSD. He replied that he was and then asked if she were worried. She said yes, to which, Youngson testified, he said, “I am doing it’ or something like that. He made a kind of offhand kind of remark and kept on working.” (Evidence, page 8,637)

When the repair was finished, the cannulas were reinserted and Jesse was placed on bypass at 1532 hours. He had been on TCA for 102 minutes. It had taken Odium about 57 minutes to repair the VSD while the child was on TCA. Consulting witnesses who prepared reports for this Inquest indicated that this was a dangerously lengthy period of time for TCA. Cornel wrote that with a TCA of this length, “there would have been a probability of brain damage.” (Exhibit 353, page 65) In the report prepared by Duncan and Cornel, it was noted that it would have been preferable to repair the VSD on low-flow bypass. Hudson wrote that the 102-minute period was exceedingly long and would have been likely “to cause significant morbidity and/or mortality in a neonate.” (Exhibit 307, page 11.3) Soder testified that the time of the initial bypass “would probably have produced a bad outcome.” (Evidence, page 44,203) Soder, too, thought it would have been appropriate to repair the VSD on low-flow bypass.

Odium was asked why he chose to repair the VSD on TCA. He responded:

Because I felt that it would be easier to do. The field was bloodless, we did not have the cannulas in the way in this small baby, and I thought it would be easier to get the VSD accomplished under circulatory arrest.

Q: What do you mean by easier?

A: Easier in the sense that, from the technical point of view, in a very, very small baby, the advantage of circulatory arrest is that you don't have the cannulas in your way, and you don't have venous return coming back to the heart, so the field is bloodless. (Evidence, page 25,868)

Odium testified that it took between 50 and 90 minutes for him to complete the repairs on TCA. He was asked if it would have been possible to repair the VSD and the ASD on bypass. In regard to the VSD, he said:

Yes, I think that might have been an option. I don't know how easy it would have been to do it on bypass, in terms of the technical aspect of it in a very small baby, the issues of the cannula clutter and the venous return and the visualization and the exposure. So there is a trade off. (Evidence, page 25,873)

He noted that while the ASD could have been closed on bypass, closing the ASD only added two or three minutes to the total time on TCA. Odium was asked whether or not he recalled Swartz's questioning of his decision to undertake the VSD repair during TCA.

Yes, Dr. Swartz the anaesthetist as well as the perfusionist did point out to me the circulatory arrest time, and there was a comment to the fact that, isn't this kind of long and you are doing the VSD, and my reply was, yes, it is long, and we do have a VSD to do. And that was the extent of the conversation. (Evidence, page 25,885)

When asked why he continued with the VSD repair under TCA, given the worries over time, he said:

Because it was my preference for exposure reasons and my experience to get this done under one circulatory arrest period. I do know that some of these periods will exceed 60 minutes, 70 minutes or even 80 minutes, but I was trying to weigh the potential difficulty of doing it under low flow with the blood return and exposure issues, and at 40 minutes felt that the exposure was better and that it would be easier to tackle the VSD without the interference of the cannulas and the return. (Evidence, page 25,886)

In his testimony Odium said that it had always been his intention to perform the major repairs while Jesse was under TCA. In a pre-operative note in the chart, however, Odium had indicated that he in fact intended to use deep hypothermic circulatory arrest with low-flow bypass. He maintained, in fact, that once the major

repairs were completed, he went on low-flow bypass for the completion of the operation. The team went back on bypass at 1532 hours.

The dislodging of the cannula

Youngson testified that at approximately 1630 hours, while Jesse was being rewarmed, she heard a member of the operating team gasp. She turned to see that the aortic cannula had been dislodged. With the removal of this cannula, Jesse was no longer receiving blood from the bypass machine. Michael Maas, the perfusionist, turned off the bypass machine to stop it from draining blood from the child. According to Youngson:

At that point in time, there is this concerted effort by the two surgeons to get this cannula back in. They were having a very, very difficult time getting this cannula in. They were just taking it and trying to shove it back into the aorta, any way just to get it back in and get back on pump. To me that was their objective, to just get this cannula in, and let's get this baby back on bypass. Neither one of—

Q. Just taking it and trying to shove it back in?

A. Neither one of them could seem to do this. I know that Odim tried a couple times, couldn't do it. B.J. took it away from him and said, let me try. And she tried a couple of times, she couldn't get it in. Sort of back and forth like this. They were rough. (Evidence, page 8,641)

At the same time, Youngson testified, she was suctioning blood from the operative field in an effort to assist the surgeons to recannulate Jesse's aorta. By Youngson's estimate, it took approximately five minutes to re-insert the cannula.

In notes that she made right after the operation, Youngson wrote:

During the rewarming process the Aortic cannula was dislodged and fell out. Both the surgeon and the assistant (DR. Hancock) struggled for 6 or 7 minutes to replace the cannula. They were very disorganized and panicky. They argued with each other and grabbed the cannula and instruments from on [sic] another and it was very obvious that NEITHER ONE HAD THE SKILL OR EXPERTISE TO HANDLE THIS SITUATION. [Capitalization in the original.] Dr. Odim was extremely rough, "jamming" the cannula in again and again. Prior, to this event there had been some problems with the purse string sutures breaking. Instead of replacing them the surgeon asked the scrub nurse to shorten the rubbers on them so that they were now approx. 2.5 to 3 cm. long and much too short to work with. It was noted that the surgical field was extremely messy and unorganized throughout the case.

During the time that the surgeon was trying to reinsert the cannula these purse strings hampered their efforts because they were so short. As well there was almost no communication from the surgeon to the perfusionist and he (Mike Maas) had to resort to asking the scrub nurse what was taking place. It fell on the scrub nurse to inform the perfusionist to de-air the cannula again and again during this event, and to keep him informed as to what was happening. (Exhibit 20, Document 278 D)

Swartz corroborated this account. She testified that the surgeons were scrambling to control the bleeding and to re-insert the cannula.

Well, one person would try, then the other person was trying, then the other person would try. It was a very disorganized surgical field. And there was bleeding, they were suctioning, and it was—they were trying to push it back in. (Evidence, page 16,275)

During this period (which she estimated lasted five to seven minutes) Swartz was transfusing blood to Jesse through an intravenous line.

In his testimony, Maas said that the cannula became dislocated at 1630 hours. He testified that while he did not know how it became dislodged, there could have been no reason for it being removed at that point in the operation. He said Odum stated that the cannula was out.

So, obviously, for me that is a major event, and we have to shut the pump and all the systems down, without exsanguinating the patient.

Because if I continue to leave the venous line open, and I have no in-flow, I will drain the patient totally of blood in seconds. (Evidence, pages 7,051–7,052)

The anaesthetic record indicates that the total time from the cannula coming out and its re-insertion was six to eight minutes. Swartz testified that she did not record the times as the events were occurring, but made the entry after the end of the operation by checking the computer readings from the anaesthetic machine and determining that the cannula had been dislodged at 1630 hours.

The perfusion record indicated that the cannula was out for approximately one minute. Maas testified that the entry in the perfusion record was not made while attempts were being made to re-insert the cannula, but after the problem had been resolved. Neither he nor the other perfusionist, Dave Smith, had recorded the time, and the figure of one minute was an estimate that Smith had entered into the record. This estimate was based on Maas's guess that the cannula was out for one to two minutes. Maas said that, after reviewing the anaesthetic records, he was satisfied that the cannula was more likely out for five to six minutes. The time on the anaesthetic record is likely more accurate, given that it was determined retrospectively from computer-generated records.

Maas also testified that it appeared that Odum and Hancock experienced difficulties reinserting the cannula:

You could tell they were struggling at the table, as far as we could tell, to get this thing back in. They are dealing with very, very small areas, first of all, very small exposures, very small vessels. And already it has a major repair on the vessel, the suture lines.

It has had two cannulas sites in the aorta, when they initially cooled the patient and the going back on again. I can imagine that would be very difficult to get that back in. (Evidence, page 7,055)

Maas said that this was the first time in 18 years that he had witnessed such an event. He further testified that, after the operation, he had asked Odum what had happened.

And he had no explanation for how it became dislodged. And we asked him, I asked him what happened next. And he explained there was a rent in the aorta, and he had to repair that, and it made his initial repair inadequate, I guess, and that's why we had to go back and do a second circ arrest to repair that. (Evidence, pages 7,072–7,073)

(Odum's subsequent testimony suggests that in his response to Maas's question he was referring to a later event in the operation.)

The testimony of Irene Hinam and Dave Smith corroborated the account of Maas, Youngson and Swartz.

In their testimony, Odum and Hancock surprisingly said that they could not recall the cannula being inadvertently removed. Nor could they recall the events described by Swartz, Youngson, Hinam, Smith and Maas. Odum was asked if he could help explain the difference in the evidence that he and Hancock gave, compared with the evidence from the nurses, perfusionists and anaesthetist.

I really can't explain it, I've looked at these records and the problem I have is I'm trying to match up my recollection of the events with two different records and I'm getting confused as I try to do that. (Evidence, page 25,991)

From the weight of the evidence that has been presented, including both the testimony and the records kept by the anaesthetists and the perfusionists, it would appear that this event did, in fact, happen. At 1630 hours, the aortic cannula somehow became dislodged. From this time on, a series of problems occurred that eventually led to Jesse's death in the operating room.

Once the cannula was reinserted, shortly after 1630 hours, Jesse remained on bypass until taken off at 1802. However, the team was not able to get proper blood pressure readings from the lower part of Jesse's body. This problem suggested that there was a lack of blood flow to Jesse's lower body. A number of steps were taken to determine the reason for this poor blood flow. It was suspected that the aortic cannula itself was creating the blockage. In a post-operative letter to Jesse's doctor, Odum wrote, "There was a problem with obstruction from the arterial cannula which is not unusual for babies this size with a 5 mm aorta." (Exhibit 8, page MAG 21) This obstruction from the cannula meant that it was necessary to remove the cannula. However, when it was removed at approximately 1810 hours, there was no improvement in lower body blood pressure.

In his operative report and in his testimony, Odum stated that he believed the purse-string tourniquets probably caused the continued obstruction. These were tourniquets that he placed in the aorta when he removed the cannula (to close the hole through which the cannula had been inserted).

It was agreed at the time that the only option was to return to bypass and attempt to find the obstruction to blood flow and repair the cannulation site. To go back on bypass, it was necessary to reinsert the cannula. Odum once more experienced difficulties with cannulation. In his evidence, he said:

[W]e struggled to get the cannula back in. There is no question I felt at that time took an eternity. We simply could not get the aortic 8 French catheter back in and seat right. Multiple times it went in and came out we could just not get it to sit straight in the lumen, and ultimately after several minutes I had to go with a larger cannula to get it back in the aorta and go back on pump, and in the course of doing that, we disrupted the anterior suture line of our repair and had to repair that site and, unfortunately, that certainly played a role in Jesse's demise. (Evidence, page 25,992)

According to Odum's testimony, the cannula was finally re-inserted at 1832.

According to Swartz, at this point Odum said he had torn the original repair of the aortic arch. The team went back on bypass at 1834 hours. According to Odum:

Once we got back on bypass, it became quite clear that with the larger cannula in and the friable tissue around it, that we essentially had encroached our anterior suture line.

Q: Sorry, go ahead and finish it.

A: And that we had an area of our anterior suture line that needed to be repaired. And the question was, can we repair this without having to use circulatory arrest? (Evidence, page 26,057)

Odum made the decision to go back on TCA to repair the tear in the anterior (or front) of the original repair to the aorta with pericardium. While this carried considerable risk for Jesse, it was felt that there was no other option available to the team. TCA was re-instituted at 2015 hours.

During the second period of TCA, Swartz was relieved by another anaesthetist and left the OR. While she was out of the OR, Swartz spoke with Ward and informed him of the first unplanned dislodging of the aortic cannula at 1630 hours. She testified that after she returned to the OR, Ward subsequently entered and spoke with Odim. While she could not recall the specifics of what Odim told Ward, she did recall that Odim did not mention the dislodging of the aortic cannula. In his testimony, Ward said that while he could not recall the specifics of what he was told by Swartz and Odim, he had had trouble at the time reconciling what he had been told.

The repair was redone while Jesse was on TCA for an additional 67 minutes. He was placed on bypass once more at 2122 hours. His body was then rewarmed and efforts were made to start his heart beating once more. These efforts included defibrillation, pacing and treatment with a variety of drugs, including adrenalin. However, his heart never started beating on its own. Odim, Ward, Swartz and Casiro concluded that it was not possible to resuscitate Jesse. He died in the OR at 2239 hours.

Swartz testified that, following Jesse's death, Odim said to her that he should have been more meticulous in his cannulation. Odim said that he recalled speaking with someone after the operation and stating that the cannulation had been the Achilles heel of the operation.

Youngson also testified that after Jesse had died, Odim spoke to Ward about informing the parents.

Dr. Odim looked over at him, and he said, I guess you will have to go up and tell the parents that Jesse has died. He said I think it is best that we just say that we couldn't wean Jesse off of bypass, and best not to mention that, you know, we had had this problem with the cannula. (Evidence, page 8,662)

Swartz confirmed this conversation. In her testimony, she said that "Dr. Odim suggested that it would—they should say that they had trouble weaning from bypass." (Evidence, page 16,330) She testified that she was surprised by this comment:

The reason I was is because when a child dies, it is a very stressful situation for everybody, including the family. And so the question is, when do you—how do you approach telling the sort of the sequence of events or the true events that have taken place. And you don't want to hurt them. Because you are not sure how to do this, probably the best thing to do is just say it. But I was, I thought, how do they know what to say to the family? How can they actually say this to the family and when will the family actually find out what happened, and will the family ever find out what happened? And those were the thoughts that were in mind at the time. (Evidence, page 16,331)

Youngson was similarly upset by the conversation.

I was shocked. I mean, Jesse Maguire was my worst nightmare come true. This was what I had been afraid of all along, that something like this was going to happen, and here it had happened.

And whatever, what little respect I had for this surgeon at that point, it was dropping by the month or by the week. That was it, I lost all respect for him, because I felt you screwed up here, and you don't even have the courage to go out and admit it to these parents. You don't have to go out and say I screwed up, but you can at least be honest with the parents and tell them about the problem. (Evidence, page 8,665)

In his testimony, Ward testified that he had asked Odim what he thought the parents should be told.

And he said, Well, why don't you just tell them that—basically they'd been kind of pre-warned that things weren't going well. So I think he suggested, from memory, that we just inform them of basically the fact that Jesse hadn't come off pump.

Q. Um-hmm.

A. And then he would deal with the other stuff or we would deal with the other issues later, the technical issues and why there were problems coming off pump and exactly what the problem was. (Evidence of Dr. Ward, pages 105–106)

Ward said it was standard not to go into the technical issues at that point. Martin Corne, the lawyer representing Jesse's parents, suggested to Ward that Odim specifically told Ward not to tell the parents about the cannula. Ward testified:

I can't remember that specifically, but I think I've said on more than one and probably more than three occasions already that it's customary for us to go out and tell the parents that the child has died and that's usually enough for the parents to cope with at once. To talk about the technical issues at that first instance is usually not useful and it goes right over their head.

Q. Whether it's useful or not, Sir, did Dr. Odim tell you not to tell the parents about the cannula—the problem with the cannula?

A. I can't recall that specifically. What I'm trying to indicate to you is what we usually say is, Okay, I'm going out there. What do you want me to say to the parents? Now, specifically what was said, I can't honestly recall. But that wouldn't surprise me because it's not something that you usually address in the first instance. (Evidence of Dr. Ward, pages 187–188)

Odin testified that he could not recall this conversation. He testified that he did speak with Jesse's parents that evening.

I don't remember the specific wording, but the gist of the conversation was that we had done the operation, things were looking good, the heart was beating strongly, and there seemed to be a problem at the cannulation site, and I took the cannula out and we had to repair that area which required going back on bypass.

After we had done that, essentially the heart was not strong enough to sustain things, and that was sort of the gist of what I told Mrs. Maguire. She was obviously distraught, and I welcomed her to, at any other time, if she wanted to talk some more about things, but that's the gist of what I told Ms. Maguire when I got out of the operating room and met her. (Evidence, page 26,092)

Richard Shumila and Laurie Maguire had spent most of the day of surgery at the HSC. At approximately 1930 hours, Laurie Maguire went to the Women's Pavilion for medication. While she was away, Ward came to speak with the family. According to Richard Shumila, Ward said that there were problems weaning Jesse from bypass. Ward then went to the Women's Pavilion and informed Laurie Maguire. This was the first indication that Jesse's parents had received that Jesse's operation was not going well.

Laurie Maguire said that between 2300 and 2330 hours, Odin, Ward and Casiro came out with the news that it had not been possible to wean Jesse from bypass. She testified that "Dr. Odin was fairly cool, but Dr. Ward was crying. And, well, they—I mean it was obviously traumatic for them as well." (Evidence, page 4,155) She testified that no one spoke to her about cannulation at that time. She also testified that Ward said it would be appropriate to arrange a meeting in approximately six weeks time to discuss the issues surrounding Jesse's death. However, she said that she chose not to follow up on that offer at that time.

POST-MORTEM FINDINGS

An autopsy ordered by the Chief Medical Examiner was conducted by Phillips on November 30, 1994, with Odum and Ward attending the examination of the heart. Phillips had noted that, according to information related to her by Swartz, there had been a dislocation of a cannula at one point in the operation before the child was weaned from bypass. This was the event that the witnesses said occurred at 1630 hours. When Odum heard what Phillips had been told, he told her that her information was not accurate.

The autopsy indicated that the repairs undertaken by Odum were intact. However, the heart had suffered severe ischemic damage that had led to death. The report detailed extensive myocardial ischemia and contraction band necrosis.

Phillips also noted that the septal leaflet of the tricuspid valve had been tethered to the pledget closing the VSD. Because Jesse's heart never started beating after surgery, it is not possible to determine the impact that this would have had on the functioning of his heart. (The tethering is not depicted in Diagram 8.8)

The autopsy also left a question as to whether or not the initial blockage of the aorta was ever completely addressed. In the course of the autopsy, Phillips was unable to push a probe through the aorta past the site of the anastomosis. However, when she opened the aorta, she could find no obstruction.

Ward testified that, while it appeared that the VSD had been closed appropriately, he had concerns about the repair to the aorta.

And the arch repair by then—the probe that was put through didn't pass through easily and as it passed through the transverse arch or the—I can't remember – I think—or the repair site anyway, it didn't pass easily, and I wasn't totally convinced at that stage that everything was open. The trouble is that the specimen in that circumstance has not got blood flowing through it so it's not stretched; it's, if you like, collapsed down.

Q. Um-hmm.

A. So the tissues and artificial tissue and patches will fold without the pressure of the blood within it.

Q. Um-hmm.

A. So you can—your probe can get caught up on folds, if you like, of artificial tissue and/or real tissue and not slide through. But generally, if you work your way through, you can get it through. But we weren't able to, from memory, get it through just passing it through, but when it was opened right up, it looked patent. So it may have been just—

Q. Um-hmm. What does that mean?

A. Well, it may have been just snagging up on tissue planes and it certainly looked as though it was probably potentially open. (Evidence of Dr. Ward, page 99)

Taylor was asked if he felt the second repair was properly done. He answered that “the second repair looked to be about as good as one might expect, because the opening is the same as the ascending aorta, the vessel that is supplying that, sort of leading into the anastomosis.” (Evidence, page 43,298) He was then asked about Phillips' inability to pass a probe through the aorta.

Well, a 3 millimetre probe would be about the right size for the circumference that was measured. We measured circumference of 1 centimetre. So if everything was flat and there were no obstructions, then I would have expected a 3 millimetre probe to go across the anastomosis.

Having a probe get caught up like that, in my experience, usually is a result of a fold or a flap, that when you push the probe into something it gets caught up in it. So that suggests to me that maybe there was some flaps or folds as a result of the anastomosis repair. (Evidence, pages 43,300–43,301)

He said that Phillips's observation that there was a fold in the pericardial patch was one potential explanation. However, he said, it was also possible that the probe had become caught in a buckling of the inner lining of the aortic anastomosis.

Taylor also raised issues about the VSD patch. In his report Taylor wrote:

[T]he VSD patch was buckled to convexly project into the left ventricular outflow tract. These are anatomical substrates for proximal obstruction that may have contributed to the child's cardiac failure. (Exhibit 336, page 11.1)

In her testimony, Phillips said that at the time she examined the heart, it appeared to her that the VSD patch was intact. In his testimony, Taylor testified that he could not state whether or not the buckling was an operative problem.

FINDINGS

As noted at the outset, this case gave rise to the following questions:

- Should the operation have been performed in Winnipeg or should Jesse have been referred out of province?
- Were Jesse's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should Dr. Andrew Hamilton have assisted in this operation?
- Was a cannula inadvertently dislodged at 1630 hours?
- Were all the repairs intact?
- What was the cause of the poor perfusion following the initial repair?
- Were Jesse's parents fully informed about the circumstances surrounding his death?
- What was the cause of death and was it preventable?

Should the operation have been performed in Winnipeg or should Jesse have been referred out of province?

■ Finding

The evidence tends to suggest that the team in Winnipeg should not have performed Jesse's surgery. To once more make use of Soder's assessment, the evidence suggests that:

the skill and dexterity of the surgeon performing these operations were insufficient for the challenge of successfully repairing infant hearts with complex malformations. (Boldface in original) (Exhibit 345, page 8)

This operation required considerable skill. Cornel called it a high-risk procedure, with a fatality rate of 15 per cent. In this case, Cornel concluded that "Technical errors were made in the

course of this operation which precluded a successful outcome.” (Exhibit 353, page 67) Specifically, he was referring to the problems with cannulation. In addition, Cornel stated that this condition is so rare that it takes a surgeon many years to gain experience in the appropriate care of such patients. In their joint report, Duncan and Cornel wrote:

Other technical issues relate to our questioning a relatively inexperienced team’s capabilities to do technically difficult surgery on a neonate with a small aorta. Was the option of a remote referral provided? (Exhibit 354, page 14)

One can point to the following areas as evidence of the problems with the operation as performed in Winnipeg.

- ***The length of the first period of TCA.*** Consulting witnesses who appeared before this Inquest indicated that a TCA of over one hour was almost certain to lead to severe damage to Jesse Maguire, even if the rest of the operation had gone smoothly.
- ***The decision to repair the VSD on TCA.*** Given the length of time it took to repair the aortic arch, the evidence suggests that Odim should have conducted this repair on low-flow bypass. By failing to do so, he contributed to the overly long period of TCA.

In his testimony on this point, Cornel stated that he would repair a VSD on TCA only if he could keep the entire period of time on TCA under 45 minutes. In Jesse’s case, the total initial period of TCA was 102 minutes. When Odim decided to proceed with the VSD repair, Jesse had apparently already been on TCA for over 40 minutes. Cornel acknowledged that it is easier for the surgeon to perform this portion of the repair under TCA, but it is also apparent that there is no benefit to the patient when the TCA is as long as it was in this case.

- ***The difficulties in recannulating Jesse’s aorta at 1630 hours.*** Recannulation, in all likelihood, initiated a series of events that led to the need to put Jesse on bypass and TCA for a second time, with fatal results.
- ***The lengthy period of time that preceded the decision to separate from bypass and remove the cannulas.*** Hudson’s report on this point is telling. He writes:

The attempts to separate from the first session of CPB lasted from approximately 1615 to 1800. If the team had diagnosed and treated the problems encountered during this time more expeditiously, the total time on CPB would have been shortened, which might have favourably influenced the outcome. (Exhibit 307, page 11.6)

In his testimony, Hudson was even more explicit, stating that during the 105 minute period the team determined that it could be the cannula that was causing the obstruction. That being the case, they decided to go off bypass and remove the cannula. After pointing out that in the chart Odim had observed that this was a known problem, Hudson testified, “my point there was that if this is a known problem, that it shouldn’t have taken an hour and three quarters to develop a plan of management to attack it.” (Evidence, pages 40,042–40,043)

- ***The difficulties surrounding the removal of the cannula at 1810 hours.*** Odim indicated that he believed that the sutures he put in place after removing the cannula at 1810 hours might have continued the obstruction that he thought had originally been caused by the cannula. This required him to re-insert the cannula.

- *The difficulties in recannulating Jesse's aorta at 1842 hours.* During recannulation, the initial repair was torn.
- *The length of the second repair.* Witnesses testified that the length of the second period of TCA placed Jesse at considerable risk.

Were Jesse's parents provided with sufficient information to allow them to give informed consent to the procedure?

■ Finding

Jesse's parents were apparently aware of Odim's relative lack of experience in performing this type of surgery in an unsupervised setting. Richard Shumila recalled Odim telling them that he had not done this type of procedure before, but that cardiac surgery was his specialty. The difficulty was, of course, that like most parents (and patients), it is difficult to know how to evaluate this information.

However, the parents were not told of the program's recent problems; nor were they offered the option of transferring their son out of province for surgery. In their testimony, Cornel and Duncan stated that it might well have been possible for Jesse to have been transferred safely. This should have been discussed with his parents. This evidence tends to suggest that Jesse's parents were not provided with sufficient information to allow them to give informed consent to the procedure.

Should Dr. Andrew Hamilton have assisted in this operation?

■ Finding

This was a high-risk operation that fit the criteria under which Hamilton was expected to assist Odim. Both Hamilton and Blanchard testified to this fact. Unfortunately, as noted earlier, the evidence is not clear as to whether this instruction had been properly communicated to Odim or to the rest of the PCS team.

Was a cannula inadvertently dislodged at 1630 hours?

■ Finding

While Odim and Hancock could not recall this event, the testimony of the anaesthetist, perfusionists and nurses, coupled with the anaesthetic and perfusion records, all suggest that this event took place.

Were all the repairs intact?

■ Finding

Phillips and Soder, in their reports, concluded that all of the repairs were intact. It is not possible to argue with that finding. However, that simply means that the repairs had not failed.

Unfortunately, the repairs were never tested, as Jesse died without his heart having started to beat on its own.

What was the cause of the poor perfusion following the initial repair?

■ Finding

It is not possible to provide a definitive answer to this question. In his report, Cornel wrote that:

The difficulty with the aortic cannulation site may have been the result of poor positioning of the cannula, an unsuitable cannula or overly generous purse string sutures. (Exhibit 353, page 66)

In his testimony, Taylor said:

If the cannula or catheter is placed in a vessel that it may be too big for, it can strip the inner lining of that vessel and they form flaps as they are stripped back by the cannula or catheter. (Evidence, page 43,292)

Taylor said that the risk of this occurring increases if the cannula is inserted in a hasty manner, or if the cannula is too large.

The evidence from the autopsy also suggests that even after the initial repair, the aorta may have been partially blocked. The evidence suggests that, even if the aortic arch had been successfully repaired before Jesse died, it may not have been functioning properly before Jesse was put on bypass for the second time after 1830 hours.

All of the possible explanations for the subsequent problems with blood flow and pressure relate to surgical actions.

Were Jesse's parents fully informed about the circumstances surrounding his death?

■ Finding

There are two issues that require comment about the information made available to Jesse's parents. The first is "what was told to them on the night of Jesse's death?" The second is "what was told to Jesse's doctor, Dr. S. Collison?"

As noted earlier, both Swartz and Youngson testified that they heard Odim tell Ward not to tell the parents about the problems with cannulation that occurred during the procedure. Swartz and Youngson interpreted this statement as an attempt to cover up the events that had taken place during the operation. Given their experiences, both in the previous year and on the day of the operation, it is not surprising that they put such a negative interpretation on Odim's comments. Neither Odim nor Ward were able to recall the instruction not to mention the problems with cannulation.

It should also be noted that Swartz and Odim gave Ward differing accounts of what had transpired during the operation. This placed Ward in a difficult position. It would not have been possible for him to determine accurately which account was correct at that time; nor would it

have been appropriate to provide the parents with the account of either Odim or Swartz alone. It also would have been inappropriate for Ward to have advised the parents at that time of the conflict in the views of the surgeon and the anaesthetist. The best that Ward could do was to advise the parents that Jesse could not be weaned from bypass, and that more information would be shared with them when they were ready. This is what he did.

The evidence would suggest, therefore, that Ward's actions were appropriate to the moment. Similarly, if Odim's advice was simply that, on that evening, the parents should not be given detailed information about the events surrounding Jesse's death, then it was an appropriate instruction. However, the instruction was appropriate only as long as it was accompanied by an intention to be forthright with Jesse's parents when the opportunity presented itself.

Jesse's parents did deserve to receive a full accounting of the events surrounding Jesse's death. The evidence suggests, however, that they did not receive such an accounting.

In his November 28 letter to Collison, Odim neglected to mention the inadvertent decannulation that took place at 1630 hours. While Odim has testified that this event did not take place, the evidence suggests clearly that it did. It is difficult in fact, to determine why Odim continued to maintain, even while testifying, that the event did not occur, despite the overwhelming evidence to the contrary.

In his letter to Collison, Odim also stated, "despite what was a relatively smooth repair issues with cannula site obstruction necessitating repair and revision prolonging the circulatory arrest and total pump time clearly had a bearing on this child's outcome." (Exhibit 8, page MAG 22) The evidence—particularly the length of the initial TCA and the inadvertent decannulation—indicates that this was not a smooth repair.

The evidence also suggests that Odim did not give the referring doctor a full and accurate account of what occurred in the OR before the death of Jesse Maguire.

What was the cause of death and was it preventable?

■ Finding

Taylor, in his report, concluded as follows:

The proximate cause of the death of this child was myocardial injury resulting from excessively long circulatory arrest and cardiopulmonary bypass times. A major factor leading to the prolonged times was thoracic aortic obstruction complicating the initial repair of the interrupted aortic arch. This was thought clinically due to an aortic cannula that was felt to be relatively large for the abnormally small vessel, then subsequently to a stenosing aortic suture line. Attempts to correct this obstruction led to disruption of the anastomotic site requiring further circulatory arrest and cardiopulmonary bypass. (Exhibit 336, page 11.1)

Based on all of the evidence, the conclusion drawn by Taylor seems to be the correct one. The evidence suggests Jesse died because his heart had undergone an excessively long surgical procedure, from which it could not recover. The length of the operation was increased, it would appear, by the surgeon's inexperience, a dislodged cannula and an anastomotic tear caused by attempts to reinsert the cannula. Therefore, the evidence suggests that this was a preventable death.

The length of time that Jesse underwent total cardiac arrest also probably meant that, even if he had survived the operation, he would have suffered severe brain damage.

The tragic events of this case not only heightened the tensions in the OR, but soon became the subject of some discussion with the heads of the various departments.

MEETING OF THE DEPARTMENT HEADS — NOVEMBER 28

On November 28, the day after Jesse Maguire died, Odim met with Blanchard, Craig and Postl. The meeting had been previously arranged.

Postl testified that, at this meeting, Odim spoke of the need to consolidate post-operative care and reduce the number of anaesthetists. Postl also testified that “the tone and content of discussion was almost precisely what was in the letter.” (Evidence, page 35,516) As a result, Postl began to wonder if it might be impossible to resolve all of the team issues. He also was surprised by some of the items included in Odim’s proposed mission statement. The most surprising was the concept of performing heart transplants in Winnipeg. At the meeting there was discussion of whether there should be an external review or if it would be more appropriate to await Lindsay’s arrival.

In late November or early to mid-December, Postl in fact met with Lindsay. They spoke about the Pediatric Cardiac Surgery Program. According to Postl, Lindsay indicated that he was open to reviewing the program. The need for an external review became more apparent to Postl after his meeting with Lindsay, as he became aware of the events that had occurred in the OR during the operation on Jesse Maguire.

THE IMPACT OF THE MAGUIRE CASE

The Maguire case had considerable impact on the persons who participated in the operation. Within days, several of the participants took their concerns to Giddins, Craig and Postl.

Ward said that, while he had approved of the Wiseman Committee decision to proceed to offer a full service, including high-risk cases, he began to have reservations following the Maguire case. “I wondered at that time, which was towards early December, then I kind of wondered about the high risk surgery at that point in time.” (Evidence of Dr. Ward, page 108) He wondered if there should not have been a different surgical approach in this case. He was also concerned that Odim and Swartz had given him differing accounts of what had happened to the cannula during the operation. Ward said that he communicated his concerns to Giddins. In his testimony, Giddins said he asked Ward to speak with Odim and straighten out this conflict. According to Giddins, Ward never reported back to him on the issue and he did not investigate the matter himself. Shortly afterwards, Ward went on vacation and when he returned, the program had been shut down.

Following Jesse Maguire’s death, Swartz said, she was shattered and devastated. Within 24 hours, she spoke to both McNeill and Craig and expressed her concerns with the operation.

Youngson stayed off work the day after Jesse's death. She returned to work on November 29 and went to see Isobel Boyle, outlining her concerns with the program. Boyle arranged for Youngson and Hinam to meet with Postl. According to Youngson, Postl gave them a sympathetic hearing, but then told them what Youngson had been told by others. This was that Duncan had experienced similar problems in his first year and that it could be expected that not all high-risk cases would be successful. Youngson outlined once more her concerns about surgical technique and bleeding.

Boyle gave this description of the meeting with Postl.

So the three of us met with him the following day and Carol and Irene described the OR situation with him. And they—and when I would talk to them, you know, in terms of what can we do, I mean, they were so dedicated to going back for the children and the families, and that they thought if we don't go in there, what are they going to do?

Brian also asked them, he asked them if they wanted the program stopped; and it wasn't the program they wanted stopped, they wanted the incidences to stop. And he also asked them, what would make it—what did they think might make it better? And they said that certainly the cases that Dr. Hamilton had been involved in seemed to go better. (Evidence, page 32,709)

Postl recalled that the nurses made it clear that problems they had flagged early in the year were still present. Postl said:

I was struck by the intensity of their feeling about this situation. I was struck that they truly believed that these were very significant issues. And I was struck that they seemed very uncomfortable and, in fact, at least one of them was tearful during this description. (Evidence, page 35,544)

Casiro testified that he had expected Jesse Maguire to survive surgery. During the course of the Maguire operation, Casiro had spoken with Swartz, who had told him about the inadvertent removal of the cannula. Casiro subsequently spoke with Odim and was troubled by the fact that his version of the story did not mention the dislodging of the cannula and the problems encountered while reinserting it.

Casiro did not keep his troubled thoughts to himself. He spoke to Seshia about the conflicting versions and his own lack of understanding of what went wrong. He said he faced an ethical dilemma.

Well, it is sort of being torn between the loyalty or allegiance to the institution and the program, and to the patient and the family. And, you know, what is in the best interests of the patient, which is ultimately what we are advocating for.

And in my own mind, I start to question, asking, well, if I have this level of concerns, should I share this with the parents the next time I have a complex case that needs to have surgery? (Evidence, page 37,989)

Casiro indicated that he also spoke with Postl on December 2. (Postl placed this meeting three weeks later, on December 21.) He told Postl about his uncertainties with the program and said that he thought the issues regarding these cases (ID and Maguire) needed clarifying. He also told him about his ethical concerns.

According to Casiro, Postl told him he would speak to Blanchard. He also told him that he was seeking to have Lindsay review the program. Casiro said that Postl was jolted when he told him he was thinking of telling patients about his concerns.

Joan Borton was also becoming increasingly distraught over the outcomes. During this period Giddins encountered her at a time when she was in tears over events in the program. He told her that many people were worried about her. This shocked her. He then asked, "Are you with us?" to which she answered no (Evidence, page 18,243).

And I said to him, you think I should leave. And he said, well, yes. I said, well, I have been trying to leave. I have taken steps. Isobel has been involved. You know, it's just that I can't just do anything as a nurse. And he said, well, no, of course, you can't just do anything, but there are some things that you can do. And I went, well, why don't—what about if we have a meeting with Isobel. I will call Isobel and the three of us will sit down and really talk about what this is all about. And he agreed. (Evidence, pages 18,243–18,244)

The three met and a decision was made to find a term position for Borton outside the Variety Children's Heart Centre.

Hinam testified that by this point, she believed that no one who knew anything about the program would have allowed his or her own child to be operated on by this team. Hinam testified that she asked Kesselman if he would allow any of his children to undergo an operation in the Winnipeg program. She said at first he said he would not because he was personally acquainted with everyone involved. She asked Kesselman if that would still be his view if the Winnipeg surgeon were the best in the country. According to her testimony, Kesselman said that on that basis, he would allow his child to undergo cardiac surgery in Winnipeg. She said that other people involved in the program had said to her that they would not allow their children to be operated upon in Winnipeg.

The Wiseman committee didn't seem to have accomplished anything. And I just, I guess it was just like you felt like you were batting your head against a wall. (Evidence, pages 11,555–11,556)

In his testimony, Kesselman gave the following account of the conversation:

I recall that she kept asking me this, and I kept saying the things that I said to her, well, you know, that I think it's probably different for me, the inference being that if my child needed brain surgery or something, I might want to go somewhere else. And she kept on. I actually got quite irritated, and I just kind of said that to kind of end it, because she had asked me many, many times.

I think that probably wasn't the best thing to say. I think that was probably somewhat ill considered on my part. If this, you know, is to be taken as my views, other than really just a personal conversation. (Evidence, page 34,142)

Hinam testified that she went to see Boyle, who took her to see Postl. She said that she went to see Postl twice, once with Youngson.

I told him about this informal survey that I had taken, and how angry I was that we were continuing when people that didn't know any better, with only people that didn't know any better's kids. Because nobody that I talked to that day would ever let their children be done here. (Evidence, page 11,557)

In the wake of these discussions, Postl called Blanchard. He spoke with him about the concerns that the nurses and Casiro had expressed. One of the ideas that Postl and the nurses discussed was to have Hamilton present when Odim operated. Postl was impressed that the nurses had such confidence in Hamilton. Postl and Blanchard agreed that, for future cases, Hamilton would assist Odim. However, Postl could not recall if they had specified the kinds of cases at which this assistance would be provided. Postl thought that this would help to alleviate the concerns of those who had spoken with him, while he waited for Lindsay to arrive and review the program.

The dilemma that Hinam put to Kesselman was not always hypothetical. Donna Feser testified that a friend phoned her that autumn to ask about the program because a relative had a child scheduled to undergo surgery at the HSC. She asked Feser if she would allow this to happen if this were her child. Feser told her no.

I felt a moral obligation. And when I say I put myself in her position, I also was thinking, I was thinking of the child, I was thinking of the parents, I was thinking of the people that I had already seen go through this process, and seen the suffering, seeing the suffering of the Goyal family. (Evidence, page 30,042)

One cannot take issue with Feser's actions, which were taken on the basis of what she viewed as a moral imperative. However, when coupled with Borton and Hinam's testimony, it gives rise to two observations.

The first is that it would appear that people who had access to inside information were being warned away from the program, although these warnings were not being given or condoned by the program's leadership. Secondly, one is left with the sense that, just as Hinam had predicted in the spring, the program would have been subjected to a much more intensive review much earlier if the parents of the children who died had enjoyed greater socio-economic status and greater access to the workings of the hospital and the medical system.

THE CASE OF JR — DECEMBER 2

JR was born on November 21, 1994. At birth, he was diagnosed with an atrial septal defect, a ventricular septal defect and tricuspid atresia. He also suffered from a clotting disorder that was not diagnosed until after his first operation on December 2, 1994. He was transferred to the HSC on November 25. Following his transfer to the HSC, he underwent a balloon atrial septostomy and two separate operations. The septostomy took place on November 25. The first operation took place on December 2 and the second on December 8. After surgery, JR was transferred to the NICU, with an open chest. His chest was closed on December 14. He remained in the HSC for a further six months, because of coagulation problems and his ongoing cardiopulmonary distress. In the spring of 1995 JR was transferred to Saskatoon, where he underwent additional cardiac surgery. He was then returned to the Winnipeg PICU for further care.

On December 2, 1994, JR's oxygen saturation had fallen dramatically. It was felt that if a Blalock-Taussig shunt was not inserted, JR could have a cardiac arrest on the ward. Odum was consulted, and the child was scheduled for emergency heart surgery in the Children's Hospital.

The placement of a Blalock-Taussig shunt was a closed-heart procedure that did not require that the child be put on CPB. However JR was a neonate whose condition was fragile. Obviously there was concern about the state of his health and about his ability to withstand the operation.

More important, however, was the concern that, while the placement of a Blalock-Taussig shunt was a closed procedure, there was always an inherent risk that the shunt would not do what was expected of it. For any one of a number of reasons, the chances of having the operation suddenly become one where open-heart procedures would be required, while perhaps remote, were real. There was a clear possibility that the team might require the use of the CPB machine.

As a result of the speed at which the case proceeded, however, the operation could not take place in OR Theatre 2. This was the usual pediatric cardiac operating room, but it was being used for another operation. Instead, JR underwent his operation in OR Theatre 1. Both Wong and McGilton were worried about proceeding with the operation, since the OR they would be using lacked equipment that was available only in

OR Theatre 2. McGilton and Wong were particularly concerned because, if bypass became necessary, the perfusion equipment that would be needed could not fit into OR Theatre 1.

Wong said that, once he became aware of the emergency nature of the case, he agreed to go ahead with the procedure. While Wong was the anaesthetist initially, Ullyot replaced him later in the procedure. There was nothing unusual in this, since the operation was a closed heart, as opposed to an open-heart, procedure. Ullyot said that she had had considerable past experience with the placement of B-T shunts, although this was the first time that she had worked with Odim.

At approximately 1645 hours, Odim announced that the shunt was open. It was expected that this would cause a decrease in blood pressure and an increase in oxygen saturation. However, this did not happen. At the time, Odim said that he could feel blood flowing through the shunt. Eventually the blood pressure and the oxygen saturation reached acceptable levels, and at 1730 hours Odim began to close the chest. When he finished closing the chest at 1800 hours, both the blood pressure and the oxygen saturation fell. At Ullyot's suggestion, Odim loosened the sutures and opened the chest. However, JR's oxygen saturation and blood pressure did not improve.

Odim examined the shunt and found that it had clotted, even though he had treated JR with heparin. After attempting, without success, to unblock the shunt and after having consulted with Giddins by telephone, Odim decided to construct a central shunt. (This central shunt would connect the aorta to the main pulmonary artery.) Once this shunt was in place, however, the pressure and oxygen saturation problems were still not resolved.

Odim considered going on bypass and putting in a third shunt. In preparation for this, a call was put out for a perfusionist. Todd Koga, who was on call, was paged and rushed from home to the Children's Hospital. By the time he arrived, Odim had decided not to put in a third shunt. Instead he found he could maintain JR's oxygen saturation at an acceptable level by treating JR with inotropic medication. JR was taken to the NICU with his chest open.

Following that operation, a heart catheterization was undertaken. According to Reimer, who gave the anaesthetic for the catheterization, JR was unstable and suffered two cardiac arrests during that procedure.

In the NICU, JR's shunt once more became clotted. Tests were conducted and the results indicated that JR had a blood condition that increased the tendency of his blood to clot. He was treated with anti-coagulants and a decision was made to put in a third, larger shunt. This operation took place on December 8.

At that time Odim placed a 4-millimetre shunt, larger than the 3.5-millimetre shunts he had used previously. He hoped that a larger shunt would be less likely to become blocked or occluded. As a result of the larger shunt and the anti-coagulation medication, JR's oxygen saturation improved. However, he was once more returned to the NICU with his chest open.

JR's previously undiagnosed blood condition contributed to the fact that his initial operation was very long, particularly for what was expected to be a relatively straightforward shunt procedure. The case was a matter of concern for the nursing staff in both the OR and in the NICU. McGilton testified that she had never seen a shunt become blocked in that manner, had never seen an eight-hour shunt operation and had never seen a shunt patient sent to the NICU with an open chest.

Armitage testified that the clotting of the shunt created a chaotic situation in the NICU. She said that Odim once again requested equipment that was not kept in the unit. She testified that many NICU nurses

were becoming alarmed by the fact that so many of the cardiac patients were coming back from the OR in very serious condition. While it would appear that there were reasonable explanations for the problems that arose in this particular case, the atmosphere had become so tense and suspicious in the hospital about the program that even explainable events were given only negative interpretations.

BLANCHARD'S MEETING WITH UNRUH AND ODIM — DECEMBER 5

On December 5, 1994, after Postl had spoken with him, Blanchard telephoned Unruh. The call was to inform Unruh that, despite the efforts of the Wiseman Committee, there were still ongoing reports of problems in pediatric cardiac surgery. Blanchard said that it would be useful to involve Hamilton in the team to a greater extent. He asked Unruh to attend a meeting later that day, at which Blanchard would inform Odum of this decision. He wanted Unruh to be present at the meeting to provide support to Odum, who he thought would be demoralized by the decision.

Blanchard testified that while he thought that Odum needed help, Odum did not appear to feel he needed assistance.

And perhaps he hadn't thought about it, you know, and when you are in the middle of a swamp, you know, you are so busy with the alligators you may not think of everything, but he didn't seem to— what shall I say—I got the feeling or maybe he told me that he hadn't thought about that. (Evidence, page 36,638)

Odum himself testified that Blanchard felt having Hamilton in the OR was a means of having someone there who could see things from a surgical perspective and verify Odum's account of how the operations were proceeding.

On the day after this meeting, Blanchard sent Postl the following memorandum:

I met with Jonah Odum and Helmut Unruh on December 5th. It was agreed that Dr. Andrew Hamilton will assist Dr. Odum with all neonatal and all other high-risk cardiac operations. (Exhibit 19, Document 268)

Blanchard copied Odum and Hamilton with this memorandum, while Postl sent a copy of the memorandum to Boyle.

While there can be little doubt of the meaning of this memorandum, Odum testified that the memorandum did not reflect the agreement that had been reached at the December 5 meeting. In particular, he said, he understood that he was to have Hamilton's assistance for only open-heart neonatal cases and not for all neonatal cases.

Blanchard was asked what the memorandum meant by the phrase "all neonatal."

Well, I meant neonatal, I believe that is patients in the first month of life.

Q Certainly. I guess the question that's come up is, did you mean, did you mean all neonatal cases, including closed and open, which would—or what did you mean in that regard?

A Okay. I can't remember what I meant. I should have been more specific, but, I mean, the three of us generated this thought. The way it stands it would mean all neonatal, but probably what we had in mind was all open neonatal cases. (Evidence, page 36,639)

According to Unruh, at the meeting Blanchard informed Odim that the only way the program could be salvaged at that point was to have Hamilton present for “all of the major cases.” (Evidence, page 35,210)

The difference between Odim’s recollection of the agreement and the wording in the memorandum is particularly significant in light of Blanchard’s response when he was asked to explain the purpose of the December 6 memorandum to Postl.

I think the memo was written for several reasons. One is to underscore with Jonah that we expect this, it isn’t an option. And the other was to inform everyone else – it wasn’t a problem for Dr. Hamilton, we knew that, just to inform everyone else that they would expect this to happen. And I think it would also serve to reassure Dr. Postl, who had told me that he had been informed that things went well, you know, in these complex cases when Dr. Hamilton was present. (Evidence, page 36,641)

It is difficult to square the clarity of the memorandum with Odim’s and Blanchard’s evidence. Postl initiated the request to have Hamilton present because of concerns that had been presented to him about surgical outcomes. The memorandum did indeed provide him and the nursing staff with a measure of assurance.

However, if Blanchard and Odim had not agreed to what the memorandum said, then it would appear that it was a false assurance. Either Blanchard worded the memorandum in a manner that did not reflect the understanding between Odim and himself, or—as the evidence in the later Petkau case suggests—Odim chose to disregard the memorandum. Blanchard was not clear in his testimony as to the nature of the agreement. It would have been appropriate if Odim or Blanchard had corrected the impression that was left by the memorandum. In light of their failure to do that, they ought to have abided by the written memorandum.

Giddins testified that he did not receive a copy of the December 6 memorandum; nor was he told of its specific contents. He did say that Postl informed him that formal arrangements had been made to have Hamilton assist at operations.

THE CASE OF KQ — DECEMBER 7

On December 7, Odim, with Hamilton as his assistant, operated on KQ, a six-week-old child with total anomalous pulmonary venous connection (TAPVC) and a large ASD. This high-risk operation went well. She was discharged on December 22, 1994.

McGilton, who was a circulating nurse for this procedure, said that Hamilton played a leadership role in the operation. Reimer, however, was less certain if Hamilton’s presence was significant, since Odim performed the bulk of the procedure himself.

THE WISEMAN COMMITTEE MEETING OF DECEMBER 7

The committee met again on December 7, for the first time since October 17. In the intervening period, the deaths of Jesse Maguire and Ashton Feakes had occurred. The main topic at the meeting was the proposed centralization of post-operative care. It appeared that the NICU nurses were now more amenable to

the single-unit proposal, although it was recognized that the PICU nurses would require additional training in caring for neonatal patients.

However, at this meeting Kesselman raised concerns about the impact that the consolidation would have on the resources of the PICU. Nor was it possible for Cardiology to provide any additional support for post-operative care. McNeill moved that the post-operative care process remain unchanged for the moment, since existing resources would not support the single-unit approach. While it was recognized that this decision was necessary, Odim's disappointment was recorded in the minutes.

The members of the committee were not informed of Blanchard's directive of December 6; nor, in keeping with Blanchard's instructions, were they informed of Odim's letter of September 25, despite the fact that Wiseman had been given a copy of it on October 28. Although Wiseman may not have been aware of the December 6 directive, certainly by that time Odim had seen the directive or was aware of its contents from the meeting he had had the day before with Blanchard. The information was a matter of considerable interest and importance to committee members and should have been shared with them.

At the meeting's end, Wiseman reported that, in view of recent events, the surgical procedures carried out in September, October and November would be reviewed. The matter was not put to a vote of the committee, and apparently came directly from Wiseman. This could have done to meet Seshia's expression of concern that the program outcomes were still problematic. However, the recent events to which Wiseman referred were undoubtedly the cases of Ashton Feakes, JR, ID and Jesse Maguire. Wiseman may also have been influenced by Odim's letter of September 25. He reported that it was also expected that when Lindsay took up his duties, he would provide guidance for a further review of the program. The committee's reviews were to be performed at a meeting set for December 16. That meeting was never held.

ULLYOT MEETS WITH POSTL — DECEMBER 9

On December 9, Ulyot met with Postl to discuss a range of issues, including the Pediatric Cardiac Surgery Program. She told Postl that the four anaesthetists were not happy with the program and still had concerns.

Postl spoke with his vice-president, Helen Wright, during this period. According to her testimony, Postl sought her advice on how he might close down the Pediatric Cardiac Surgery Program if he became convinced that such action was necessary. In recalling that conversation, Wright said Postl did not discuss specific cases with her, but he indicated that there were growing concerns with the program. She said Postl indicated that he was examining options if a worst-case scenario arose. She told him that he could go to the Medical Advisory Committee (MAC) and ask that the program be stopped or that Odim's privileges be suspended or revoked. She also advised him to make sure that he had a firm understanding of the statistical results of the program. She said that if the MAC rejected this recommendation, he could then appeal to the President and the Board.

In December, Wright also heard from Boyle at least twice about nursing concerns with Odim's surgical competence. Wright said this was after her discussion with Postl. She indicated that, in previous discussions with Boyle, she had thought that the nurses' concerns related more to communications and interpersonal relations. Wright believed that Postl was taking steps to address these concerns. Within a short time, he had.

THE CASE OF ERIN PETKAU

ISSUES

Erin Petkau died on the morning of December 21, 1994, after undergoing surgery to insert a Blalock-Taussig shunt on December 20.

The issues that this case gives rise to are:

- Were Erin's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should the ventilation intra-operatively have been different?
- Was the Blalock-Taussig shunt too small?
- What led to the shunt failures?
- Should Dr. Andrew Hamilton have assisted in this operation?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Erin Petkau was born at Morden District General Hospital on December 17, 1994, at 0706 hours. The child of Walter and Barbara Petkau, she was born at 41 weeks gestation and weighed only 2,610 grams.

On December 18, after Erin had cyanotic spells and a heart murmur was detected, she was transferred to the HSC. On admission to the HSC at 2007 hours, her colour was pink and her oxygen saturation was good. She was also noted to have good femoral pulses and peripheral perfusion.

Tests conducted on December 18 and 19 identified:

- Tetralogy of Fallot with a marked aortic override above a large ventricular septal defect and right ventricular hypertrophy
- either an atrial septal defect or a patent foramen ovale
- severe pulmonary valve stenosis
- small pulmonary arteries
- a patent ductus arteriosus.

Erin's aorta was positioned over the top of the ventricular septum (and thus termed an 'overriding aorta'), rather than being attached to the left ventricle. She had a large hole in the septal wall separating the ventricles. In addition, her ductus arteriosus was open and she had either an atrial septal defect or a patent foramen ovale, linking her atrial chambers.

Erin was treated with antibiotics for a possible infection. Dr. Soni saw her at 0400 hours and performed an echocardiogram. Soni assessed Erin as a pink Tetralogy of Fallot and recommended treatment with prostaglandin if there was a decrease in oxygen saturation. Giddins concurred with this assessment and indicated that surgery to insert a shunt was required. According to Barbara Petkau, Soni told the family that Erin would likely need surgery within one or two weeks.

THE DECISION TO OPERATE AND CONSENT

On the morning of December 19, Giddins conducted a second echocardiogram. He concluded that, while Erin's oxygen saturation was satisfactory, she would be in trouble once her ductus arteriosus closed. For this reason, he concluded that a shunt was required.

Erin was treated with prostaglandin to keep her ductus arteriosus open. Giddins testified that this was done in response to her history and heart condition and not as a response to any decline in her condition.

At 1610 hours on December 19, Erin became very cyanotic during feeding and stopped breathing for about 30 seconds. She was ventilated by hand with oxygen, and secretions were suctioned from her lungs. She started to breathe again and her colour remained pink until 1620 hours, when she stopped breathing again. After three attempts, an endotracheal tube was inserted and a moderate amount of thick secretions were suctioned out. A chest X-ray was interpreted as being normal.

Giddins testified that, on December 19, he discussed the need for surgery within the next one to two days with Erin's parents. He recalled explaining the operation as a relatively simple procedure, in which a tube would be placed between two blood vessels. He testified that he did not recommend any alternatives because he did not believe there were any; nor did he discuss having the operation undertaken at a different centre. In his testimony, Giddins said that he thought that surgery had a five to ten per cent risk of mortality. He indicated that he did not discuss risk with the parents. Because Odium was not available for a consultation that weekend, no date was set for surgery.

When the Petkaus went to visit Erin on Monday, December 20, they were told that they could not see her because she was being prepared for surgery. This surprised them, since they had yet to meet the surgeon. They had thought that surgery would not take place for several days. They said they were told that while Odium had previously been unavailable, he now was available and ready to operate. Barbara Petkau testified:

We just thought at the time, well, like, better sooner than later. If it has to be done, get it done and over with, and we can be on our way. They more or less assured us that we would be out of there by New Years. (Evidence, page 2,523)

On December 20 at noon, Odium assessed Erin and determined that she needed a Blalock-Taussig shunt to provide her with a stable source of blood flow to her lungs. He then spoke with the family. In his testimony, he said:

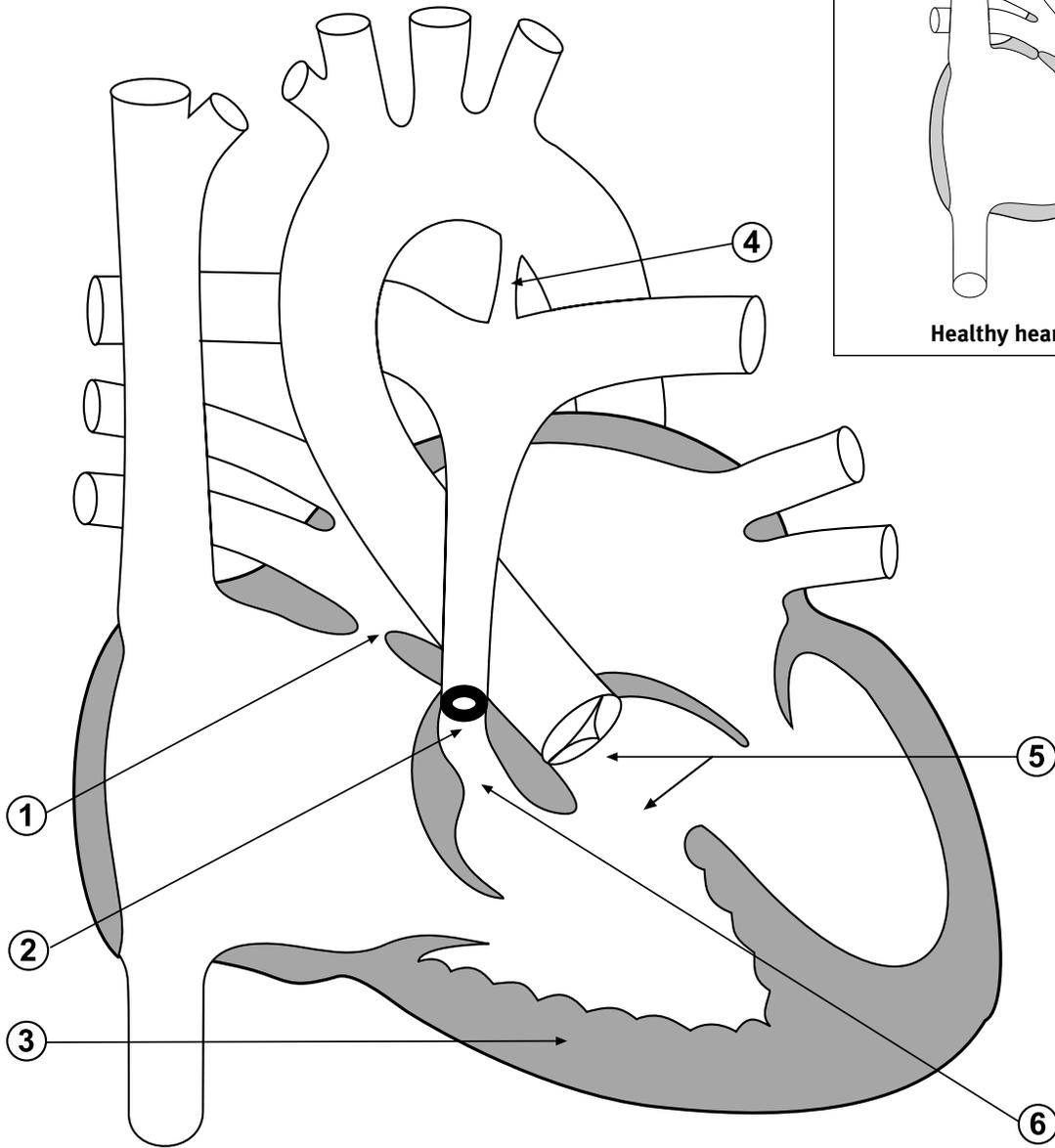
I don't remember the exact wording of the conversation except to discuss that the child needed to have a shunt for pulmonary blood flow, talked about the anatomy of the child and talked about what happens next after a shunt in terms of the child would need another operation to fix the heart, talked about the problems that you can get with shunts, including redoing them or the shunt blocking and that essentially was sort of the gist of my conversation. I don't remember the wording, the exact wording. (Evidence, page 26,238)

He also spoke to Erin's parents about risk. He testified that:

I essentially told them that there are risks from a shunting procedure of bleeding, of clotting, having to do the shunt again, that there were risks of death and I told them that 8 to 12 or 8 to 10, I don't recall the exact ball park, of patients would have problems with a shunt including death. (Evidence, page 26,240)

He testified that he did not believe he had indicated what per cent of that eight to twelve per cent were at risk of dying.

Diagram 8.9 Erin Petkau – pre-operative heart



- 1 – Atrial septal defect
- 2 – Severe pulmonary valve stenosis
- 3 – Right ventricular hypertrophy
- 4 – Patent ductus arteriosus

- 5 – Ventricular septal defect with overriding aorta
- 6 – Right ventricular outflow tract obstruction

Barbara Petkau testified that Odim had drawn them a picture of the heart and indicated its lesions. Furthermore, he told them that it was a very low-risk operation. Barbara Petkau also testified that, as a result of her discussions over the weekend with Soni and Savani, she was left with the impression that Odim was one of the best available surgeons.

PRE-OPERATIVE STATUS

During the night of December 20, Erin's extremities were very cool, and she was placed under a radiant heater. She was very irritable and tremulous but settled with sedation.

In his report, Hudson raised a potentially serious point. He wrote that:

A coagulopathy was present before surgery. I was not able to locate any notations in the chart that indicated that anyone involved in the care of this patient was aware of these results. Intraoperative and postoperative bleeding were major problems that likely contributed to the death of this patient.

The failure to diagnose and treat this coagulopathy before surgery are major deficiencies in the management of this patient. (Italics and bolding in original) (Exhibit 307, page 12.14)

Hudson subsequently revised this conclusion. Documentation was presented to him indicating that there had been a pre-operative administration of Vitamin K, the treatment that he believed had not been provided. Secondly, he agreed that the lack of bleeding in the early stages of the operation indicated that Erin did not have a coagulopathy pre-operatively:

I would agree with Dr. McNeill's conclusion that those results then, in a neonate and in the context of having been given vitamin K, are at best mildly abnormal. (Evidence, page 40,049)

With the resolution of this issue, it can be concluded that the diagnosis, pre-operative care and surgical plan were appropriate in this case.

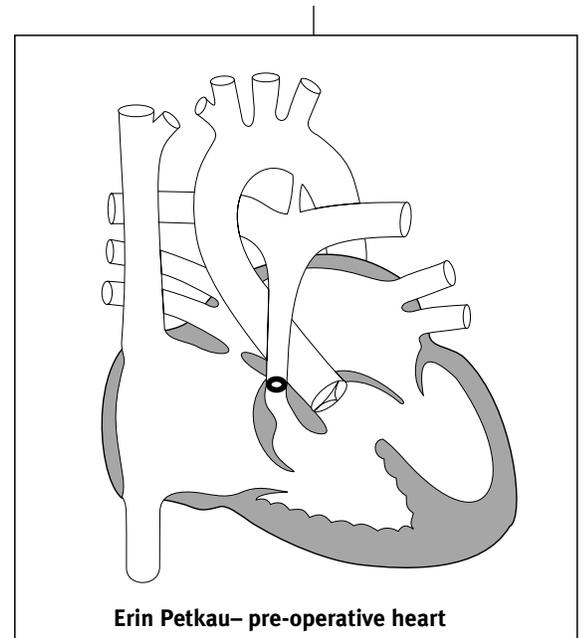
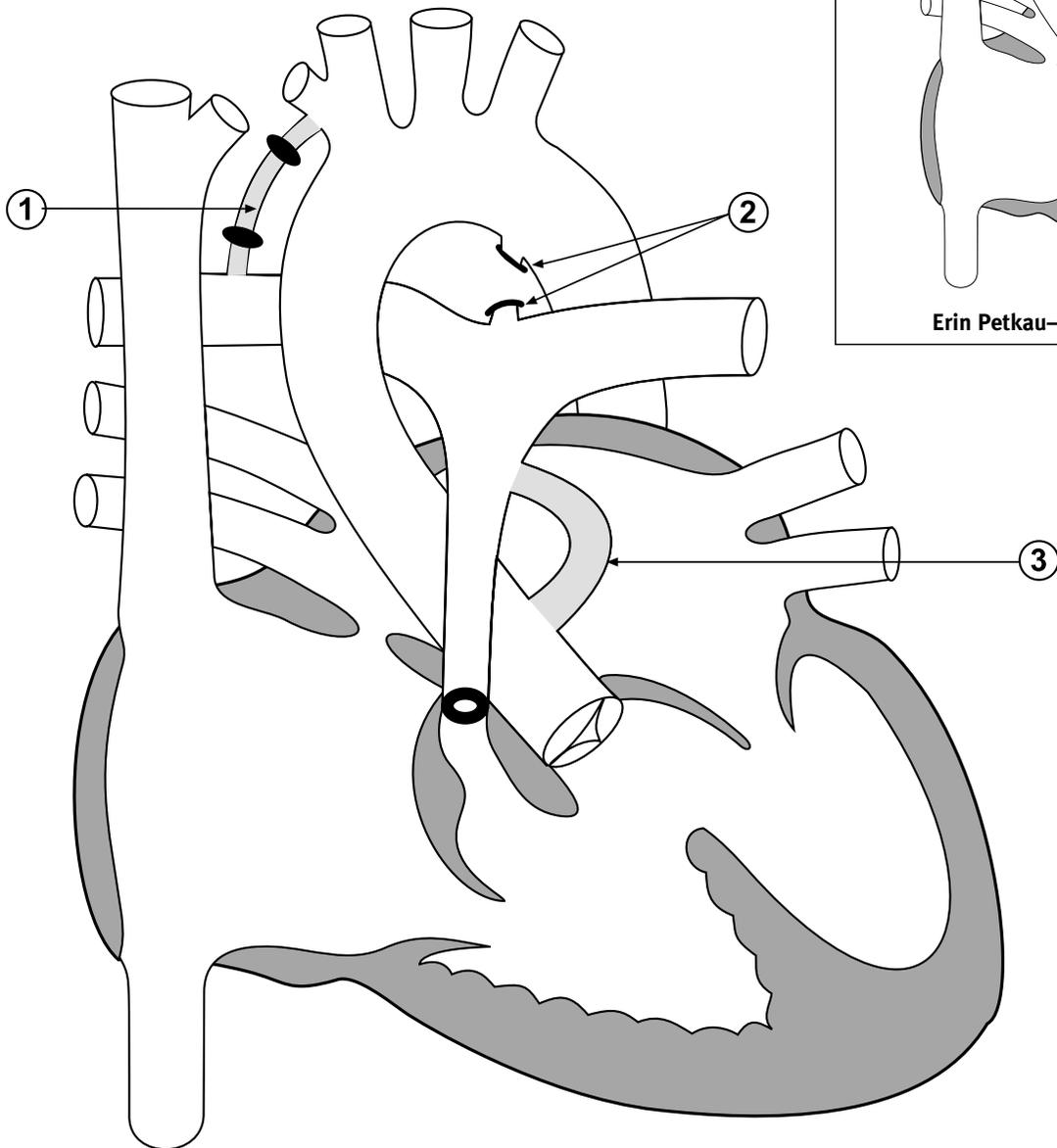
THE OPERATION — DECEMBER 20

Starting at 1240 hours on Tuesday, December 20, Erin underwent what was expected to be the insertion of a Blalock-Taussig shunt. It would become necessary during the procedure for Odim to ligate the ductus arteriosus and to insert a central shunt. As a result, the operation became very lengthy. Erin died on the morning after surgery in the NICU.

To conform with the written instruction from Blanchard as set out in the memorandum of December 6, 1994, Odim was required to call Hamilton to have him assist with this procedure. Odim testified that he did not because "that wasn't my understanding of my conversation with Dr. Blanchard." (Evidence, page 26,256)

Odin stated that he called Hancock because she had been assisting him throughout the year. "I could have called anyone I wanted who might be available to assist me." (Evidence, page 26,257) He further testified that he understood that he was to have Hamilton's assistance at only open-heart neonatal procedures, not all neonatal procedures. The evidence suggests that on that point Odim was not correct. In failing to have Hamilton present for this procedure, Odim was acting outside the written directive that he had received.

Diagram 8.10 Erin Petkau – post-operative heart



Erin Petkau- pre-operative heart

- 1 – Modified Blalock-Taussig Shunt, clipped
- 2 – Ligation and division of ductus arteriosus
- 3 – Central shunt

The operating team is set out in the accompanying chart.

TABLE 8.9: Persons involved in the operation on Erin Petkau, December 20, 1994

<i>OR team member</i>	<i>Persons involved</i>
Surgeon	J. Odum
Surgical assistant	B.J. Hancock
Anaesthetists	A. McNeill, N. Svorkdal (resident)
Scrub nurses	H. Skomorowski, C. McGilton, A. Glenday
Circulating nurses	C. Youngson, K. Rodgers, K. Cox, and H. Skomorowski
Perfusionists	T. Koga, C. McCudden

TABLE: 8.10 Length of phases of the operation on Erin Petkau, December 20, 1994

<i>Phase of the operation</i>	<i>Time taken</i>
Induction	1 hour 15 minutes
Bypass	1 hour 39 minutes
Total surgical time	10 hours
Total operating-room time	11 hours 50 minutes

During induction, Odum performed a cut-down for the insertion of an arterial line. This procedure involved surgically exposing an artery in the wrist and then inserting a monitoring line.

According to Cornel and Hudson, Erin had a metabolic acidosis at the start of her operation that continued throughout surgery.

The initial chest incision was made at 1355 hours. In the operation, Odum used a 3.5-millimetre Gortex tube graft to connect the subclavian artery to the right pulmonary artery. When the shunt was opened at approximately 1510 hours, the systemic blood pressure fell. Odum testified that he became concerned that this was a sign that too much blood was being shunted to the lungs, as opposed to the body. (The systemic pressure falls when there is not sufficient blood flow to the body.) Erin became increasingly acidotic as a result. Odum believed that his only options were to make the shunt smaller or close the ductus arteriosus, thereby reducing blood flow to the lungs. As a first step to doing this, he stopped the flow of prostaglandin, in hopes that the ductus arteriosus would close on its own. He then manually pinched the ductus arteriosus and the pressures went up. After speaking with Giddins by phone, Odum decided that he would ligate the ductus arteriosus. He hoped that this would reduce the blood flow to the lungs and improve systemic blood pressure. At the same time, McNeill was transfusing additional fluids and treating Erin with dopamine in an effort to increase her blood pressure.

Throughout this portion of the operation, McNeill ventilated Erin with 100 per cent oxygen. In his testimony, Odum said that it might have been appropriate to reduce the amount of oxygen with which Erin was being ventilated after the shunt was inserted. He testified that oxygen would have dilated the vessels leading to the lungs, thus increasing pulmonary blood flow at a time when he wanted it decreased. He testified that he was not aware that Erin was being given 100 per cent oxygen at that time and he did not inquire about a change in oxygenation.

The PDA was ligated, with some improvement. However, each time Odum attempted to close Erin's chest, her blood pressure dropped. Odum testified that at one point the pressure was so low that there was no pulmonary blood flow through the shunt. The decline in blood pressure and blood flow created the possibility of clotting in the shunt. There was also less blood going to the coronary arteries, which perfuse the heart muscle itself, threatening to weaken the heart. McNeill began treating Erin with epinephrine, a stronger inotrope.

Odum reopened Erin's chest at 1610 hours and examined the Blalock-Taussig shunt. He found the shunt blocked with clotted blood. He was able to momentarily open the shunt by passing a catheter through it, but the shunt soon closed again. This took place at approximately 1700 hours.

Blockage of the shunt created a new problem, since at this point, with the ductus arteriosus closed, the shunt was the only source of blood flow into Erin's lungs. To reverse this, Odum released the ligature on the ductus arteriosus. An infusion of prostaglandin was restarted. However Erin's pressures remained low and the ductus arteriosus failed to reopen.

Odum testified that, at that point, he was not able to determine the cause of the problem.

I was wondering whether the pulmonary arteries were too small in this child, and we were having problems with the outflow bed. Because I was perplexed, I had never been in a situation where I was just so over shunted with a 3.5 millimetre shunt.

Q: And what happened then?

A: When the shunt occluded, we were still faced with a tremendous acidemia and requirements for inotropes. And Erin needed, you know, another shunt, needed pulmonary blood flow, because now we had no pulmonary blood flow. (Evidence, page 26,292)

From 1700 hours onwards, there were periods when Erin's blood pressure and oxygen saturation were acceptable, but these periods did not last for more than fifteen minutes. By 1840 hours, her blood pressure and oxygen saturation had fallen again and were not responding to treatment. During this period, she suffered a reduction in oxygen supply to her tissues (hypoxemia) that was, at times, life-threatening.

Odum concluded that creation of a second shunt was necessary. To do this, he would have to use bypass, so that he could gain access to the small blood vessels that were to be connected by a central shunt.

Barbara Petkau testified that, at approximately 1830 hours, Savani informed the family that the initial shunt procedure had not gone well. As a result, Erin would be put on bypass and a second shunt inserted.

The anaesthetists packed Erin's head in ice at approximately 1900 hours, when the perfusionists were called. The team went on bypass at 1927 hours. The move to go on bypass was delayed when it was discovered that the single venous cannula that was being used was too small to supply an appropriate level of blood flow from Erin to the bypass machine. Koga had recommended a smaller-size cannula, since he was under the impression that Odum would be using two cannulas for the venous return, whereas Odum intended to use only one cannula. Although the problem lasted only a few minutes, it was further evidence of ongoing communication problems between team members.

Following the operation, team members also had differing accounts of how the original cannulation problem arose. McNeill felt that Odum should have recognized that the cannula was too small before he inserted it. Odum said that Koga had simply failed to provide him with the appropriate cannula. However it is obvious that Odum failed to notice that he had been given the wrong-size cannula for what he intended.

By the time bypass was initiated, two and a half hours had passed from the time that the shunt had clotted. Once bypass was initiated, Odum constructed a four millimetre central shunt. He also clipped the original B-T shunt to ensure that it did not reopen and create excessive pulmonary blood flow once again. The team then attempted to wean Erica from bypass, which had lasted for 109 minutes. High doses of inotropes were required to allow separation from bypass, which took place at 2106 hours.

When Erin first came off bypass, her blood pressure was low and was treated with dopamine and epinephrine. She required this treatment to maintain her blood pressure at acceptable levels while in the OR.

Erin's condition was so serious while she was coming off pump that the OR team called Giddins and asked him to come down to the HSC. The team also requested that a chaplain be called to the hospital. NICU nurse Armitage called the chaplain and took him to see the Petkaus. The parents were told that Erin's situation looked serious. Shortly afterwards, Giddins arrived at the HSC. By that point Erin had been successfully weaned from bypass. Giddins communicated this news to Erin's parents and told them that things were looking well for Erin. Unfortunately, this was very shortly after Armitage and the chaplain had left the Petkaus with the impression that Erin's condition was bleak. The unfortunate timing of these two events was distressing for Erin's parents. This was particularly so since Giddins, quite unintentionally, had left them with what proved to be an overly optimistic picture of Erin's condition.

After Erin came off bypass, she suffered extensive bleeding. This was due to a number of causes, including the fact that she had been treated with heparin to prevent clotting. She also had some surgical bleeding from her chest wall at the site of the insertion of the right atrial catheter (a small pressure monitoring line) and at the site of the Blalock-Taussig shunt. In her testimony, McGilton said that it took approximately three hours to control the post-bypass bleeding. She said that Odum made several attempts to close Erin's chest. However, he had to abandon each one because the closure caused the blood pressure and oxygen saturation to fall and was accompanied by bleeding from the chest.

Giddins commented that the bleeding did not surprise him:

The fact that it hadn't been bleeding during the case and the fact that it perhaps starts to leak a little bit, if there is a coagulopathy or tendency to bleed, doesn't particularly surprise me. You are not making it water proof. You are making a near water proof seal that depends on blood clotting to completely finish the job, but a little area that needed one extra suture doesn't strike me as being unusual. (Evidence, pages 4,547–4,548)

McNeill gave this description of the cause of the coagulopathy:

I would attribute it to the effect of bypass on her coagulation status; and because of her size, she would have had a significant dilution of clotting factors and platelets because of the bypass situation, and whatever contribution there would be during bypass to platelet function deterioration, and then the massive transfusion post-operatively, which would further exacerbate the problem. (Evidence, page 13,614)

When the drapes were removed before Erin was taken to the NICU, it was discovered that she had been bleeding from the cut-down site in her wrist. In their evidence, McNeill and Odum differed in their accounts of the amount of bleeding that took place. McNeill viewed it as an extensive hemorrhage, while Odum said that it was insignificant. McNeill was asked about the significance of this bleeding.

Well, the major significance of it was that this was of a covert bleeding site that we wouldn't have actually seen during the period of time when we were trying to volume resuscitate her. And whenever somebody is being transfused, you use their hemodynamic profile to determine whether you are adequately transfusing them. So, you know, it wasn't, we weren't actually aware that she was bleeding from her wrist, but we would have, we don't only use the bleeding that we see to replace blood loss. (Evidence, page 13,629)

While this blood loss would have been replaced by transfusion, it increased the volume of blood that needed to be transfused, thus raising the likelihood that Erin would develop a coagulopathy. There was no apparent explanation for the bleeding at the cut-down site. There was no evidence of bleeding when Erin was draped; nor does it appear that the line became dislodged during the operation.

After the bleeding sites had been identified and sutured, and resuscitative drugs and large amounts of blood products had been given, Erin was taken to the NICU with her chest incision covered with a silastic membrane.

In his report for this Inquest, Hudson wrote:

There was massive intraoperative hemorrhage. The surgeon's and anesthetist's comments indicate that inadequate surgical hemostasis [this refers to the surgeon's control of bleeding] was an important cause of the bleeding. The patient received a total 800–900 ml of blood products during surgery, including albumin, PRBC [packed red blood cells], platelets, FFP [fresh frozen plasma] and cryoprecipitate. This is over 3 times the blood volume of this patient (~90–100 ml/kg). (Exhibit 307, page 12.14)

In his testimony, Odum said he judged that the need to keep the shunt open was of greater significance than the need to bring the coagulopathy under full control.

By the time Erin left the OR, her heart had been subjected to considerable extremes in blood pressure and oxygenation. She had undergone an extremely lengthy operative procedure and suffered extensive bleeding. The evidence suggests that her system would have been very weakened as a result of this operation.

Erin arrived in the NICU at 0028 hours on December 21. Initially Odum considered her vital signs satisfactory. However, by 0200 hours, Erin had suffered a series of episodes in which her oxygen saturation fell significantly, and she was treated with massive doses of inotropes. She continued to have the same problems with bleeding, low oxygen (hypoxemia), metabolic acidosis and low calcium (hypocalcemia) that she had in the OR.

In response to the fall in her oxygen saturation, Erin's chest was reopened at 0225 hours. This was done in the NICU with the assistance of a nurse who was not scrubbed in and without the assistance of an anaesthetist. After discovering a clot blocking the central shunt, Odum flushed the shunt and passed a catheter through it.

Hudson questioned the propriety of opening the chest in the NICU without the presence of an operating-room nurse and an anaesthetist. He said that optimal management of the case would be "difficult or impossible" in their absence. (Exhibit 307, page 12.15)

The reopening of Erin's chest in the NICU was followed by a period of significant bleeding. In his testimony, Odum said that the underlying post-operative problem was Erin's declining cardiac output, caused by her weakened heart. This decline led to lower blood pressures and the blocking of the shunt. The problems were

complicated by her small pulmonary arteries. The weakness of her heart muscle arose from the fact that, for the previous 18 to 20 hours, her heart been subjected to variations in blood pressure and oxygen saturation.

At 0500 hours, Erin's heart rate and blood pressure fell. These were signs of primary cardiac failure. Decreases in blood pressure led to a slowing of blood flow through the shunt and increased the chances of clotting. Giddins testified that as he understood it, Erin's problems were primarily with her heart rate and blood pressure and not with the shunt itself.

From 0500 hours onwards, Erin deteriorated rapidly, suffering a cardiac arrest on several occasions. For two hours, continuous efforts (including cardiac massage and flushing of the shunt) were made to resuscitate her. According to Hudson, Erin once again was given transfusions, which amounted to three times her blood volume, in response to what he termed a massive hemorrhage. (In his report, Hudson stated that Erin did not receive clotting factors post-operatively, but the post-operative record contradicted this statement.)

Erin's parents were summoned to her bedside. Barbara Petkau testified that she felt that it was only at this point that she was made aware that her daughter was near death. Erin died in her mother's arms at 0750 hours.

Armitage testified that she believed that some of Odim's comments about Erin's death were too technical and possibly insensitive to the parents. However, when giving her testimony, Barbara Petkau could not recall the comments.

AUTOPSY FINDINGS

De Nanassay performed the autopsy that had been ordered by the Medical Examiner on December 22 at 1530 hours. The report was released on February 20, 1995.

The cause of death recorded on the autopsy report form was:

Immediate Cause of Death:

Myocardial insufficiency post cardiac surgery for TOF.

Antecedent Causes:

Complete blockage of central shunt by coagulated blood. (Exhibit 9, page PET 9)

Erin's weight at autopsy was 900 grams more than her pre-operative weight. (She had weighed 2,610 grams at birth.) This was presumably due to fluid accumulation. Examination of the heart revealed extreme stenosis of the pulmonary valve, a ventricular septal defect and complete blockage of the central shunt (aorta to main pulmonary artery) by coagulated blood. De Nanassay noted that the pulmonary valve (as had been thought before surgery) was markedly narrowed and would have severely restricted outflow from the right ventricle.

Thus, the main source of blood flow to Erin's lungs was from the central shunt Odim had installed between the aorta and the main pulmonary artery. However, de Nanassay found that the central shunt was completely occluded by coagulated blood, thereby preventing any flow through it. De Nanassay concluded that, if the central shunt became blocked while Erin was still alive, any potential blood flow to her lungs would have been limited to what could pass through the extremely narrowed pulmonary valve. He also concluded that most of the non-oxygenated blood in the right ventricle was likely shunted into the left ventri-

cle through the ventricular septal defect. The outcome would be minimal oxygenation of blood in the lungs, or central cyanosis. De Nanassay believed these findings explained the repeated episodes of oxygen desaturation and the repeated cardiac arrests, since Erin's heart would have been supplied with blood that was less than adequately oxygenated.

Concerning the microscopic examination of tissues, de Nanassay wrote:

The two organ systems of major interest (the heart and lungs) are both essentially within normal limits. There is no evidence of ischemic changes in the myocardium. One tiny focus of subepicardial contraction band necrosis in the right ventricle more likely relates to traumatic causes in the course of surgery than ischemic damage. Both lungs were free of congestion or inflammatory changes. (Exhibit 9, page PET 12)

De Nanassay concluded:

On the basis of the post-mortem examination the major pathological condition was that of a complete blockage of the central shunt. This factor would have to be coordinated with the clinical picture and analyzed in (the) context of other pertinent clinical information. The actual cause for coagulation of blood within the central shunt is not readily obvious from the morphological examination alone and clinical correlation might be helpful. (Exhibit 9, page PET 12)

Dr. W. Halliday, a neuropathologist, examined the brain and found recent hypoxic-ischemic damage.

Taylor reviewed the microscopic slides of the heart and lungs. He found the lung sections poorly expanded, with areas of recent onset bronchopneumonia. He found excessive numbers of amniotic fluid cells that Erin had inhaled or aspirated. He also found clumps of platelets and fibrin thrombi (which help to form blood clots) in both Erin's lungs and brain. These clumps were more prominent than those usually found in children who died shortly after undergoing bypass (Exhibit 336, page 12.3).

Taylor concluded:

Abnormal coagulation, both thrombosis and bleeding, was a significant factor in the death of this child. ... However, the coagulopathy appears confined to the surgical field, with no evidence of major bleeding or thrombosis in other organ systems. (Exhibit 336, page 12.1)

Taylor found mild to moderate myocardial contraction band necrosis and ischemic damage to the muscle of both ventricles. (Exhibit 336, page 12.5)

In commenting on the autopsy specimen, Cornel and Duncan wrote:

The aortic end of the surgical graft appears very small. [This refers to the second shunt.] Clot material in the shunt may have occurred either post-mortem or prior to death. The anatomy was poor with very small pulmonary arteries – we suspect there was poor run-off from the shunt. (Exhibit 354, page 15)

FINDINGS

As noted at the outset, this case gave rise to the following questions:

- Were Erin's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Should the ventilation intra-operatively have been different?

- Was the Blalock-Taussig shunt too small?
- What led to the shunt failures?
- Should Dr. Andrew Hamilton have assisted in this operation?
- What was the cause of death and was it preventable?

Were Erin's parents provided with sufficient information to allow them to give informed consent to the procedure?

■ Finding

The family seems to have been fully informed as to the risks associated with the particular procedure that Erin was to undergo. However, they were not informed of the program's recent history, including the summer shutdown and the intention to have the program reviewed by an external examiner. They were entitled to know this information, before giving their consent. This evidence tends to suggest that Erin's parents were not provided with sufficient information to allow them to give informed consent to the procedure.

Should the ventilation intra-operatively have been different?

Odim testified that he thought that, in providing 100 per cent oxygen after the B-T shunt was opened, McNeill had violated a basic tenet of the ventilation of neonates. He testified that, if the level of oxygen given to Erin had been reduced, her oxygen saturation would have decreased, with a resultant lessening of the excessive blood flow to her lungs. As a further result, Erin's systemic blood pressure would have been increased when the shunt was opened and the problems with low blood pressure and acidosis avoided.

Odim testified that he relied on the anaesthetists for management of oxygenation and ventilation. He said that this had not been a problem in previous cases. He said he told McNeill that there was too much pulmonary blood flow and asked for her help, but he did not inquire about the amount of oxygen being delivered.

This is a serious question. Hudson and Soder, both of whom are anaesthetists, were questioned on this point. Their testimony indicated that there was nothing inappropriate about the amount of oxygen delivered by McNeill during the stage of the operation when the pulmonary blood flow was excessive. It was suggested that lowering the oxygen might have had a positive effect in terms of blood pressure, but this action carried with it other risks.

■ Finding

It is not possible to state on the basis of the evidence what might have happened. However, it can be stated that McNeill's actions were considered reasonable practice. The underlying issue here, as it is in many of the cases under review, is of the extremely low level of communication and heavy reliance by Odium on what he believed to be 'standard practice' in any given situation.

Was the Blalock-Taussig shunt too small?

Cornel questioned Odim's use of a 3.5-millimetre graft, which he said was difficult to work with and could easily occlude. Cornel said that he preferred to use five-millimetre grafts. He said that the artery providing the blood, not the size of the shunt, governed the amount of blood that was shunted. In his report he wrote:

Stark and DeLaval recommend use of larger size grafts and I have found that a 5mm graft can be used in virtually every patient. I have used a 4mm graft on only 2 or 3 occasions. Flow is controlled by the subclavian artery rather than by the graft itself. There is a much higher failure rate in small grafts. (Exhibit 353, page 71)

In his testimony, Duncan said that when he wrote his report, he had not heard of anyone using a 3.5-millimetre shunt. He said that in Vancouver, however, where he had subsequently taken up a position at the British Columbia Children's Hospital, 3.5-millimetre shunts were used in that program, with good results. He testified that the issue was the length, as well as the diameter, of the shunt. A long, thin shunt, he said, was more likely to clog. He said that one reason why there was a good chance of the B-T shunt clogging was the fact that the pulmonary vessels were so small. Soder testified that it was common to use 3.5-millimetre shunts at the Izaak Walton Killam Hospital for Children in Halifax, where he worked.

Giddins was asked if he thought that the shunt was too small.

No, I don't think so. This was a relatively small child, weight of 2.6 kilos. Normally, 3.5 millimetre shunts, in my experience, are standard for normal newborn weights, which is three, 3.5, even 4 kilos. Also she had small lung blood vessels, and the standard size normal newborn size shunt would, I would think, be perfectly adequate for her situation of size and lung blood vessel size. (Evidence, page 4,534)

Giddins was also asked why the central shunt was larger:

Also, going up a size seemed to me, although I don't remember being part of that decision, it seemed to me a very reasonable decision, in view of the fact they had been having difficulties up until that point in the—not at the very beginning, but up until that point with low oxygen saturation levels. In other words, this shunt had potentially more to do than the first one. This shunt would provide more flow to both sides than potentially just one side. (Evidence, page 4,537)

■ Finding

From the testimony that was presented it would appear that the use of a 3.5-millimetre shunt was a reasonable choice, although it led to a higher degree of difficulty for the surgeon.

What led to the shunt failures?

■ Finding

There is no conclusive evidence as to why the B-T shunt and the central shunt failed. The evidence indicates that a B-T shunt was an appropriate choice for this child and that switching to a central shunt was also a reasonable decision. The evidence also indicates that at the outset, both shunts were patent—indeed, following the opening of the B-T shunt, Erin had difficulties with too much blood flow.

Witnesses to this Inquest suggested, without reaching firm conclusions, that Erin's problems were related to underdeveloped (hypoplastic) pulmonary blood vessels, low cardiac output, hypoxia and acidosis. These problems were all inter-related and fed upon one another.

As described above, problems with inadequate blood pressure and cardiac output led to both shunts eventually clotting. It should be noted that Odum experienced difficulties with the central shunt when he tried to close Erin's chest. This speaks to the technical difficulties of this procedure, particularly in ensuring that the shunt does not bend or buckle when the chest is closed.

Questions were raised about technical issues. In their joint report, Cornel and Duncan wrote:

Despite the fact they are not regarded by some as difficult, an aorto-pulmonary shunt is one of the most technically demanding surgeries. The second shunt, despite having been done on bypass, was inadequate at the aortic orifice. (Exhibit 354, page 15)

In his report, Cornel wrote, "The cause of failure of the central shunt is not clear but a technical problem is the most likely." (Exhibit 353, page 72)

This operation was extremely long and accompanied by extensive bleeding. Erin's death was one of these that led Soder to conclude in his report that the:

skill and dexterity of the surgeon performing these operations were insufficient for the challenges of successfully repairing infant hearts with complex malformation. [boldface in the original] (Exhibit 345, page 8)

Should Dr. Andrew Hamilton have assisted in this operation?

■ Finding

It was in response to concerns about Odum's skills that Blanchard informed Postl (and, through Postl, other persons involved in the program) that Hamilton would assist Odum in all neonatal surgery. Hamilton should have been involved in this operation.

What was the cause of death and was it preventable?

Erin had been in the operating room for 12 hours because of all the problems and complications associated with the surgical procedure. This would have left her in a weakened condition. In addition, she experienced severe problems with both clotting and bleeding. The clotting of the central shunt, which cannot be definitively explained, led to a loss of blood flow to her lungs and her eventual heart failure.

■ Finding

Cornel's conclusion that the failure of the central shunt was due to technical problems, combined with Soder's conclusion that the skill and dexterity of the surgeon were not adequate to the challenge of this procedure, clearly suggests that the death was possibly preventable.

REACTIONS TO ERIN'S DEATH

The death of Erin Petkau brought the long-simmering crisis in the Pediatric Cardiac Surgery Program to a head. Her death, coming so quickly after the death of Jesse Maguire and the complications suffered by JR and ID, demoralized almost everyone involved with the program.

Giddins testified that the Petkau case left him saddened, exhausted and perplexed. He said the outcome had shaken his confidence in the program.

I remember being shaken, just in the course of events, that all things considered, particularly in the neonatal intensive care unit, that the outcomes and the efforts involved in the preceding months didn't seem to correlate.

Everybody had been working, extraordinarily busy on numbers of both simple cases, more complicated cases, cases that seemed to go without a hitch and cases that seemed to go with lots of hitches. (Evidence, page 4,581)

Youngson had left the OR before the end of the case, having participated in the Petkau case until 1530 hours, when her shift ended. At the time she left, the operation had been progressing well. She learned of Erin's death from McGilton when she came to work the following morning. Youngson testified that she spent the Christmas holidays in a state of desperation. She resolved that when she returned to work in January, she would contact a co-worker whom she believed knew the then-Minister of Health, James McCrae. Through this person, she intended to contact McCrae and communicate her concerns about the program. However, on her first day back at work in January, Youngson was informed by Swartz that the program had been suspended pending an external review, rendering her plan to approach the Minister of Health unnecessary.

McGilton had been involved in the Petkau case until Erin was transferred from the OR to the NICU. When McGilton arrived for work the following morning, she asked how the baby was doing. When Odim told her that the Erin had died, McGilton testified that she broke into tears.

I just, I left and I went into another room where there wasn't anything going on and kind of got myself together.

I went to the desk, and Karin Dixon asked me if I was okay, and I lost it again.

She phoned Isobel and said that I should go see her, and I did talk to her later that day, and told her that I absolutely couldn't do it anymore. That was it. And what had happened, and it was—she said that she would talk to somebody and do something, but I don't know who she talked to. (Evidence, page 10,648)

Following this conversation, Boyle spoke with Postl:

There was a case booked for the next day, and ICU was very busy, there was some insistence that that case be done. And I said, Brian, I can't ask those nurses to go back in there, I just can't do that. I said, we are three days, four days before Christmas, ICU is full, we don't have a bed there, we have two kids already, cardiac kids in the unit, or what it was. I said it is hard, I can't find extra staff to staff at this time, and most of all I couldn't get the nurses to go in. (Evidence, pages 32,712–32,713)

McNeill said that when she heard that Erin had died, she experienced a sense of total frustration.

I think, I mean, it was an accumulation of things up until then. We had had some events in cases that we had been doing over the fall that were difficult to understand or were concerning, and we

were involved in this process of review that at times felt inadequate, and almost impotent really, and to be involved again on a personal level with a patient who died, just mounted to that sort of feeling. I felt really we weren't progressing, or we hadn't made any strides forward from where we had been in the couple of months before. (Evidence, page 13,653)

She decided that she would withdraw from pediatric cardiac anaesthesia. Before taking any action on this determination, she spoke with Seshia, who questioned her about the course of the operation. Seshia then met with Postl.

I told Dr. Postl that we had now had problems with two babies with B-T shunts. I told him that we had a baby who was paralyzed, okay, following an arterial switch, which he already knew, and he knew about Jesse Maguire. I indicated that ethically, I was also speaking generically for my colleagues, that we would have difficulty ethically referring a neonate for cardiac surgery here. (Evidence, page 33,583)

Seshia was very disturbed by the fact that two procedures, which in her opinion, were low-risk, had gone so wrong. Postl asked her what she thought should be done. She said that she told him "I don't think we can go on with things the way they are." (Evidence, pages 33,584–33,585) Postl agreed to set up a meeting for later that day.

Seshia then met with McNeill and Swartz, who told her of their concerns over mortality with the program. The two anaesthetists also told Seshia of their concerns about Odim's problems with cannulation and the duration of the procedures.

In his testimony, Postl said he believed that it was on this morning, not earlier in December, that Casiro came to him with his concerns with the program.

POSTL CALLS A MEETING

Later that day, Postl convened a meeting in the HSC's Community Services Building on William Avenue. Present at this meeting were the pediatric section heads involved in the program: Seshia, Giddins, Ullyot and Kesselman.

It should be noted that no one from the Department of Surgery was present. Giddins said that he indicated that it was inappropriate for Odim not to be at the meeting. He said that if Odim was not going to be present, he felt he should not participate. Postl testified that, in response, he told Giddins 'to sit down', that those present were there to discuss the outcomes and that he was expected to participate (Evidence, page 35,566).

Postl told those in attendance that he thought the Pediatric Cardiac Surgery Program should be shut down and asked if they had any thoughts on that. He recalled that all of them agreed, although Giddins did so reluctantly because, as Postl recalled, he was not sure that there was support from the data to make such a decision.

Seshia indicated that the neonatal staff was losing confidence in the Pediatric Cardiac Surgery Program. She spoke both of the deaths of patients and the extended stays in ICU of those infants who survived surgery. Others brought up concerns with the length of bypass times and problems with pacemakers. It became apparent that the neonatologists had lost confidence in the program and were reluctant to refer even emergency cases to it.

A decision was made that such cases would, for the immediate future, be referred out of province. Since no elective operations were scheduled for the Christmas period, this meant that the program was temporarily inactive. Those at the meeting expressed the hope that the PCS program would be reviewed by Lindsay when he arrived in Winnipeg in January 1995.

According to Postl's testimony, the question was raised as to what would happen if the Department of Surgery chose to keep the program active. Postl indicated that his response at the meeting was that he would instruct all Section Heads of the Department of Pediatrics not to participate in the program.

Postl telephoned Craig and Blanchard and informed them of the conclusion reached at the meeting of his section heads. Craig was supportive. Blanchard accepted the decision, although the nature of the program's suspension was not determined at that point. Blanchard took it upon himself to speak with Odim. He told Postl that he would encourage Odim to take his holidays. The following day, Postl informed Wright of the decision. On December 22, Blanchard issued a memorandum stating that Odim would be on vacation for two weeks (Exhibit 19, Document 271).

Blanchard testified that he spoke with Odim, on either December 21 or December 22.

Well, I can't remember the details of it either, but we reviewed the particular case briefly, and then I told him that there has been a crisis of confidence, and it is not going to be possible to carry on in the near future. And I suggested to him, that being the case, he should take advantage of the gap and take a proper holiday. (Evidence, page 36,667)

In his testimony, Odim recalled that the meeting was with Postl, not Blanchard.

And I was called into Dr. Postl's office and he told me at that point that the program was going to suspend its activities, that there was too much tension within the hospital coming from the ICU staff and the nursing staff, and that they were simply going to wait until the end of the year when the new chief came to review the program.

And he felt that since they were suspending activities, I probably would need to take a break and I could use a rest, and he suggested that I take a vacation, you know, take my Christmas holidays. (Evidence, page 26,351)

Odim testified that this decision came as a surprise to him. He said that he did not ask Postl any detailed questions about who had raised the concerns.

It was clear that I was having difficulty rounding the troops towards my ends and my goals and my concept of a team. And it seemed that decisions were just being postponed and postponed, and I was sort of beginning to wonder whether it was really going to happen. And that was sort of my state of mind, and I did not get into a question and answer dialogue with them as to who and, you know, what group, what facet? (Evidence, page 26,354)

Erin Petkau was not the last child to undergo a procedure in the PCS program in Winnipeg, however. On December 21, Odim performed a scheduled ligation of a PDA on a two-and-a-half-year-old child. He performed this surgery after being up all night with Erin Petkau and taking a brief nap at the hospital. On December 22, he implanted a pacemaker in a five-year-old child.

The autumn and early winter had been a tragic and difficult period for everyone involved in this program. In September, the Wiseman Committee had released a report indicating that, after a period of review, serious communication issues had been resolved and the program was ready to undertake high-risk operations. However, by the end of September, Odim had written a letter that indicated a deep sense of frustration and

a lack of confidence in his colleagues. This lack of confidence was reciprocated and only increased, as difficulties arose in the operating room and in the intensive care units.

Professionals are expected to rise above personal animosities. However, a team that is meant to perform pediatric cardiac surgery cannot function successfully in the absence of trust and confidence. Nothing was done in the Wiseman Committee to examine the roots of the distrust that program members felt towards each other. Little took place after the Pediatric Cardiac Surgery Program returned to full service to ensure that the team functioned as a team. This became increasingly apparent to the department heads throughout the autumn of 1994 and led to their decision to commission an external review. The decision to have Hamilton assist at Odim's operations represented a positive move in response to concerns and recommendations from a variety of people involved in the program. When Erin Petkau died following an operation in which Hamilton should have been asked to assist, the issues of surgical outcomes and lack of faith in the surgeon came together once more. The department heads had little choice but to stop the program, pending the outcome of a review.