

Chapter 6



THE RESTART OF PEDIATRIC CARDIAC SURGERY IN 1994

JANUARY 1, 1994,
TO MAY 17, 1994

PROBLEMS FROM THE BEGINNING

1993 had been a hard year for the Pediatric Cardiac Surgery Program at the Winnipeg Health Sciences Centre (HSC). The program had lost its director, its surgeon and all but one of its cardiologists. In retrospect it appears that there was confusion as to who was going to be responsible for monitoring and assessing the new surgeon's surgical performance. Finally, the hospital was in the throes of a large-scale structural re-organization that engaged the attention and energies of many key people involved in the Pediatric Cardiac Surgery Program.

Stemming partially from these difficulties, 1994 was to be a year of tragedy for all associated with the program. Twelve children died, conflicts arose among many of the people involved with the program and, by the end of the year, hospital officials had moved to suspend it. The program has never been restarted.

This chapter describes and discusses the events of the first four-and-a-half months of 1994, concluding with the events of mid-May 1994, when the entire group of pediatric cardiac anaesthetists at the HSC announced that they would not provide service to the program unless a review was undertaken. In particular, the chapter focuses on five children who died while undergoing, or shortly after undergoing, pediatric cardiac surgery at the HSC. Those deaths in particular seem to have been at the centre of the anaesthetists' decision.

However, the events of 1994 must be seen as being more than a series of discrete operations with successful or unsuccessful outcomes. While each child's experience with the pediatric cardiac surgery program was unique, a number of issues arose during the investigation of each case, and many of them repeated themselves. These include a lack of preparation and orientation before the resumption of surgery in February, the lack of attention to building and maintaining a functioning team, problems with decision-making (particularly in terms of case selection), questions of experience and skill levels, confusion over roles and responsibilities, a lack of monitoring of the program and a lack of post-operative analysis of problems.

These are complex and inter-related issues and they do not always lead to simple conclusions. For this reason, this chapter will also discuss in detail many issues concerning the structure and functioning of the Pediatric Cardiac Surgery Program in general, as well as examining five individual deaths.

THE START-UP

JANUARY 1994

When Dr. Jonah Odum accepted a position with the HSC in November 1993, it was expected that he would take up his appointment in January 1994. His arrival however, was delayed until the beginning of February. Odum had to complete research work he was involved in at Harvard, as well as arrange a move to a new city. As an American citizen, Odum also had to acquire a work permit from the Canadian government. Before a permit would be issued, the HSC had to demonstrate to federal immigration officials that it had tried to find a suitable Canadian for the position and that there were none. At one point, HSC officials had to seek the assistance of provincial politicians to resolve the matter.

Orientation and integration

Dr. Robert Blanchard, head of the HSC Department of Surgery, and Dr. Agnes Bishop, head of the Department of Pediatrics, were the line managers responsible for the PCS program. The program faced the following difficulties:

- The VCHC had only one cardiologist
- The director of the Variety Children's Heart Centre was a junior cardiologist who only held the position in an acting capacity
- The surgeon was at the start of his career and new to the HSC
- There were no other pediatric cardiac surgeons on staff to mentor or monitor Odum
- The rest of the surgical team had not worked together for six months.

It is worthwhile addressing the issues identified above in detail.

The VCHC had only one cardiologist

Where there had once been four cardiologists at the VCHC, there was now only one. That one cardiologist, Dr. Niels Giddins, had a large clinical workload and very few people to whom he could turn for support. He would have been extremely overworked for the first half of 1994, if his only responsibility had been to provide cardiology services. However, he was also the acting director of the VCHC.

Giddins was so busy that, even after the program gained access to a transesophageal echocardiography probe in 1994, he did not have the time to become familiar with its operation.

The director of the Variety Children’s Heart Centre was a junior cardiologist who only held the position in an acting capacity

No evidence was presented to this Inquest to suggest that Giddins was ever properly prepared for the responsibilities that he had to shoulder when he took over the position of medical director of the Variety Children’s Heart Centre.

The VCHC was largely the creation of Giddins’s predecessor, Dr. George Collins. A senior cardiologist, with international experience, Collins had shaped the Centre and had been able to act as a mentor to the other cardiologists and to the previous surgeon, Dr. Kim Duncan. Perhaps without fully realizing it, the heads of surgery and pediatrics had allowed Collins to exercise monitoring functions that were properly theirs. It does not appear that anyone ever directly told Giddins that he was responsible for supervising surgical outcomes in the program, a responsibility for which he lacked both the time and experience. Giddins said that he was “never given a distinct list by Dr. Collins or Dr. Bishop of a formal set of administrative responsibilities.” (Evidence, page 3,303)

Bishop did recognize that Giddins was being asked to shoulder a considerable burden, for she relieved him of many of his HSC and University of Manitoba duties.

The surgeon was at the start of his career and new to the HSC

Odim was not a newcomer to surgery. He had trained in a number of major urban hospitals in North America. However, he had limited experience as a primary surgeon, had rarely acted in a supervisory capacity and had never held a senior position before coming to Winnipeg. On the face of the evidence, it is clear that he had also always worked in large programs, with access to considerable resources. While the HSC is by no means a primitive institution, its pediatric cardiac surgery program did not have the same caseload nor the same resources as had been available to the program in Boston, where Odum had most recently trained.

As events developed, it also soon became apparent that there were institutional protocols at the HSC that differed from those in the institutions where Odum had trained. These differences were to lead to confusion and, at times, conflict, between Odum and the other staff at the HSC. These conflicts might have been avoidable with a proper orientation session, since it appears that Odum often became aware of the HSC’s protocols only after the fact.

In some measure, Odum must take responsibility for this lack of familiarity with the HSC’s limitations and differences. He ought to have taken it upon himself to become fully aware of the limitations and peculiarities of the HSC. He need not have accepted them; there may well have been good reason for change. However, as the service chief, he should have known of them before the team resumed surgery in February. In fact, in a number of instances, Odum rejected more than one opportunity to learn more about the peculiarities of the HSC or shape the program to fit his image of how a program ought to run. These opportunities will be discussed in this chapter.

However, of greater concern is the fact that no one in the HSC appears to have undertaken to provide Odum with an organized and systematic orientation. Duncan, Odum’s predecessor, had not been asked to provide a written orientation that could be given to whoever succeeded him. Nor, it appeared, did Odum ever contact Duncan to gain any insight as to what he could expect in Winnipeg.

There were no other pediatric cardiac surgeons on staff to mentor or monitor Odim

Odim was also assuming a position that was unique within the structure of the hospital—one that lacked the usual support associated with surgery in other surgical programs. Neither Blanchard nor the acting head of cardiovascular and thoracic surgery, Dr. Helmut Unruh, were pediatric cardiac surgeons. The only experienced pediatric cardiac surgeon to assist Odim, if he should face any technical or clinical difficulties, was Dr. Jary Barwinsky, whose own experience did not include operating on neonates and small children.

In light of these issues, the situation in early 1994 therefore clearly called for a careful reintroduction of pediatric cardiac surgery. Attention should have been paid to both mentoring and monitoring Odim and Giddins, as they took on new and difficult responsibilities. Instead, it appears that in large measure both men were left to sink or swim. Blanchard, Bishop and Unruh did not appear to appreciate the sudden loss of the leadership role that Collins had played at the Centre. They appear to have assumed that the VCHC would simply continue to run without their direct involvement, even though it now had a new and overworked director.

There were a number of factors that contributed to the lack of attention paid to orientation. The major players overseeing the PCS program at the beginning of 1994 were either distracted by other matters or were under the impression that other persons were seeing to such an orientation. In addition, Bishop was immersed in other pressing issues, particularly the changes being implemented by the hospital as a result of the Curran Report.

In short, no one appeared to believe that it was his or her responsibility to plan for the orientation and integration of the new surgeon. As department heads, Blanchard and Bishop must bear the responsibility for this failure. In addition, both Unruh and Giddins should have taken steps to develop a planned orientation and integration. At a broader level, however, the administration of the HSC as a whole should have ensured that there was a more formalized orientation of new doctors. The practice of the HSC in 1994 was to leave such matters to the initiative of individual department heads. Many contemporary institutions, on the other hand, provide a more structured orientation for all new staff.

There was a second orientation issue that needed to be addressed. Not only was the changeover from Duncan to Odim poorly handled, but the changeover at the top of the Variety Children's Heart Centre from Collins to Giddins was also not well managed.

FEBRUARY 1994

The restart of the program

Odim took up his duties on February 14, 1994, and performed his first operation on February 28. By March he was performing very complex operations. Until May 1994, when the program was reduced in scope, it would appear that only one pediatric cardiac surgery patient was referred out of province. When compared with the way that Collins helped to ease Duncan into his role as a pediatric cardiac surgeon, this has to be seen as a very rapid start.

Three inter-related issues from this period are deserving of discussion. These are the lack of attention that was paid to team building, the cool response that was given to those nurses who sought orientation sessions to prepare themselves for working with Odum and the approach that was taken to case selection.

Team building

Operations are not performed simply by a collection of individual professionals, but by teams, which require a high degree of trust and strong communication. Teamwork improves over time, through the experience of working together. For this reason, any time there is a hiatus or a new member is introduced to the team, particularly as key a member as the surgeon, the team must undergo a process of rebuilding. As was noted in Chapter Five, the pre-surgical preparation set up at the VCHC by Duncan and Collins involved a series of meetings where team members prepared as a team for the forthcoming surgery. In addition, there were post-operative meetings that served as a forum for discussion of outcomes. Collins and Duncan had worked hard to develop a feeling of trust and open communication, as they recognized that without these, such meetings could easily turn into acrimonious encounters or simply become routine events where difficult questions were avoided and not addressed.

It is worthwhile comparing the startup of February 1994 with the sort of team building that had taken place under Collins. After de la Rocha's departure, Collins and Barwinsky had spent a number of months preparing for the restart of pediatric cardiac surgery. During this preparatory period, steps had been undertaken to ensure that proper equipment was in place, that staff were appropriately trained and that a general awareness of the program's direction and goals was developed, so that all people 'were on the same page' when pediatric cardiac surgery was recommenced. Collins had organized training sessions with nurses and throughout his tenure had met regularly with the surgeon and other medical personnel involved in the cases to assess how things were evolving. Pre-operative meetings were held at which the types of cases that were going to be scheduled for surgery were discussed and the nature of the various operative procedures was outlined. Opportunities were provided at these meetings for members who were going to participate in the program to ask questions and information was shared. Little of that occurred before Odum began to operate in 1994.

Despite the importance of understanding how a surgical team functions, little attention seems to be paid to the issue by the medical institutions that use teams. That was the case for the Pediatric Cardiac Surgery Program at the Children's Hospital in early 1994.

While Giddins was consumed by his workload, as the acting medical director for the Centre, he held a major responsibility for ensuring that the restart of the program in February 1994 took place smoothly and carefully. Odum, as the chief surgeon for the Pediatric Cardiac Surgery Program, also had a responsibility to do so, but seemed to other staff—especially the nurses—to be oblivious to its importance. The failure to ensure that the program started carefully and methodically was to come back to haunt the hospital throughout the year.

The nurses' attempts to initiate an orientation

Shortly after Odim arrived in Winnipeg, Giddins introduced him at a meeting of senior nursing staff. After that meeting, Giddins believed that Odim would arrange his own meetings with other members of the operating-room team, such as the anaesthetists and the nurses. From the evidence, it appears that Odim did eventually meet with most of the team personnel. However, the meeting with the senior nursing staff amounted to the only event approaching a formal orientation that Odim ever received.

The problems with the lack of a proper startup can best be understood in the light of efforts of members of the nursing staff to initiate a proper orientation session with Odim. Before any operations were undertaken, Odim attended a meeting with heads of each nursing department with whom he was to work. According to Donna Feser, the pediatric intensive care unit (PICU) manager, this meeting was attended by the nursing heads of that unit, the neonatal intensive care unit (NICU), nursing director Isobel Boyle and Joan Borton of the VCHC. Each of the nurses gave a description of how their units operated. Feser testified that at this meeting she informed Odim that the PICU was a closed unit. She also said that at this meeting she asked him about his approaches to post-operative care. She testified:

I was interested in what he needed from the nursing staff post-operatively, if there was anything special or anything different that we needed to know in order to look after his patients. Because, as we all know from experience, each doctor usually has preferences.

Q: Right.

A: And will have certain little things that they like to have done, or certain things in place, or certain things available to them. And I asked him, and he said really nothing, nothing special. He did point out, though, that he had information from Boston, that he had some, he had information that he would give us from Boston that detailed pre-op and post-operative care. (Evidence, pages 29,815–29,816)

Feser said that Odim eventually provided her with an academic article written by three doctors. She said this was not the sort of surgeon-specific information for which she was looking.

What I expected was information on what his expectations were pre-op, what they were post-op, and any additional information that he felt we should know in order to better look after his patients. And after looking through it, it was just another article, it really wasn't helpful. (Evidence, page 29,817)

This was to become a recurring issue for the PICU and the NICU nurses. Feser testified that Odim only visited the PICU ward itself a few days before performing his first operation, and the visit was the result of her prompting.

The NICU nurses had similar experiences with Odim. Senior NICU nurse Joan Armitage said that the staff in the NICU sent a memo to Odim requesting specific information from him about his approach to surgery. She gave this description in her testimony of the type of information that the NICU staff wanted:

My primary expectation would be that, first of all, Dr. Odim be very specific with us in terms of his philosophies, he needed to tell us that his surgeries were going to be more reparative versus our previous experience had been somewhat more palliative. Therefore, because they were more reparative the children and babies would come back to the units far more critically unstable than we had known before, that we would be dealing with a lot more delayed sternal closures, and that in general the level of our practice would just have to be stepped up just a tiny bit. (Evidence, page 29,413)

She also said she would have expected Odim to present a series of educational in-services to give the NICU nurses an insight into his approach to surgery and post-operative care. Instead, the NICU nurses also received a copy of an academic article. Armitage said it was of no value in preparing the nurses to deal with Odim's patients.

It was information that we already had had with our previous experience, so it certainly didn't tell us what Dr. Odim's approach would be. (Evidence, page 29,412)

In his testimony, Odim explained that the article had been given to him by Dr. G.W. Wernovsky, a Boston doctor under whom he had trained. Odim had asked him for something he could distribute to his new team to allow them to prepare for working with him. It was apparent from his evidence that Odim never did appreciate the lack of utility of the material he provided to the ICU staff.

The relationship between operating-room nurses and the surgeon must be one in which both have a degree of confidence in and an ability to communicate well with each other. They do not have to like each other, but they do have to be able to work well together in order to accomplish the ultimate objective—doing what is best for the patient. Surgeons must be able to assume that those items essential to the performance of the operation will be present. The nurse must be confident that—emergencies aside—there will be no expectations and demands that are not a usual or expected part of the procedure or have not been clearly communicated from the outset.

Senior pediatric operating-room surgical nurse Carol Youngson sought to arrange meetings with Odim and the OR nursing staff to discuss how he wanted things done for the surgical procedures which he was going to perform. In addition, she attempted to organize a dry run in the operating room. She was, however, largely unsuccessful in her efforts to get Odim to work with her in preparation for the initial operations.

She did manage to arrange a meeting with Odim and others, including Carol McGilton and Karin Dixon (the OR unit manager), before the restart of the program. At the meeting, Youngson had hoped to discuss Odim's surgical preferences and his equipment needs, as well as what sort of differences he might bring from his training in Boston to the Children's Hospital OR. However, instead of engaging in such a discussion, Odim simply presented the nurses with a copy of some preference cards that had been prepared for another surgeon in Boston with whom Odim had trained. He told the nurses that they could use those cards, since they represented the approaches to which he was accustomed.

Preference cards are cards or sheets of paper that outline an individual surgeon's wishes or preferences for individual surgical procedures. On each card, specific operations are identified and a brief description of the procedure is set out, along with a list of equipment that the operating-room nursing staff must prepare and have ready. The cards usually set out how equipment is to be handled and prepared. The preferences can also reflect information specific to the surgeon, such as whether a surgeon is right or left-handed, what size gloves he or she wears, whether the surgeon wishes music to be played in the OR, what type of music and so forth.

The OR nurses usually develop and maintain these cards and use them as a checklist in their preparation for a particular operation and for a particular surgeon. The cards are important tools for nurses to ensure that what goes on in the OR goes as smoothly as possible.

While preference cards were in place for the operative procedures undertaken by Duncan, Youngson had not expected Odim to have his own set of preference cards. Indeed, she viewed the meeting that she had organized as the first step towards preparing a set of cards for Odim.

Youngson soon came to the conclusion that the cards that Odim had given her were not helpful. In her testimony she said at times they gave too much detail, at other times too little. And while Odim may have trained with the surgeon for whom the cards were developed, Odim still had his own preferences, which at times varied from the information on the cards. In addition, the cards referred to equipment that was not yet at the HSC and was in some cases not readily available in Canada.

As a result, Youngson chose to use Duncan's preference cards. As Odim performed each specific procedure, Youngson and her staff would use one of Duncan's cards to prepare for the case, amend the card to take into account what Odim needed and then make up a card for Odim.

Odin demonstrated foresight in having arranged to have a set of preference cards. However, the fact that those cards did not appear to reflect his actual preferences and that he did not take the time to engage the OR nurses in a discussion of his preferences foreshadowed other problems that were to arise.

For example, Youngson asked Odim to consider doing a dry run of an operating-room procedure with the OR staff, but was rebuffed. Youngson wanted a dry run so that Odim could familiarize himself with the physical layout of the OR, where equipment went, how lines were arranged, how and where he preferred to stand and for the OR personnel to acclimatize themselves to Odim's approach. In particular, Youngson believed that the physical space and equipment in Winnipeg would not match Odim's previous experiences.

American hospitals are almost always very well equipped, at least from what I heard, always have state of the art equipment. You know, we had good equipment, but I don't know that I could call it state of the art all of the time. (Evidence, page 8,345)

Youngson testified that Odim said he did not think a dry run was necessary. He told her that he was prepared to accommodate himself to the way that the operative staff had done things under the previous surgeon and that they would not have to do things differently. If there was a need to change things, he felt that those matters could be addressed as time went on. While disappointed, in Youngson's view, it was not her place to insist that the surgeon participate in a dry run. Considering that the purpose of having one in the first place was to establish a relationship among team members, including Odim, the surgeon's refusal to participate rendered a practice session without him futile in her view.

Youngson also proposed a dry run when she met with Odim and perfusionist Chris McCudden, later in February 1994. Odim recalled that discussion and testified that he would have agreed to a practice run if McCudden and Youngson had insisted, but he recalled that McCudden was uncertain, while Youngson was not insistent that a dry run be done. McCudden recalled that Youngson had raised the matter and that neither he nor Odim saw the utility of such an exercise.

The meeting between Odim, McCudden and Youngson took place in the OR, again at Youngson's instigation. At that time, McCudden and Odim discussed issues relating to perfusion, while Youngson showed Odim the sorts of cannulas and suturing equipment used at the HSC. At that time she again attempted to determine his preferences. According to her testimony, he gave the same response that he had given when earlier asked to participate in a dry run, namely that he would simply work with the existing equipment.

The perfusion team as a whole met with Odim as well, before the restart of operations. At that meeting, Mike Maas recalled that they also offered to conduct a dry run. Odim turned the offer down, saying he believed it was not necessary.

Odim also attended one of the anaesthetists' Wednesday morning rounds, at their invitation, before the start of the surgical program. At what Dr. Ann McNeill described as a casual meeting, Odim said that he would be willing to adapt to their local methods and approaches, as well as making suggestions for changes.

CASE SELECTION

During the period that Collins was the head of pediatric cardiology at the HSC, pediatric cardiac surgery was carried out by three different surgeons: de la Rocha, Barwinsky and Duncan. Collins ended de la Rocha's Winnipeg career because he was not satisfied with de la Rocha's surgical results. Flowing from his experience with de la Rocha, Collins was careful to ensure that the program never again took on cases that were beyond the skill level of the attending surgeon. This meant, if necessary, erring on the side of caution and sending children out of province.

While the HSC was attempting from the outset of Collins's arrival to establish itself as a heart centre capable of treating any and all patients referred to it, in very few years did the program actually do all possible cases. From its inception, the pediatric cardiac surgery program at the Children's Hospital regularly referred patients to other heart centres in the country, including Saskatoon, Edmonton, Vancouver and Toronto.

While it was always understood that cases could be referred out of province, there also seems to have been an inclination not to refer cases away unless there was a good reason for doing so. What those reasons were seem to have hinged on the question of whether or not the surgeon felt capable (or felt the team was capable) of performing the operation in question. According to Collins, he essentially left the question for Duncan to decide, although Collins seemed not to have been too shy about expressing his view as to whether or not a particular case should be done in Winnipeg.

One would have thought that when a new surgeon arrived in Winnipeg, the entire question of which cases would be done here and which would be sent out of province would be revisited. There is some evidence that this was the case. Odim gave this description of the approach that he and Giddins had agreed upon.

The plan was essentially we would slate the elective cases and we would get a chance to meet families, and then we would tackle the emergencies as they came. So that the program would start up by vetting the elective cases on the slate, meeting with the families, reviewing the data, and booking them. And of course during this period, we would take whatever emergencies came through, like any other service. (Evidence, page 23,948)

Odim said this did not mean they would operate on each emergency, but that they would review it. The only cardiac lesion that Odim said that they expected to have to transfer out (or have an outside surgeon come in to address) was Transposition of the Great Vessels.

Despite Odim's view that this was "understood", there appears to have been remarkably little discussion of this approach with anyone other than Odim and Giddins. None of the anaesthetists could recall Odim

or Giddins discussing the matter of case selection with them before operations resumed. The same could be said of the nursing staff, the perfusionists and staff in the ICU. If there was an agreement on the matter of case selection, then the agreement appears to have included only Odum and Giddins.

At the same time, other staff involved in the program said they ‘assumed’ that the cases the surgeon would be undertaking at the outset would involve only the simplest of lesions. There seemed to be a consensus that the program should and would start off by doing only those cases that presented the lowest risk for morbidity and mortality. However, problems arose when more complex cases were undertaken more quickly than some involved in the program felt was appropriate.

While Odum said the plan was to start with the simpler elective cases, the complexity of the cases being done by the program quickly escalated. Within a month, Odum was performing operations that he described as cases of moderate complexity (the Caribou, Ulumaumi, and Goyal cases, all to be discussed in this chapter). Rather than sending any patients out of province initially, the more complex cases appear to have been simply deferred until later in the program. The problem with deferring pediatric cardiac patients, however, is that eventually—and in some cases sooner than others—the condition of the child will become more critical. In his testimony, Odum said the Caribou and Ulumaumi cases were dealt with because they had become urgent.

At least one member of the VCHC staff was surprised with the lack of formal discussion about the approach that was going to be taken to restarting the program. Nurse clinician Borton testified:

I thought that we would all sit down and find out what his experience had been in terms of slating procedures. I thought we would decide to do simple to complex cases, in that order. I thought he would want to know what we had done before in terms of pre-operatively, and what our routines were. (Evidence, page 18,121)

This did not take place. Within the first four months, Odum had undertaken a first-stage Norwood reconstruction, a particularly difficult procedure. The decision to offer this operation was undertaken by Odum and Giddins without any prior discussion with the neonatologists or the anaesthetists (or any other member of the surgical team).

Given that both Odum and Giddins were new to their positions in 1994 and quite inexperienced, their department heads—Bishop and Blanchard—ought to have ensured that there was a better plan in place, which would restart the program in a staged manner. There does not appear to have been any such instruction or planning.

SUMMARY

At the end of February 1994, the pediatric cardiac surgery program resumed service. While the resulting problems were not yet fully apparent, the program’s structure was clearly flawed. Lines of authority were fractured, team members had not had a chance to develop trust or confidence in one another—indeed, difficulty with communication was already emerging as an issue. Other issues that could have been identified at this point, such as Odum’s concern with the number of anaesthetists or the limitations of the ICU wards, had not been properly flagged. These problems stemmed from the fact that the Department of Surgery and the

Department of Pediatrics had not provided Odim with a strong orientation, while, at the same time, Odim appears to have declined to benefit from the more informal opportunities that had been presented to him.

SURGERY FROM FEBRUARY 28 TO MARCH 14

FEBRUARY 28 – THE CASE OF ST

On February 28, 1994, Odim performed his first surgical procedure in Winnipeg. The patient was a young girl named ST. (In this report, references to children other than the 12 who are the subject of this Inquest will be by initials.) In a closed procedure, Odim tied off a patent ductus arteriosus and repaired an aortic coarctation. The case proceeded smoothly and team members were encouraged by its success. It should be noted that in 1994 over 70 children underwent pediatric cardiac surgery at the HSC. Many of those cases passed without any significant incident. For that reason they are not discussed in this report. From this point on the report will discuss only those cases that give rise to comment.

MARCH 7 – THE CASE OF DR – THE FIRST OPEN-HEART CASE

DR was born on August 23, 1981. When she was nine years old, she was diagnosed with an atrial septal defect and was referred to the Variety Children's Heart Centre for evaluation. On March 7, 1994, DR underwent an operation to close the ASD.

Odim operated on DR one week after performing his first surgical procedure in Winnipeg. This was the first open-heart case he performed in Winnipeg. It was during this procedure that a number of events arose that caused concern for some members of the operating team. The three issues that arose were Odim's lack of familiarity with the OR setup, his problems with cannulation and his treatment of nurses.

Odim's lack of familiarity with the OR setup

In preparing to go on bypass, the surgeon must connect the patient to the cardiopulmonary bypass machine through a series of lines. In Winnipeg the surgeon, after connecting one end of each of the lines to the patient, generally handed most of the lines to a scrub nurse, who handed them to the perfusionist, telling him what each was for. In turn the perfusionist connected the lines to the appropriate bypass machine ports. Because of the cramped nature of the operating room, the surgeon handed some lines directly to the perfusionist, who was generally situated behind the surgeon.

During this operation Youngson concluded, to her surprise, that Odim was having considerable difficulty with the mechanics of the process.

It was just that Dr. Odim didn't seem to know how this all went. And at that point in time, what went through my mind was, this guy has never done this before. And I thought, no, that can't be true, he has come from Boston and Montreal, he has done all of these cases, he must have had lots

of experience. But that was the thing that popped into my mind at that point in time. (Evidence, pages 8,359–8,360)

Nurse Carol McGilton also described Odim as having trouble with the lines.

Youngson felt it necessary to assist Odim by, in effect, giving him direction, while McGilton (who was the second scrub nurse) performed a number of tasks that would normally have been undertaken by Youngson.

He was very polite about it, he thanked me, he seemed appreciative—I won't say impressed by my knowledge, he seemed to acknowledge that I knew what I was doing and sort of went with what I said. I felt kind of odd, I think it was the first time in my experience that I ever told a cardiac surgeon what to do. You know, they don't take to that very well in most instances, so I was a little uncomfortable. (Evidence, page 8,362)

Odin testified that he did not have problems placing the lines but rather asked for guidance from Youngson and chief perfusionist Michael Maas because he was unfamiliar with the setup in the operating theatre. He said that he was trying to modify his approach to the actual physical setup of the OR. He also denied he was confused about how to connect the lines.

In her testimony, Hancock did not agree that Odim seemed not to know where the lines went. She felt that the setup in every OR was different and, since they were a new team, they had to work out all the steps of where things should go. She did not seem to feel that there was anything unusual about the time it took in this case for the lines to be sorted out.

Youngson agreed that Odim did seem to be trying to adapt himself to procedures that were established by his predecessor, Duncan. However, she felt that placement of the lines could have best been reviewed in a dry run, rather than while an operation was actually proceeding and the patient was lying on the operating table with an open chest. There is merit to this view.

Odin's problems with cannulation

Once the lines were in place, the surgeon would perform the task of cannulation. There are different approaches to cannulation. The Winnipeg OR nurses were familiar with the technique that Dr. Kim Duncan had used. In that method, the surgeon placed a clamp on the part of the blood vessel intended as the cannulation site. After cutting a small hole in the clamped portion of the vessel, the surgeon would then slowly release the clamp and insert the cannula into the hole in the vessel.

In the alternative “stab-and-go” technique, the surgeon, without making use of a clamp, would open a hole in the blood vessel with a scalpel and then immediately insert the cannula. This method calls for speed and efficiency. Hesitation or fumbling with the cannula can increase the risk of blood loss.

Youngson, who had never seen the stab-and-go method used on pediatric patients, offered a clamp to Odim when it came time to cannulate. Odim declined to use it, saying he would use the stab-and-go method.

OR staff, such as Youngson, McGilton and McNeill, felt that Odim was not particularly proficient at this form of cannulation. (Even when he used a clamp, which he did later in the year, they thought that he was not proficient at cannulation.) McGilton wondered during the DR case if Odim was nervous or was simply

not used to the HSC equipment. Dave Smith, who was one of the perfusionists, noted with respect to other cases the difficulty that Odim had with cannulation, but concluded that Odim was just rusty.

After noting Odim's difficulty with cannulation, Dr. Ann McNeill was sufficiently concerned to mention it to her anaesthetic colleagues. She felt that, as a fully trained cardiac surgeon, Odim should have been quite familiar with cannulation, and that it should have been second nature to him. She felt that before going into surgery, Odim should have taken steps to familiarize himself with the line procedures that were used in the Children's Hospital, as well as the cannulas that were available.

Hancock, however, did not agree with the criticisms levelled at Odim's cannulation technique. She felt that Odim did know how to cannulate adequately, although she did notice that he sometimes cut the purse-string sutures that were designed to hold the cannula in place and would have to put in new ones. Some of his cannulations were difficult, she said, but she did not believe that Odim's cannulation technique compromised patient safety. She did, however, concede that he needed to improve in this area. She said that if she had had a serious concern with Odim's cannulating techniques, she would have discussed her concerns with him.

Odim said he used the stab-and-go method only for cannulation of bigger children and adults. He said he did so because their aortas can be somewhat calcified and the use of a clamp can crack the calcium and send debris into the bloodstream (and possibly up to the brain). For babies and small children, he said, he always used a clamp to cannulate. Dr. Heinz Reimer (an anaesthetist who worked on several of Odim's cases) and Hancock both recalled that Odim did not start using the clamp technique until halfway through the year. Odim disagreed with that recollection.

While Odim also disputed the evidence of those who expressed concern about his cannulation abilities, he did say that before the DR case, he had last cannulated a child in Boston three months earlier, in December 1993. He acknowledged that he had been doing predominantly clinical research during the last six months of his training in Boston. As a result, he had cannulated only once or twice a month during that period. He disagreed, however, with the suggestion that he was rusty at cannulating.

OR staff at the Children's Hospital had been used to Duncan's method of cannulation, which involved the use of a clamp. Odim's use of a different technique cannot be questioned on the basis that the technique might have been inappropriate. The question of what approach to use to cannulate a child is clearly one best left to the individual surgeon. However, it does seem that there were questions about Odim's mastery of the technique that he did employ.

The issue of Odim's cannulation technique and whether or not he was proficient in it was raised again and again during the course of the proceedings, particularly with regard to several of the 12 patients whose cases were investigated. Poor cannulation can lead to significant blood loss, which is very serious in young children, who have small volumes of blood. Many of the children whose cases are discussed in this report suffered from a variety of blood-loss related problems.

In addition, problems with cannulation can lead to interrupted procedures if cannulas have to be reinserted. Any lengthening of the time of a procedure increases the risk of complications to the child. Finally, if cannulas are not properly inserted, there can also be problems with blood flow to and from the bypass machine, which can create a variety of additional problems for the surgical team to address.

The OR staff at the Children’s Hospital of Winnipeg were unprepared for Odim’s particular approach to surgery in general and were unimpressed with his cannulation ability in particular. These facts undoubtedly were significant contributors to the lack of confidence that team members quickly developed in their new surgeon.

Odim’s treatment of nurses

Odim’s dealings with nurses were to prove problematic throughout 1994. During the course of the year, he and a number of nurses developed antagonistic relationships. The antagonism generally related to differences in opinion about medical issues. However, the relationships also concerned more personal matters. Witnesses testified that, shortly after the restart of the program, Odim made a number of comments that were sexist and of a sexual nature to some of the nurses. Those comments were unprofessional and offensive and, in the context of the hospital setting, demeaning to the nursing profession. Much of what was said during the course of those conversations was heard *in camera*, and is not worthy of repetition. While Odim testified that he had no recollection of having made these comments, the specificity of the recollections of the numerous witnesses who overheard them, and the vagueness of Odim’s denials, all combine to bring about the conclusion that Odim made the remarks as alleged.

Odim also came to resent the way he felt the nurses, and Youngson in particular, tended to compare him with Duncan. This led him to make a number of sarcastic and inappropriate comments about the relationship between the nurses and his predecessor. When operations were not proceeding smoothly, Youngson testified that Odim would turn to her and say he was sure that this was not the way that Duncan would have handled the case.

On another occasion, in an obvious reference to Duncan, Odim sarcastically asked Youngson, in front of other members of the operating team, if she had heard from her “beloved” recently. Odim’s comments could have done little but create a distrustful and negative atmosphere between him and the nurses. Other remarks made by Odim later during the year also contributed to this atmosphere.

THE CASE OF GARY CARIBOU

ISSUES

Gary Caribou’s death, on March 15, 1994, was the first death under consideration by this Inquest. His case gave rise to the following questions:

- Was there an inappropriate delay between the time of his diagnosis and the date of the operation on his heart?
- Was his mother provided with sufficient information to allow her to give informed consent to the procedure?
- Was Gary healthy enough to undergo an operation?
- Did the length of surgery contribute to his death?

- Did a post-operative abdominal drainage procedure contribute to his death?
- What was the cause of death and was it preventable?

BACKGROUND AND DIAGNOSIS

Gary Caribou was an Aboriginal child, born on August 22, 1993, to Charlotte Caribou and Morris Dell of Lynn Lake, Manitoba. His birth appeared normal and without complications.

In November 1993, Gary's mother took him to the Lynn Lake Hospital because he was having difficulty breathing. A chest X-ray showed that he had pneumonia and Gary was treated with an antibiotic and a bronchodilator, both of which seemed to provide some relief for his wheezing and laboured breathing. Dr. Trevor Schlam also identified a heart murmur and referred Gary to Dr. M. Levy in Thompson. In his letter of referral, Schlam asked Levy to check for a congenital heart abnormality and further examine Gary's respiratory problems, which Schlam thought might be cardiac in origin.

Throughout Gary's treatment there were to be differences of opinion amongst all the doctors as to whether the respiratory problems that Gary experienced were solely attributable to his heart condition or if they were due to lung disease.

Gary was transferred to hospital in Thompson on November 30 and stayed until December 3, 1993. He was in respiratory distress and did not respond to bronchodilators or antibiotics. He was also diagnosed with failure to thrive. This is a state of poor health that describes a child's inability to grow and develop in a normal manner and is often associated with heart abnormalities. Children suffering from failure to thrive are susceptible to illnesses and diseases, in addition to the heart problems they might have. The condition needs to be closely monitored to ensure that the child does not deteriorate further.

Doctors in Thompson concluded that Gary had symptoms and signs of heart failure, brought on by a large ventricular septal defect with a fairly large shunt. Tests showed his heart was enlarged. He was treated with diuretics and seemed to improve, with a decrease in his respiratory distress. An appointment was arranged with the Variety Children's Heart Centre.

On December 17, 1993, Giddins saw Gary at the VCHC. By December 20, Giddins confirmed that Gary had:

- a moderately sized ventricular septal defect
- mild enlargement of both ventricles
- a muscular right ventricular outflow tract with muscle bundles.

He noted that there was a large left to right shunt, allowing blood to move inappropriately through the hole between the ventricles. Muscle bundles develop when portions of the heart are required to work harder than normal. These bundles can block or limit the flow of blood in an unhealthy manner, but in Gary's case, there was no actual obstruction to the outflow of blood from the right ventricle (or outflow tract obstruction). Muscle bundles also have implications for cardiac surgery, as their presence can make it more difficult to perform certain operations.

On examination in clinic, Giddins found Gary to be in heart failure. Gary's liver was enlarged. He was also small for his age, weighing only 5.5 kilograms, instead of an expected 6.5 kilograms. Giddins increased the dose of Gary's diuretics and also started him on digoxin, a drug used to treat congestive heart failure by strengthening heart contractions. Giddins did not recommend surgery at that point. He believed that if Gary was treated with aggressive nutritional support, he might grow out of the problem. While he suggested a follow-up assessment in two months, Giddins also added a caution: "The prognosis must be considered to be uncertain." (Exhibit 5, page CAR 2)

Giddins relayed his conclusions to the doctors who had referred Gary to him. However, there is no indication of what Giddins related to Gary's parents at that time. Charlotte Caribou testified that on this initial trip to Winnipeg, she was informed that Gary had a hole in his heart and that the options were to let it close on its own or to perform surgery. She said that Giddins essentially made the decision in favour of waiting. She returned to her home community with the expectation that she would be called back for another appointment.

Charlotte Caribou was not very knowledgeable as to her rights as her son's legal guardian, nor, if her conduct and demeanour on the witness stand is any indication, would she have been very assertive about them. She had spent most of her life in the remote Northern community of Mathias Colomb First Nation. While she was quite conversant in English, she had limited education, and spoke primarily Cree. Furthermore, she had had limited or no experience with this type of situation. As with many people, she said that she relied almost totally on the medical authorities.

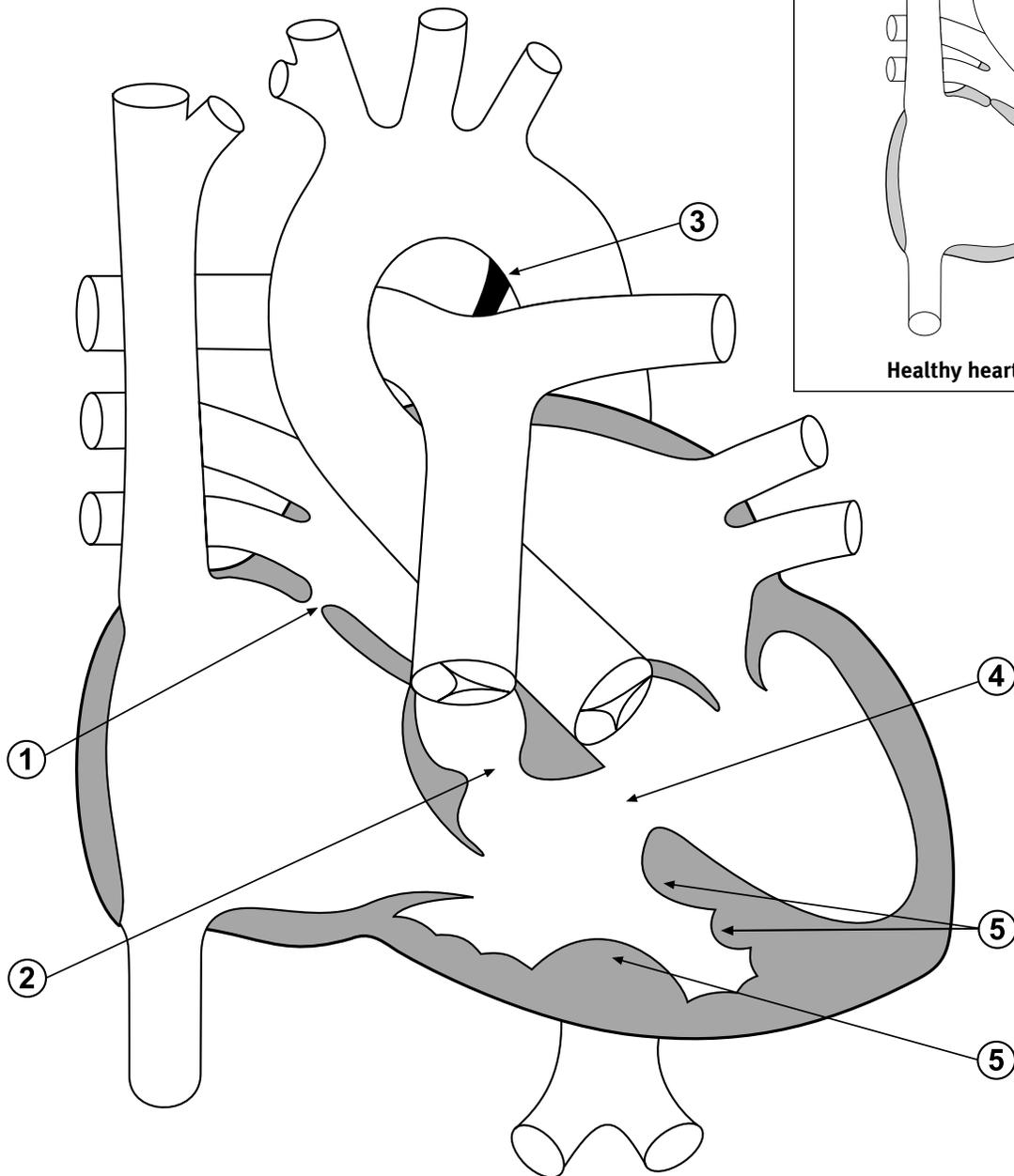
Gary returned to Lynn Lake, where he was re-admitted to hospital on December 27, 1993. There he was treated for two months for failure to thrive and congestive heart failure. During this period, Schlam remained in touch with Giddins and the VCHC. Gary was unable to suck the volumes of formula required to increase his weight. A tube was therefore inserted through his nose and down into his stomach, so that larger volumes of formula could be given through the tube. When attempts were made to give him bolus feeds (or a larger volume at one time), Gary vomited. To prevent further vomiting, he was placed on continuous feeds through the tube into his stomach. This degree of forced feeding had limited success.

THE DECISION TO OPERATE

The possibility of Gary growing out of his heart condition depended on his increasing in weight and size. His low weight, small size, and poor breathing were associated with his poor heart function. Therefore, it is noteworthy that Gary's condition did not improve significantly during the intervening period. He suffered two episodes at the hospital where he had a high fever, although tests did not show that he had developed an infection. He was, however, treated with antibiotics during this period. (In fact, he was receiving antibiotics when he was admitted to the Children's Hospital for surgery.) Gary's increased expiratory wheezing also disturbed the doctors in Thompson. They were not able to determine if his apparent asthma originated from his heart or from a problem in his lungs (Exhibit 5, page CAR 58).

Gary was transferred to the HSC in Winnipeg for assessment on February 28, 1994. On admission to the HSC, his weight was up approximately one kilogram from his December 1993 weight of 5.5 kilograms,

Diagram 6.1 Gary Caribou – pre-operative heart



- 1 – Patent foramen ovale
- 2 – Right ventricular outflow tract obstruction
- 3 – Ligamentum arteriosus (former ductus arteriosus)
- 4 – Ventricular septal defect
- 5 – Abnormal right ventricular muscle bundles

but he was still far below the normal weight for a child of his age. On admission the doctors could hear a great deal of wheezing throughout both lungs, although Gary had fairly good air entry into both lungs.

Gary's case was presented at the March 7 pediatric cardiac surgery conference. A heart catheterization done that day confirmed the earlier findings. However, the catheterization study also demonstrated significant muscle bundles in the right ventricular outflow tract. Odum concluded that surgery was necessary to correct the VSD, which he did not believe would close on its own. He believed Gary was showing signs of congestive heart failure. Odum predicted a stormy course for Gary's recovery because of his frail condition. This would be the first time that Odum would undertake such an operation on his own. It would also be the most difficult case the team had undertaken under Odum's direction to that point.

None of the medical consultants retained by the Inquest disagreed with Giddins's and Odum's diagnosis. Dr. Gary Cornel testified that he believed that by March 7, surgery was the only reasonable choice. He did suggest that Gary was in better condition for surgery earlier than he was on March 14, when surgery was actually performed. Since the delay was to see if Gary could be strengthened for surgery, it would not have been wise to wait any further. However, the question remains as to whether or not the operation should have been carried out in Winnipeg.

CONSENT

On March 9, Odum met with Charlotte Caribou. In a letter to Giddins, he said he discussed the surgical plan to close the VSD in detail with her. Odum said he also discussed how the increased pressures in the ventricles and the borderline pulmonary vascular resistance suggested that the post-operative course might be difficult. In addition, Odum said that he explained all the potential risks to Gary's mother. He indicated that she seemed to understand, and that she gave her verbal and written permission for surgery.

It appears that Charlotte Caribou may have been adequately informed as to Gary's cardiac defects. She was aware that he had a hole between his ventricles that had to be patched. Whether or not she understood or was aware of the other issues that made up the risks that Gary faced is an entirely different question. Importantly, she seems not to have been aware of any concerns about Gary's physical strength or his failure to thrive. Also, she was not aware that there were any issues surrounding the team members and their collective and individual experience.

In his testimony, Odum said he did not discuss with Charlotte Caribou his previous experience in performing this operation. He said it was not his practice to discuss his experience, unless the parents specifically asked him about it. He said this had also been the practice of the people under whom he had trained. As noted in Chapter One, in obtaining consent, professional practice is not the sole determinant of the information that must be provided to the patient or the patient's parents.

Odum's surgical practice (as opposed to the period he spent as a surgical resident) was less than one month's duration when he spoke with Charlotte Caribou. This means that he had only been involved in obtaining consents to perform surgery on his own for little more than three weeks. In other words, Odum's habit of not providing information about his experience was not a practice of long standing, but one that he had recently adopted.

When asked if this meant that the onus was on the parents to ask about his experience, Odim said:

What I'm trying to say is that when I see patients in my office, I don't have a list of my procedures that I have done, a C.V. that I give to my patients as I meet them. We discuss the situation. Many families will ask questions. Some will ask, well, how many have you done; some will not ask how many have you done. It is just not something that's been part of my practice. (Evidence, page 24,069)

Odim said he did not feel that the fact that this was the first time he was performing this procedure as the primary surgeon in a new setting elevated the risk in any fashion. He also said that he did not raise with Charlotte Caribou the possibility of having the operation performed in another centre.

He did acknowledge that experienced surgeons generally have lower risks of morbidity and mortality than do inexperienced surgeons, largely because of the benefits of experience. Odim did not feel, apparently, that such information was something that he ought to have shared with Gary Caribou's mother.

PRE-OPERATIVE CONDITION

While there was little disagreement with the decision to operate on Gary in March, questions have arisen as to whether or not he was in fact healthy enough to undergo surgery. Some of the consulting witnesses who assessed this case raised concerns about whether or not Gary Caribou was suffering from an infection at the time of his operation. If this was the case, then it may not have been appropriate to operate. Cornel, for example, stated that Gary's preoperative status was possibly compromised by an undiagnosed chest infection.

As early as November 1993, it had been noted that Gary was experiencing wheezing throughout both lungs. From the end of December, he had suffered through two bouts of fever while in Lynn Lake and had been treated with antibiotics, although tests had not indicated that there was an infection.

On February 28, when he was readmitted to the HSC, extensive wheezing was again noted, along with moderately severe subcostal and intercostal in-drawing. Subcostal and intercostal in-drawing are indications that a patient is having difficulty breathing. The first seven ribs are attached to the breastbone by costal or rib cartilages. Subcostal means under the rib and intercostal means between the ribs. These terms together describe the situation in which a person's breathing is so difficult that the skin below or between the ribs is sucked in each time the patient takes a breath. Thus, Gary's breathing difficulties were worse than they had been in December.

Gary's liver was also enlarged. This was a sign that he may have had heart failure or he may have had lung congestion from a lung problem that was not related to his heart problem. The enlarged liver could also indicate that, because of the very fast rate at which Gary was breathing, his lungs had become overinflated and were pressing down on his liver.

There was ongoing discussion among Gary's doctors as to whether or not Gary suffered from a lung problem that was primarily due to his heart problem, or if he had a lung problem that was primarily due to reactive airways disease.

Because of the varying opinions as to the cause of Gary's breathing difficulties, there were also differing views as to how this condition should be treated. McNeill testified that there was a question as to whether or not to increase Gary's diuretics. She said that Giddins was of the view that it would make no major difference to Gary's condition, since the primary problem was significant reactive airways disease.

However, the Pediatric Service did, on occasion treat Gary with extra doses of diuretics as needed to cope with his heart failure. In addition, respirologists had concluded that Gary did not have an acute viral infective process but suggested that something more be done to improve his heart condition, which could be in the form of more or different medication. Odum, Giddins and McNeill also concluded that there was no infection but that Gary's breathing problems could not be addressed until his cardiac problems had been dealt with by surgery. McNeill also testified:

What I am saying is the respirologist, the cardiologist and myself all believed that his respiratory status was a combination of primary respiratory reactive airways disease, with a contribution from his cardiac condition. (Evidence, page 13,072)

Gary's breathing problems and the doctors' differences of opinion continued right up until surgery. On March 1, Giddins examined Gary and heard wheezing. He noted that Gary's chest X-ray showed over-inflated lungs, with mild enlargement of the heart. He wrote that the X-ray suggested "signs of more chronic respiratory nature than pulmonary edema." (Exhibit 5, page CAR 81)

Pulmonary edema, or fluid in the lungs, occurs when the heart is in failure. In this condition, blood backs up in the lungs and fluid from the blood passes into the tissues of the lungs. Giddins suggested discontinuing the digoxin and then the Lasix, a diuretic. This drug helps the body get rid of excess fluid and treats pulmonary edema. Giddins indicated that the obstructive airways required treatment. He also suggested doing a test to rule out cystic fibrosis, and consulting with the Respiriology Service.

On March 2, the digoxin was discontinued, but the Lasix was still given twice a day and sometimes an extra dose was required. The report from the chest X-ray taken that day suggested "the findings may be the result of pulmonary edema." (Exhibit 5, page CAR 109)

On March 3, despite being treated with Ventolin, a bronchodilator, Gary had increased respiratory distress. He had decreased air entry in both lungs, with increased wheezing and took longer than normal when exhaling (a sign of increased respiratory difficulty). He had gained 278 grams in three days and 108 grams overnight. (This rapid weight gain was considered a sign of fluid retention.)

At 1445 hours the senior pediatric service resident wrote, "RSV [Respiratory Syncytial Virus test] negative but may have underlying lung disease (obstructive)." (Exhibit 5, page CAR 49) This assessment suggested that Gary's current respiratory status was likely the result of his heart problems and possibly related to discontinuing the digoxin. At the time, Gary was given an extra dose of Lasix.

Later that day, Dr. Salvador, a cardiology resident, saw Gary and determined that his current respiratory distress was not due to sudden heart failure but was the result of either a respiratory infection or his having had a viral infection. Salvador maintained it was too soon after stopping digoxin (24 hours) for Gary's problem to be heart failure. Salvador suggested that Gary not be given any digoxin that day. He added that if the next day it appeared that heart failure was exacerbating the chest condition, Gary should then be treated with digoxin. The results of a chest X-ray taken that day indicated a slight worsening of the pulmonary edema.

On March 4, Giddins wrote in the chart that there was no need for digoxin and commented that there was certainly significant shunting (from the VSD). Dr. K. Bergen noted that although there was still significant wheezing present that day, a change to another bronchodilator, called vaponephrine, had made a significant improvement in Gary's chest. The antibiotic, which had been started in Lynn Lake, was stopped. During this time Gary also continued to have occasional regurgitation and/or vomiting with coughing spells. The tests for cystic fibrosis and RSV infection were negative.

From then until the evening of March 8, Gary's condition remained relatively stable. However his weight increased 400 grams from March 7 to March 8 and an extra dose of Lasix was given in the morning of March 8. Bergen noted, "Lasix in extra doses have [sic] also been used to decrease wheezing secondary to CHF [congestive heart failure] identified by large increase in weight." (Exhibit 5, page CAR 58)

On March 10, a respirologist examined Gary and found he had wheezing when breathing, along with mild in-drawing. His weight had also increased. The same specialist noted that Gary had respiratory symptoms related to his cardiovascular status, but these symptoms were responding to vaponephrine. He also suggested increasing the diuretics and restarting digoxin. It was noted later that day that Gary had an occasional discharge from his nose.

That same afternoon, McNeill saw Gary in order to conduct an anaesthetic assessment. She noted that he was wheezing. He looked distressed, had flaring of his nostrils and in-drawing. (All of these were signs of difficulty with breathing.) McNeill reviewed Gary's test results and concluded that his borderline congestive heart failure was still not being controlled completely. She questioned whether or not his diuretic therapy should be increased pre-operatively. She suggested that post-operatively Gary would likely have poor ventricular function, with increased pulmonary vascular resistance, and that there was an increased risk of respiratory complications. McNeill also noted that she would reassess his clinical status pre-operatively.

When questioned, she said that she returned to reassess Gary but did not record her findings in the chart. She agreed that she should have done so. She said Gary's condition continued to vary and that no single treatment seemed to be able to correct the situation (Evidence, pages 13,084–13,085).

By that evening, Gary was in moderate respiratory distress, with a fair amount of wheezing. Another dose of Lasix was given, as well as vaponephrine, which improved his air entry.

Wheezing was noted again on March 11 and March 14, along with a large amount of nasal discharge, just before surgery. However, no further tests were conducted to see if Gary had a lung infection. Several expert witnesses commented on the decision to operate without checking further for a lung infection. Cornel stated:

The cause of the wheezing was not clear and if there was serious concerns that this was an infectious origin I feel that more viral studies were indicated. I believe this baby's respiratory problems placed him in a higher risk group for surgery. (Exhibit 353, page 11)

It is worth noting here that Gary's mother had not been told that there was any increase in his risk level from his respiratory problems.

A pre-operative infection is a source of potential danger for any patient. In its directions to parents of its patients, the Variety Children's Heart Centre specifically warns parents to watch their child for infections and colds before surgery and to advise medical staff of any such problem on admission. The importance of guarding against colds and other infections has to do with the child's ability to deal with the impact of open-

heart surgery, particularly on lung function. There is also a concern that a child with an infection could pass that infection on to other children in the PICU.

In his testimony, Cornel stated that it was his practice to postpone surgery in the face of an active viral infection.

I am concerned that we should not operate if we don't have to when there is a remedial problem in front of us. So a suggestion of a viral infection makes me back off. And a suggestion can be a running nose, a cough, a fever that is unexplained, or a fever at all.

I like all these symptoms to be clear, because if a child seems to have something mild that is going away, we do not know, without a little time, if that's a precursor to a more serious illness that is coming, or the tail end of something that has just gone. Therefore, I will usually postpone surgery if there is any suspicion of an infection. (Evidence, pages 44,688–44,689)

Dr. Robert Hudson¹ said that Gary “was still not in optimal condition at the time of surgery.” (Exhibit 307, page 1.13) He said that with appropriate therapy it would have been possible to improve his condition. “Therefore, regardless of the etiology of his respiratory distress, he was taken to the OR without optimal treatment of his cardiac and/or pulmonary problems.” (Exhibit 307, page 1.14) He wrote in conclusion that “in my opinion, this patient’s cardiorespiratory problems were not optimally treated before surgery. This is a basic standard of care in elective situations.” (Exhibit 307, page 1.15)

These experts seemed to be suggesting that as a result of his VSD, Gary was in congestive heart failure, and likely had an underlying infection lurking in his lungs. That infection they felt required treatment, or at the very least, further exploration.

Odim and Giddins, on the other hand, indicated that they were of the view that Gary was not suffering from a chest or any other type of infection at the time of the operation. Giddins pointed to the fact that Gary did not have a fever at any time after his admission until the operation and that elevated temperatures were inevitably present whenever there was an infection. Giddins acknowledged that tests for infection were not ordered before the operation but that such tests were not routinely ordered pre-operatively.

Odim similarly said that he saw no signs of an infection and that he felt Gary was in the best condition they could get him in before the operation. Giddins, as well, thought that Gary was not going to get any better and that the longer they waited, the worse his condition was likely to become.

McNeill testified that after speaking with the respirologists and cardiologists, she was satisfied that they had done the best they could to get Gary in the best possible condition for surgery. She did not believe that anything else could have been done pre-operatively to improve his intra-operative or post-operative cardiac function. She agreed with Giddins’s assessment that his cardiac lesion was the key problem contributing to his pre-operative

¹ Dr. Robert John Hudson is a member of the staff of the Department of Anaesthesia at the University of Manitoba and affiliated with St. Boniface General Hospital. Hudson graduated in medicine from the University of Manitoba Medical School in 1977. He interned and was a resident in anaesthesia from 1978 to 1980. He was a clinical fellow in critical-care medicine at the University of California in San Francisco, and was a research fellow in anaesthesia and clinical pharmacology at Stanford University in Palo Alto, California, from 1981 to 1982. He was certified as a specialist in anaesthesia by the Royal College of Physicians and Surgeons of Canada and by the American Board of Anesthesiology in 1983. He was also certified in echocardiography by the College of Physicians and Surgeons of Manitoba in 1994.

At the time of his evidence, Hudson was a full professor in the Department of Anaesthesia, Faculty of Medicine at the University of Manitoba.

Hudson was acknowledged as having special expertise in anaesthesia and was permitted to give expert evidence to the Pediatric Cardiac Surgery Inquest in that area.

status and to his cardiac problems post-operatively. In her testimony, McNeill said that she did not believe that more aggressive treatment would have made any difference in Gary's condition pre-operatively. When asked if ensuring a child was in optimal condition for surgery was a shared responsibility, McNeill testified:

It's a shared responsibility. Between, well, the anaesthetist and whatever medical person is involved, so in these cases, a cardiologist or respirologist, if there are other consultants involved, and the surgeon also has a responsibility that surgical related issues are controlled or treated or dealt with properly. (Evidence, pages 13,795 – 13,797)

When asked if she were unable to resolve the concerns she had about a child's preoperative condition, whose decision it was as to whether or not to give the anaesthetic, McNeill testified:

Well, I mean, the bottom line is that if you do not feel that you can—to give an anaesthetic to any child for any reason, medical, social, technical, whatever, it's our final responsibility or our final judgment to withhold the anaesthetic. (Evidence, page 12,930)

In Gary's case, McNeill spoke to both Giddins and the Respiriology Service before making her decision to go ahead with the anaesthetic. She testified:

So having those views expressed to me, I decided that we would go ahead, accept that his lungs were not dry, and we would perhaps have problems peri-operatively with his respiratory function because of that. Also knowing that his cardiac function was not totally normal because of the lesion that he had, and that we may have post-operative difficulties with contractility given his pre-existing, or pre-operative cardiac function, plus what we were going to be doing to him.

So that would be my assessment of going in, that he was at increased risk for both respiratory and cardiac dysfunction post-operatively. (Evidence, pages 13,098 – 13,099)

CONCLUSION AS TO GARY'S PRE-OPERATIVE STATUS

The decision that Giddins made in the fall of 1993 not to operate until it could be determined whether or not Gary's VSD would close on its own was a reasonable one. Additionally, given Gary's condition at the time of his initial diagnosis, delaying surgery in order to see if his size and strength could be improved through appropriate medical attention was also a reasonable plan.

There is insufficient information on the record to determine if the medical authorities in Lynn Lake were sufficiently attentive to Gary's development. However, it does seem clear that Gary did not gain much size or strength between the time of his initial diagnosis and his next Heart Centre visit. Giddins and Odim concluded that Gary was not going to gain any more strength or size, due in part, at least, to the fact that his cardiac condition had deteriorated to the point where it was interfering with that development. That also seems to be a reasonable conclusion.

There is a difference of opinion between those who participated in Gary's treatment and those who reviewed the case for the Inquest, as to whether or not the operation should have been delayed in order to treat Gary for his lung condition. While Giddins and Odim discounted the possibility of an infection, they did not order appropriate tests to determine if one was present or not.

The possibility of an increased risk to Gary because of his respiratory problems was not discussed with his parents before the operation, although there was opportunity to do so.

THE OPERATION – MARCH 14

Gary was taken to the operating room at 1215 hours on March 14, 1994. The members of the surgical team are set out in the accompanying chart.

TABLE 6.1: Persons involved in the operation on Gary Caribou, March 14, 1994

<i>OR team member</i>	<i>Persons involved</i>
Surgeon	J. Odum
Surgical assistant	B.J. Hancock
Anaesthetists	A. McNeill, H. Grocott (resident)
Anaesthetic nurse	I. Hinam
Scrub nurses	C. Youngson, C. McGilton
Circulating nurses	B. Ziemiński, S. Scott, K. Steindl, A. Glenday
Perfusionists	M. Maas, T. Koga

TABLE 6.2: Length of phases of the operation on Gary Caribou, March 14, 1994

<i>Phase of the operation</i>	<i>Time taken</i>
Induction	1 hour 44 minutes
Bypass	3 hours 46 minutes
Aortic cross-clamp	1 hour 39 minutes
Total surgical time	7 hours 41 minutes
Total operating-room time	9 hours 40 minutes

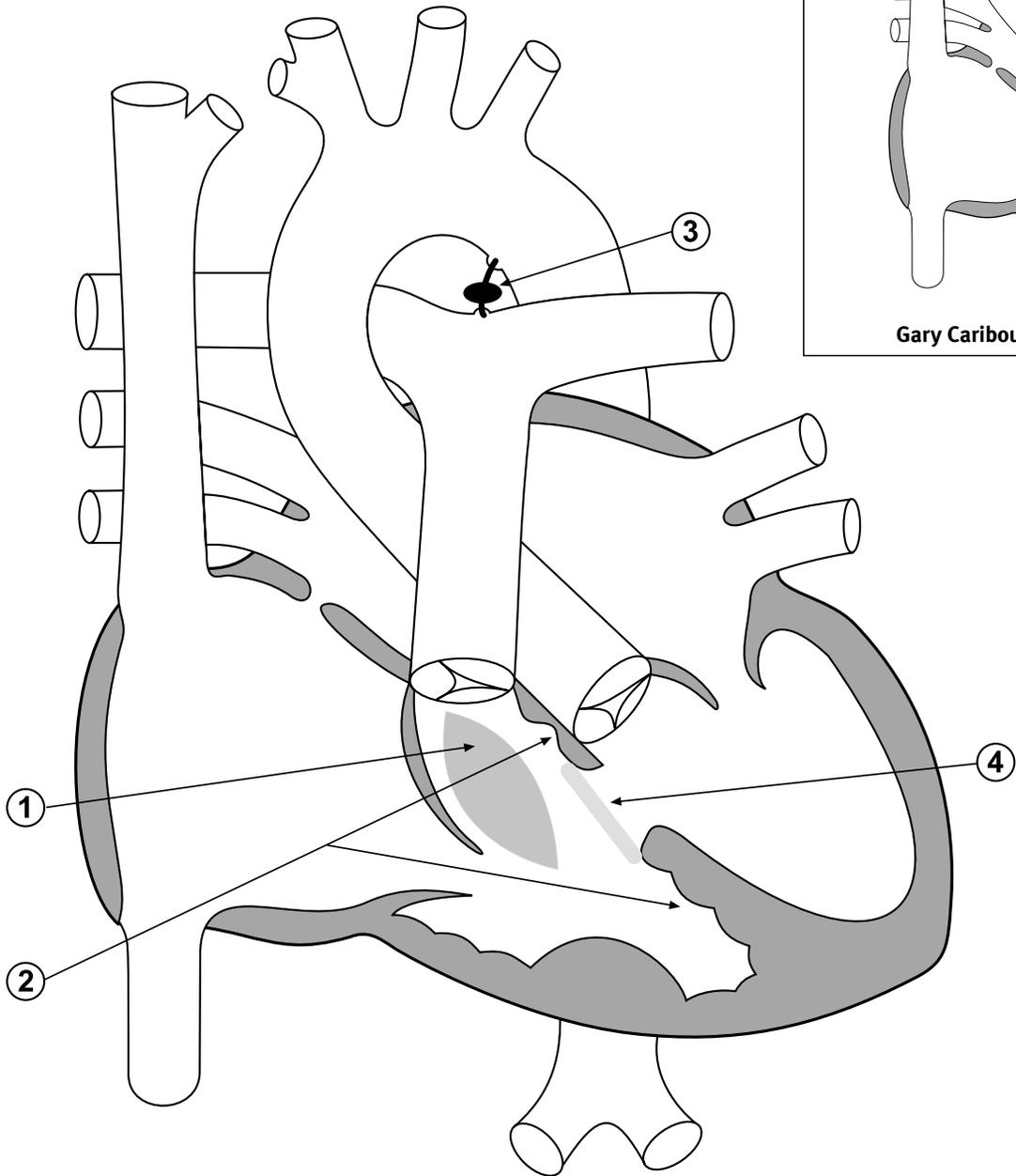
Induction took one hour and forty-four minutes. This was a lengthy time, although there was no evidence to suggest that this contributed to or caused any deterioration in Gary's health. However, the length of induction time in Winnipeg was to become a matter of conflict between Odum and the anaesthetists.

It was difficult to discern from the information on the 1994 perfusion records as to when and how much cardioplegia was given per dose and at what temperature. In his report to this Inquest, Cornel expressed concern about the adequacy of myocardial protection during CPB, since no details of the cardioplegia technique were available.

Cardioplegia is the combination of chemicals and cold solution administered to the heart to stop it from beating and to protect it during a cardiac procedure. The administration of cardioplegia is a matter largely controlled by the surgeon, who decides how and when cardioplegia is administered, but the cardioplegia is actually administered by the perfusionists through the lines connected to the CPB machine.

As events of 1994 unfolded, it became apparent that sometimes, one large dose of cardioplegia might be administered during a case (and might be considered sufficient). At other times, cardioplegia might be administered at the outset of a procedure and then, periodically while the procedure continued, further smaller doses might also be administered.

Diagram 6.2 Gary Caribou – post-operative heart



Gary Caribou – pre-operative heart

- 1 – Pericardium patch on right ventricular outflow tract obstruction with resection of muscle bundles
- 2 – Muscle bundles have been removed or resected from these areas

- 3 – Ligation of ligamentum arteriosus (former ductus arteriosus)
- 4 – Patch closure of ventricular septal defect

The record of how and when cardioplegia was administered in this and other cases was maintained by the perfusionists. However, during 1994 the perfusionists simply recorded the total amounts of cardioplegia given and not if it was administered at different times and doses.

Subsequent to these events, a new record-keeping technique has been put in place whereby each dose is recorded separately. It is this latter information that Cornel was unable to determine from the chart and which he felt was of some importance.

The evidence from the perfusionists and from the surgeon was to the effect that they felt that the administration of cardioplegia in this case was adequate to protect the heart. While Cornel's concerns are valid, they point more to a problem with record-keeping than to a problem with cardiac protection in this case. In some of the later cases, however, there is reason to feel that, based on the information available as to how cardioplegia was administered, cardiac protection may not have been adequate. It would not be reasonable to suggest the same in this case, however.

The operation involved repairing the ventricular septal defect with an artificial patch made of Dacron, patching the right ventricular outflow tract with Gary's own pericardium (tissue taken from the sac surrounding the heart), cutting out the muscle bundles from the right ventricle and, according to Odim's notes, tying off the ductus arteriosus. (Given Gary's age and the fact that no PDA was diagnosed, it is likely this was a ligamentum arteriosus.) The muscle bundles in the right ventricle initially obscured Odim's vision of the VSD. For this reason he decided to gain access to the defect through the outlet tract of the right ventricle. He placed sutures around the VSD. A Dacron patch was then secured to each pair of sutures, seating the patch over the hole. Once the patch was put in place, Odim examined the patent foramen ovale and chose not to close it. At that point the team began the process of preparing to go off bypass.

Odim was questioned on the duration of the operation and the bypass time in particular, both of which were considered to be lengthy. He said that:

there were factors that contributed to the bypass time, and potentially factors that could improve on those times. But after sort of reviewing the types of bypass times for this procedure in Winnipeg over the last eight years, I was not impressed with the fact that this time was appreciably more significant than other bypass times in our system. (Evidence, page 24,104)

He acknowledged that the times would have been shorter in Boston or Montreal, but noted that in those locations there would have been three surgeons involved in the operation. He did not believe the operation had been particularly difficult, but he did state that:

It was certainly longer in the initial period, because I was working with people who, and they were working with me, who didn't know techniques or were used to other techniques in the past. And clearly there is a lot of explanation, a lot of this is what I want you to do and that type of thing going on to get the job done. So my feeling was that these types of things would improve with time, as you worked with the personnel. (Evidence, pages 24,105–24,106)

This was one of Odim's early operations in a new setting, a fact that likely contributed to the length of time of the operation. Additionally, Odim's use of interrupted sutures when attaching patches to the heart might also have lengthened the operation. This suturing technique, known as using a pledged mattress suture (using many separate sutures), is quite acceptable but can lead to extra time being taken while the patient is on bypass. The alternative, a running suture (or continuous suture), can be put in more quickly, but is less secure.

In her testimony, Youngson said that she believed Odim's suture technique added to the length of the operation:

I remember that it was a struggle, it was difficult, especially in such a little person, a little baby, to have so many sutures in the field. They seemed to be getting tangled from time to time and it was just difficult. (Evidence, page 8,374)

Gary experienced several problems during the course of surgery. The first occurred at 1440 hours, when there was an episode of supraventricular tachycardia (a type of abnormal heart beat or arrhythmia in which the heart beats very quickly). This resulted in a severe drop in blood pressure, just before going on bypass at 1455 hours. The tachycardia was successfully treated by cardioversion (or the application of a mild electrical shock). In his report, Hudson suggested it was common for arrhythmias to occur during manipulation or cannulation of the heart. Gary's oxygen saturation was above sixty per cent during bypass until 1645 hours, when the measurement began falling. The saturation declined to 24 per cent at 1815 hours and then began climbing again.

Throughout the procedure, the team was concerned about Gary's low oxygen saturation. However, once he came off bypass and was treated with a drug used to raise blood pressure, his heart was in a normal rhythm. Odim said he was never able to reach a satisfactory conclusion as to why Gary had experienced such low levels of saturation during the operation.

Gary's chest was initially closed in the operating room. Following this, his blood pressure suddenly decreased at 2045 hours. As a result Odim decided to reopen the chest. When he did so, the chest was found to be oozing blood (a sign of coagulopathy—a clotting problem leading to bleeding). This required treatment with a variety of blood products. In his operative report, Odim wrote, "Hemostasis [stopping of bleeding] was difficult to achieve because of ongoing coagulopathy and we therefore decided to delay sternal closure." (Exhibit 5, page CAR 91)

Delayed sternal closure simply means that Odim decided not to close Gary's chest but to let it remain 'open'—but covered with a silastic membrane (a silicone rubber dressing) in order to prevent infection—while Gary recovered from the operation. This technique is one that is often necessitated by the fact that the heart and the area of the chest where the operation is performed can become swollen as a result of surgery, to the point where closing the chest can impair heart performance. Many things can contribute to swollen heart and chest tissues, including inadequate cardiac protection or the length of the procedure. Odim's operations during 1994 were generally longer than what one would normally expect. ICU staff commented that they perceived that more of his patients with delayed sternal closure had to be reopened in the ICU than they had previously experienced. Gary was transferred to the PICU with a silastic dressing covering his chest.

POST-OPERATIVE COURSE

Gary was transferred to the PICU at 2155 hours.

Within forty minutes of his arrival in the PICU, Gary's blood pressure suddenly dropped. He was rapidly given blood products and calcium. Despite this treatment, his condition deteriorated and he had a cardiac arrest at 2242 hours. He was successfully resuscitated with internal cardiac massage, epinephrine and lidocaine.

Gary remained in critical condition, with low blood pressure and high pulmonary pressure. He required the continuous administration of drugs to maintain a stable blood pressure during his entire stay in the

unit. He suffered two additional cardiac arrests during the night, both of which required treatment with open cardiac massage and the administration of multiple bolus injections of blood products.

Early in the morning of March 15 Odum decided to close Gary's chest. This created considerable consternation for the PICU nursing staff. According to Feser, closing a chest is generally considered to be an OR procedure at the HSC. She was asked if the PICU staff had been trained to assist with this procedure.

No, they are not. They are not something that we are trained in or trained for. We are not OR trained nurses, we are not trained in OR setups, how to handle things in that respect. (Evidence, page 29,850)

Feser said she was "flabbergasted" by the development. She felt that the PICU nurses had not been given the proper notification that this procedure would be undertaken. She said that in the past Duncan would have provided notification for far less significant procedures. She also said that the PICU was not properly equipped to reopen or close a patient's chest. At the time, Feser told Odum that the normal procedure was to send a patient to the OR and have an anaesthetist present when the chest was being closed. Despite her concerns, Odum proceeded to close Gary's chest, with the assistance of PICU staff. An anaesthetist was not asked to attend.

Nitric oxide was administered at 0920 hours, with no effect on Gary's pulmonary pressures. The PICU resident noted that Gary had decreased blood pressure, decreased kidney function, decreased liver function and a coagulopathy. A chest X-ray report stated, "There is a further increase in pulmonary density on both sides, most likely the result of a combination of edema and pneumonia, although a significant atelectasis [or collapse of lung tissue] might also be present." (Exhibit 5, page CAR 113)

Later that day, after concluding that Gary was suffering from acute kidney failure and fluid overload, the PICU doctors consulted the Nephrology Service. The nephrology consultant decided to drain some of the fluid in Gary's abdominal area by performing a procedure called peritoneal dialysis. This is the term used to describe a form of dialysis (or artificial kidney function) in which the patient's own abdominal (or peritoneal) cavity is used as the container for the dialysis fluid. The actual procedure involves inserting a catheter into the abdominal cavity and draining off any fluid that might have accumulated there (termed ascitic fluid or ascites). The abdominal cavity is then filled with the dialysis fluid, which cleans the blood of waste products through contact with adjacent blood vessels. After allowing time for the waste products (normally removed by the kidneys) to move into this fluid, the dialysis fluid is then drained out, taking the wastes with it.

The procedure began at approximately 2020 hours, and was carried out by Dr. Paul Grimm, a nephrologist, and his assistant, Dr. Birk. Two hundred and forty millilitres of peritoneal fluid was removed from the abdominal cavity. While the procedure was taking place, however, Gary suffered a significant episode of hypotension (low blood pressure), and his condition quickly deteriorated to the point where the doctors started external massage of his heart. He died at 2209 hours.

AUTOPSY FINDINGS

Despite the policy of the Chief Medical Examiner to hold autopsies in all pediatric intra-operative deaths, an autopsy was not held because Gary's family objected. Charlotte Caribou testified that she withheld her consent because she felt that "they cut him up enough." (Evidence, page 1,955) Her wishes were respected.

It is hard to disagree with the Chief Medical Examiner's decision to respect the wishes of the mother of the dead child. The Chief Medical Examiner, Dr. Peter Markestyn, testified that wishes of the family would be respected if sufficient information as to the cause of death was otherwise available and the attending doctor was prepared to certify the cause of death. In Gary's case, Odum had indicated to the CME's office that he was prepared to certify Gary's cause of death. He wrote that Gary died of cardiac failure (Exhibit 5, page CAR 14).

FINDINGS

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

- Was there an inappropriate delay between the time of Gary's diagnosis and the date of the operation on his heart?
- Was his mother provided with sufficient information to allow her to give informed consent to the procedure?
- Was Gary healthy enough to undergo an operation?
- Did the length of surgery contribute to his death?
- Did the post-operative abdominal drainage procedure contribute to his death?
- What was the cause of death and was it preventable?

Was there an inappropriate delay between the time of Gary's diagnosis and the date of the operation on his heart?

One of the reasons for Gary's death advanced by the consultants engaged to review this case for the Inquest was his weakness at the time of operation. A question therefore arises over the wisdom of not performing surgery in December 1993, when the condition was first diagnosed. Although there was no surgeon available in Winnipeg to perform the operation, arrangements could have been made for Gary to be sent to another heart program in another province.

Giddins testified that experience had shown that in young children, small holes in the heart could close on their own, without any surgical intervention. At the time, Giddins was unable to come to a conclusion as to whether or not surgery was required or if Gary's defect might heal on its own. Giddins believed that the possibility of the holes closing on their own was preferable to surgery, particularly in light of Gary's already frail condition. As well, Giddins thought that Gary's overall condition could be improved with medical assistance.

■ Finding

Allowing a septal defect to heal on its own is a better course than closing it surgically. Surgery has many pitfalls, including a certain degree of risk—albeit sometimes small—of a fatal outcome. Giddins's decision to wait to see if the defect in the septum would close on its own was a sensible medical decision.

Was Gary's mother provided with sufficient information to allow her to give informed consent to the procedure?

■ Finding

No one told Charlotte Caribou that the surgeon had never before performed this type of surgery on this type of patient without supervision. She was unaware of the fact that the surgical team had performed only a very few simple operations together. Additionally, she was never told that her son's chest condition placed him at increased risk for the procedure he was undergoing.

All of this clearly might have influenced a reasonable person in her decision when giving consent to this operation being performed by this surgeon in this setting and therefore, should have been shared with her. The fact that this information was not shared tends to suggest that Gary's mother was not provided with sufficient information to allow her to give informed consent to the procedure.

Was Gary healthy enough to undergo an operation?

Several of the consulting witnesses who testified laid considerable stress on Gary's pre-operative condition. Cornel wrote: "The possibility of an important contribution to the demise by an intercurrent [ongoing] viral illness cannot be ruled out." (Exhibit 353, page 12.) Dr. Walter Duncan² concluded that Gary had experienced severe heart failure pre-operatively and died of lack of blood flow or low cardiac output post-operatively.

■ Finding

There is some evidence to suggest that Gary might have had a chest condition at the time that the operation was scheduled. While some significant features of an infection may not have been present (notably a fever), the evidence suggests that the surgeon and the cardiologist did not gather enough information to completely discount the existence of an infection.

Because of the tremendous importance that has been placed on the impact of infections on the recovery of pediatric cardiac patients, and the valid concerns raised about this issue by the consulting witnesses, Drs Giddins, Odim and McNeill should have ensured that proper tests were conducted to exclude the possibility of a chest infection before proceeding with the operation.

² Dr. Walter J. Duncan was, at the time of his testimony, a member of the staff of the Department of Pediatrics at the British Columbia Children's Hospital. A 1974 graduate of the College of Medicine at the University of Saskatchewan, Duncan interned at St. Paul's Hospital in 1975. From 1975 to 1982, he was at the Hospital for Sick Children in Toronto: as a resident in pediatrics (1975–1977), resident in pediatric cardiology (1977–1978), and clinical fellow in cardiology (1978–1979). He was certified as a fellow of the Royal College of Physicians and Surgeons of Canada in pediatrics. He was certified in general pediatrics by the American Board of Pediatrics in 1980, and was also certified by the Royal College of Physicians and Surgeons of Canada in pediatric cardiology in 1981. He held the positions of assistant professor of pediatric cardiology and pediatrics (July 1979 to June 1982) at the University of Toronto and was the section head of echocardiography during that time at the Hospital for Sick Children.

In 1982 he was appointed associate professor and then professor in 1988 in the Department of Pediatrics, Faculty of Medicine, University of Saskatchewan. He then was appointed professor in the Department of Pediatrics at the University of Ottawa and chief of the Division of Cardiology at Children's Hospital of Eastern Ontario.

In 1998 he was appointed to the Department of Pediatrics at the University of British Columbia and joined the staff of the British Columbia Children's Hospital.

He was acknowledged as having special expertise in pediatric cardiology and was permitted to give evidence to the Inquest in that area.

Did the length of surgery contribute to his death?

Considerable weight was also placed on the damage that was done to Gary by the length of the procedure.

Hudson wrote that:

... the need to leave the chest open because the patient cannot tolerate the hemodynamic effects of sternal closure is also more common after unduly prolonged CPB. Such severe cardiac failure in the early post CPB period suggests that there was significant myocardial injury during CPB. (Exhibit 307, page 1.14)

In their joint report, Cornel and Duncan stated that:

The etiology of the demise of this child remains uncertain. Contributing factors may have been an abnormal coagulation status, abnormal lung function and a relatively long surgical procedure. (Exhibit 354, page 2)

Dr. Christian Soder³ indicated in his report for this Inquest that:

The skill and dexterity of the surgeon performing these operations were insufficient for the challenge of successfully repairing infant hearts with complex malformations. Surgical factors were the prime determinants of fatal outcome in 9 of the 12 deaths. (Boldface in original) (Exhibit 345, page 8)

The case of Gary Caribou was one of the nine that Soder identified in which surgical factors were a prime determinant in a fatal outcome. In particular, he identified the lengthy bypass and cross-clamp time, and the excessive bleeding.

■ Finding

While a clear cause of death cannot firmly be established, it appears from the available evidence that the child was in a significantly compromised state when he entered the operating room, and the length of the operation seems to have been a significant contributing factor in his death. The evidence suggests that the length of the operation appears to have been directly related to the ability and inexperience of the surgeon.

Did a post-operative abdominal drainage procedure contribute to his death?

During the course of this Inquest, questions were raised about the peritoneal dialysis. The wisdom of the rapid drainage of a large volume of peritoneal or ascitic fluid was questioned by Cornel. In his view, given

³ Dr. Christian Max Soder was born in Switzerland and graduated from the University of Alberta Medical School in 1975. He interned at the University of Alberta Hospital in 1976 in pediatrics, and was a resident in pediatrics in 1977. He took a position as resident in anaesthesia at the University of Toronto in 1977 and in 1978 was a resident in anaesthesia at the Toronto Hospital for Sick Children. In 1979 he became a fellow in pediatric intensive care at the Hospital for Sick Children and in 1980 was a resident in internal medicine at the Toronto General Hospital and a chief resident in anaesthesia at St. Michael's Hospital in Toronto.

A fellow of the Royal College of Physicians of Canada, he received a specialist certificate in pediatrics in May 1980 and a specialist certificate in anaesthesia in September 1980.

At the time of giving his evidence, Soder was on the full-time medical staff of Isaac Walton Killam Children's Hospital in Halifax, Nova Scotia, was an associate professor in the Department of Anaesthesia at Dalhousie University, a lecturer in the Department of Pediatrics at Dalhousie and chief of the Department of Anaesthesia at Isaac Walton Killam Grace Health Centre. He was also the director of intensive care at Isaac Walton Killam Grace and the medical director of the STARS NS (Shock Trauma Air Rescue Society) in Nova Scotia. He was a medical adviser as well with the Department of Respiratory Therapy at Isaac Walton Killam Grace. His publication and presentation list was extensive. Soder was permitted to give expert evidence with respect to anaesthetic and intensive-care issues that arose in a review of the cases before the Pediatric Cardiac Surgery Inquest.

Gary's fragile state, any significant change in blood pressures would be difficult for Gary to cope with. In his written evidence, Cornel stated: "Rapid drainage of a large volume of ascitic fluid following the insertion of peritoneal dialysis catheter was associated with the final demise of the infant." (Exhibit 353, page 12)

The dialysis procedure involved draining ascitic fluid, injecting dialysis fluid into Gary's abdominal cavity, and then draining the dialysis fluid to relieve pressures and remove impurities. What was most important during the procedure was to ensure that there was close monitoring of any changes in pressure in the abdomen (from the fluid) on the function of the heart. This would appear as changes in heart rate and blood pressure. For example, a sudden increase or decrease in fluid pressure in the abdomen could produce a decrease in blood flow to the internal organs and to the heart itself. Thus, the key to the procedure was to ensure that flow of fluid into or out of the abdomen occurred at a rate that the heart could handle.

In many other facilities, including the Children's Hospital of Eastern Ontario where Cornel is the chief of pediatric cardiac surgery, a surgeon carries out the dialysis procedure on post-cardiac surgery patients, with the assistance of a nephrologist. In particular, Cornel said, it was important to limit the volume of liquid used and the rate at which it was drained.

Grimm testified that this was a procedure that he had performed many times previously and that in Gary's case he had followed all of the usual procedures. Grimm was assisted by Birk and by at least one PICU nurse. Neither Odim nor Hancock, (the intensivist on duty that evening) nor Dr. Ellsabete Doyle, the PICU resident, were present during the procedure.

Grimm was of the view that nothing done in the course of the dialysis procedure was a factor in Gary's death. He rejected any suggestion that the removal of fluid was conducted too quickly, pointing to the fact that while the initial fluid was being removed, Gary's blood pressure did not change, and there was no adverse reaction to the insertion of the catheter. He pointed out that the initial volume of dialysis fluid had been inserted and removed without incident as well, and that the second volume was in Gary's abdomen when Gary began to deteriorate. However, Grimm did not disagree with Cornel's view about the need to proceed slowly in the removal and replacement of fluids in this type of procedure.

■ Finding

It would appear that nothing Grimm did during the dialysis procedure was inappropriate. It is uncertain as to whether or not the dialysis procedure caused such a sudden change in Gary's blood pressure from which he was unable to recover. However, it would have been desirable for Odim or one of the intensivists to have been present while this procedure was being undertaken.

What was the cause of death and was it preventable?

It is unfortunate that an autopsy was not held. It will remain unclear if the medical issues that were part of Gary's demise could have been better determined. Coming to a conclusion as to exactly why Gary died will remain speculative, although there is sufficient information to reach some solid conclusions.

■ Findings

There is no suggestion that the surgical repair of the VSD was not successful. Although an autopsy was not performed, the available evidence suggests that the VSD was successfully patched.

However, the operation appears to have taken too long. The evidence suggests that the lengthy bypass and cross-clamp times may have significantly compromised the baby's chances of recovery. There seems to have been little more that could have been done for the baby post-operatively than was done in this case.

For these reasons, the evidence suggests that this death was possibly preventable.

POST-MORTEM ISSUES

After this case, Feser spoke with Dr. Murray Kesselman, the head of the PICU, to express her unhappiness with the fact that Gary's chest was closed in the unit. Kesselman testified that after speaking with Odim, he concluded that such closures were appropriate in the unit. In some cases, however, patients were taken back to the operating room in order to have their chests closed with the assistance of an OR team.

Feser, along with Borton and Jannell Plouffe, arranged to meet with Odim on March 22, one week after the operation. Feser felt that she needed more information from Odim about how cases would be managed post-operatively. The Caribou case had led her to believe she needed much more information than Odim had provided at their previous meeting. For the March 22 meeting, Feser and her staff had prepared a detailed list of issues that they wanted information about. Feser testified that at this meeting she also reviewed with Odim the PICU policies on the writing of medical orders. She said Odim agreed to provide a list of items to be placed in what was referred to as a cardiac bin. The bin would store the equipment needed for procedures Odim intended to perform in the PICU. Odim did not provide such a list until the end of April. On May 6, the bin was in place. However, in the intervening period, a number of very significant events had taken place, particularly the death of another child (Jessica Ulimaumi) in the PICU.

Feser testified that at the meeting on March 22, she and her staff raised a number of other concerns. She said that the PICU nurses were having difficulty with Odim's request that they call him at 0600 hours to update him on what sort of night his patient had experienced. While she recognized the benefit to the surgeon, she said the unit did not have the resources to carry this out at that time of day.

According to Feser's testimony, another issue that was discussed at this meeting was the prescribing of medications, and particularly pain relief, to patients in the PICU. Odim wished to prescribe what are referred to as bolus doses, which are given intermittently. The practice in the PICU was to use a continuous infusion. This difference later arose as a point of conflict between Odim and other doctors in the PICU. At that time, Feser said she made it clear to Odim that while he could make his preference known, the decision about medication was made by the attending intensivist. This was because the PICU was a closed ward. At the meeting, it was decided that a standard order form would be set up for Odim to use at the end of an operation. According to Feser, Odim was to:

... fill it out, but our physicians would still review it and they would still be responsible for writing orders. So they would take off of this sheet what was applicable, what we were going to use, but still write, doctors would still write their own orders post-op. (Evidence, page 29,910)

Feser also raised concerns about the types of monitoring lines that Odim used. Monitoring lines (also called intracardiac lines) are tiny tubes connected to the heart, which pass through the chest wall and are connected to monitoring devices. They are important as a means for staff to observe cardiac performance.

Normally, such lines come in one piece from a manufacturer with a connector at one end. The end without a connector is passed through the chest wall and inserted into the heart or into a blood vessel attached to the heart. The connector is then used to connect the line to a measuring device. Odim's method of insertion involved disassembling the lines.

Feser testified:

We raised a couple of concerns in doing this. I mean, there is a risk obviously – not obviously, it may be not obvious to people, but it was obvious to me from previous experience that when these lines came apart there was a risk for bleeding, there was a risk for infection. (Evidence, pages 29,902–29,903)

Reimer described the problem:

If I can describe briefly the way these are inserted, generally they are, the lines themselves are a long piece of tubing and then on the end of them is a connector called a [Luer] lock connector which is a sort of locking-type connector that allows it to be connected with other lines or with monitoring devices and so on.

However, the way they were inserted is they were inserted sort of from inside out. That is, they were placed in the cardiac chamber first, and then they had to be brought through the skin so they could be used. It's not possible to bring a connector up through the skin, or the connector that is on the catheter.

What Dr. Odim would do is cut the connector off so he could get it through the chest wall and through the skin, and then he would suture another type of—another piece of tubing with a built-in connector and he would sort of telescope the two together and tie a suture around them to secure them and that's what he would use.

One of the problems that was being expressed, and this was actually more of an ICU issue than an intra-operative issue, is that these lines were coming apart right at that connection. (Evidence, pages 19,341–19,342)

Reimer said that Duncan had approached the issue differently and in a manner that did not require that the connector be cut off. Because the tube had to pass through the skin and the chest wall, it had to be inserted into the end of a large needle and the needle then pulled the line through the chest wall in a manner that allowed the line to remain intact. Duncan had worked from the inside out, passing the needle from inside the chest to the outside, inserting the tubing into the needle and then pulling it back through the chest wall. He then connected the end of the line to the chest.

Feser testified that Odim said that the lines he used were what he was accustomed to using in Boston and that he found them to be quicker and more efficient to use. This issue would recur during the rest of the year.

Reimer said that because the problem of the intracardiac lines coming apart was a recurring one, he had proposed a solution to Odim.

The suggestion I made to him is that there is a particular type of epidural catheter that we use in anaesthesia, where we have a similar issue, and that the catheter can't be inserted with a connector already on it.

So, the way that it is designed is that there is a connector that can be attached after the catheter is inserted, and it's got—it's designed in such a fashion that it will be secure when the connector is put on after insertion.

I showed him this, and I suggested this is something that he might want to try.

Q. Did you actually show him the equipment?

A. Yes.

Q. Did you demonstrate sort of how the equipment worked?

A. I'm not sure I took it out of the package, but I certainly showed him all the parts and how it worked.

Q. All right. What was his reaction when you showed him this equipment?

A. I mean he looked at it, and—but ultimately said that he didn't think he was having a real problem with what he was using at present and didn't see a need to change. And he was also concerned about the expense of the epidural catheters. (Evidence, pages 19,342–19,343)

According to Reimer, catheters cost between two and three dollars. He testified that Odum did not believe that his method was creating any problems and continued to employ it throughout 1994.

THE CASE OF VINAY GOYAL — HIS FIRST OPERATION

ISSUES

Vinay Goyal died on April 18, 1994, after undergoing two operations in the spring of 1994 (one on March 17 and one on April 18) and after experiencing a lengthy stay in the PICU. His case gives rise to the following issues:

- Were Vinay's parents provided with sufficient information to allow them to give informed consent to the procedure?
- Would Vinay have been taken to surgery with a potential infection if his parents had not intervened?
- Did the surgeon demonstrate the skills and experience necessary to undertake this high-risk surgery?
- What was the cause of death and was it preventable?

This case will be discussed in two sections. The first section deals with events leading up to the first operation. The second section (which is separated from the first by a discussion of the case of Jessica Ulimaumi) deals with the second operation. The findings are placed at the end of the second section.

BACKGROUND AND DIAGNOSIS

Vinay Goyal was born March 2, 1990, in St. Boniface Hospital, to Vipin and Sheena Goyal. He was diagnosed at birth with a number of heart defects, including Tetralogy of Fallot. He also had Trisomy-21 or Down's syndrome. After 16 days in hospital, he was discharged home on no specific treatment or medication.

On Monday, June 4, 1990, Vinay was seen in the cardiology clinic at the Winnipeg VCHC. He was breathing rapidly, and his mother reported that his lips were blue when feeding. When seen again on November 12, 1990, following his family's return from India, Vinay appeared deeply cyanosed. He also had

clubbing of his fingers. (Clubbing occurs in the fingers and toes of some patients with heart or lung diseases. The tips of the fingers and toes become bulbous and swollen, giving them a ‘club-like’ appearance.)

An echocardiogram showed:

- a ventricular septal defect
- right ventricular hypertrophy
- significant subvalvular muscular obstruction (This meant that the passageway to the pulmonary valve was obstructed by a build-up of muscle.)
- a small pulmonary valve with a degree of supra-pulmonary valve narrowing (This means that the pulmonary artery was slightly narrowed above the valve.)

In addition, his main pulmonary artery and subsequent pulmonary artery branches were small and underdeveloped.

It was determined that Vinay was in urgent need of surgery.

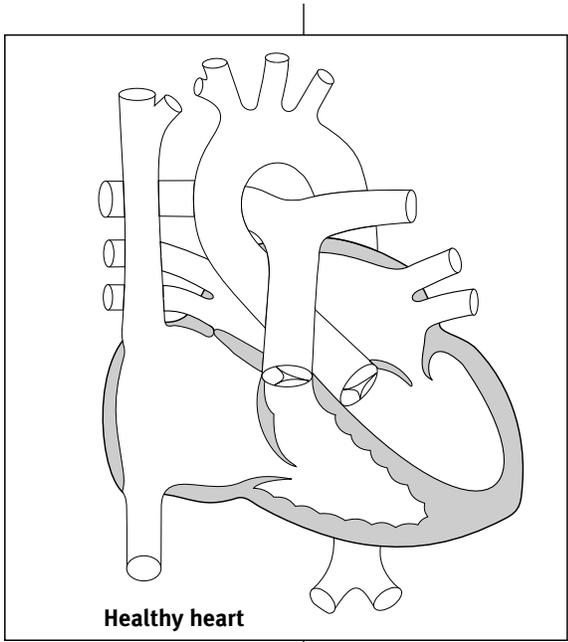
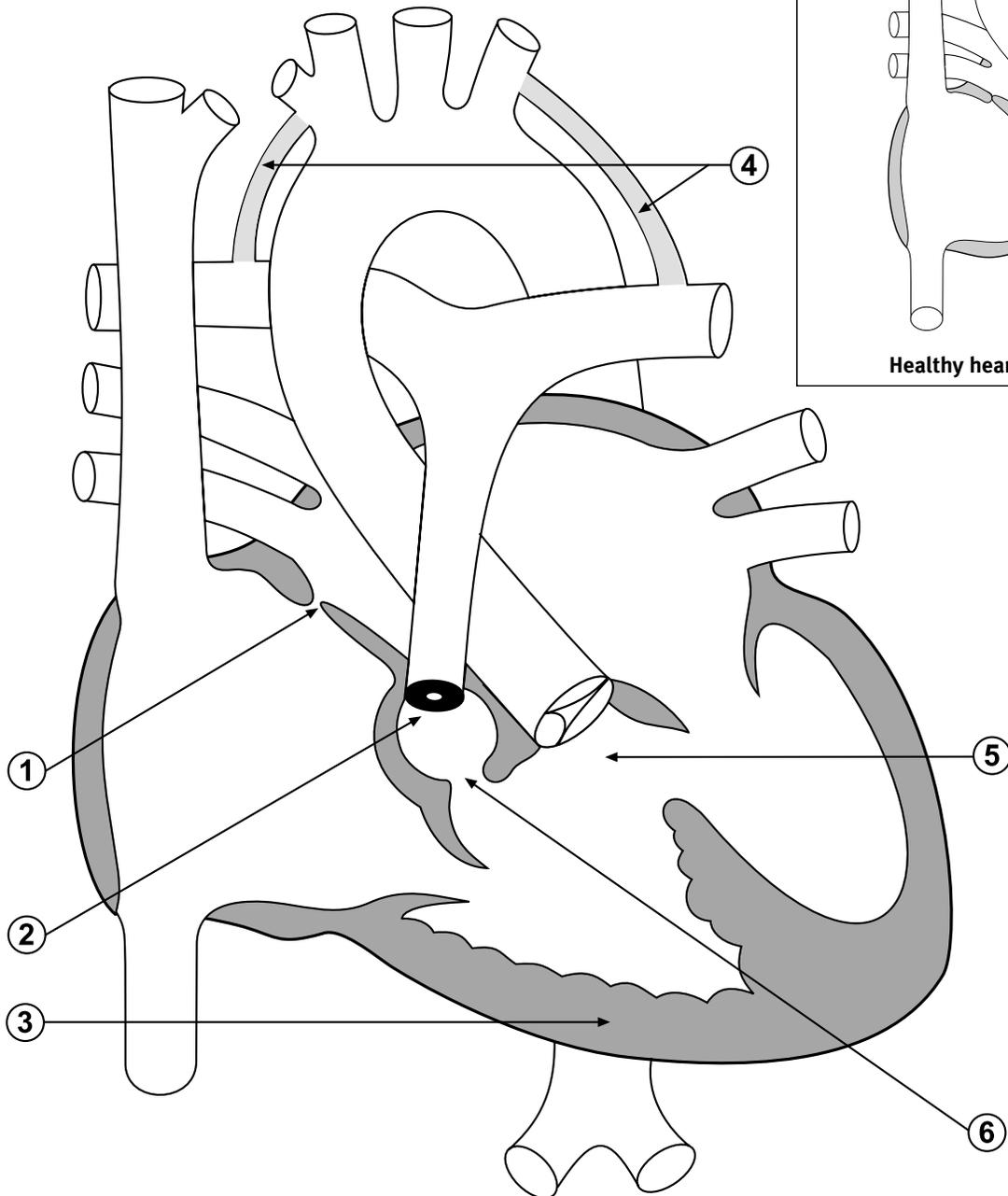
On his November 12 clinic visit, a significant upper respiratory infection was noted. However, surgery was planned for November 26, with the provision that the infection had cleared by that date. Evidently the infection cleared and on November 26, Dr. Kim Duncan placed a Blalock-Taussig (B-T) shunt in Vinay’s heart to assist his heart function. Then, when Vinay was 27 months of age, the first B-T shunt was replaced by a second, larger shunt. The first shunt had been originally scheduled for replacement in June 1992 but the operation had been cancelled to allow investigation of another condition – thrombocytopenia (or a decrease in the number of platelets in the blood).

On July 14, 1992, Dr. Rachel Yanofsky, a hematologist, determined that Vinay had compensatory polycythemia with secondary thrombocytopenia. This condition meant that Vinay had an increase in the number of red blood cells, probably because his heart condition made him cyanotic or lacking in oxygen, so his body produced more red cells to carry more oxygen. As a result of the increase in the number of red blood cells, Vinay appeared to have a reduced number of platelets, but this was because the platelets were actually diluted by the increased number of red blood cells. Yanofsky advised that the operation could go ahead and Vinay could be transfused with platelets if necessary. There were no bleeding problems during the second shunt operation on July 16, 1992.

The long-term medical plan was to undertake a more definitive repair when Vinay was older. As he grew, his increasing cyanosis and decreasing exercise tolerance indicated that a total correction was required. By the fall of 1993, Vinay was clearly cyanotic and clubbed. An October 27, 1993, catheterization showed a Tetralogy-type double outlet right ventricle, nearly complete pulmonary valve atresia with subpulmonary muscular obstruction, and a 14 millimetre non-restrictive subaortic VSD. (A subaortic VSD is a VSD that is found just below the aorta in the septal wall.)

In a November 9, 1993, letter to Dr. W. Robinson, the Goyals’ family doctor, Giddins wrote, “There are no surprises at catheterization, and I believe his anatomy is suitable for definitive repair in the new year (a decision has been made regarding a surgeon who is to start in January).” (Exhibit 7, page GOY 585) At that point Giddins discussed the need for surgery with the Goyals.

Diagram 6.3 Vinay Goyal – pre-operative heart



- 1 – Patent foramen ovale
- 2 – Nearly atretic (or small) pulmonary valve
- 3 – Right ventricular hypertrophy
- 4 – Blalock-Taussig shunts

- 5 – Ventricular septal defect (with overriding aorta)
- 6 – Right ventricular outflow tract obstruction (Subvalvular muscular obstruction)

THE DECISION TO OPERATE

In their testimony, the Goyals exhibited a clear understanding of the medical problems that their child faced. The nature of the repair seems to have been explained to them as fully as possible under the circumstances. In the fall of 1993 they were told that because there was no surgeon in Winnipeg, the operation would have to take place in either Saskatoon or Toronto. The Goyals' recollections of what took place next differ slightly. Vipin Goyal said that the family had opted for an operation in Toronto. Sheena Goyal said the family never reached a final decision. However, the Goyals said that by December they had been contacted by the HSC with the news that a new surgeon had been hired and it would be possible to perform the operation in Winnipeg.

According to the November letter from Giddins to Robinson, Giddins had intended to send Vinay's medical information to Saskatoon when he received word that a new surgeon would be arriving in January 1994. He also indicated that the VCHC nurses had advised the family of this fact. Giddins informed Robinson that he would be arranging for the case to be done in Winnipeg by the new surgeon since, Giddins believed, the family did not want to go out of the province anyway. In her testimony, Borton said the Goyals had been worried about the financial expenses involved in out-of-province surgery.

A February 2, 1994, VCHC checkup revealed no change in Vinay's condition since the previous fall. Giddins, in a letter to Robinson, stated that Vinay "was literally at the top of our list for discussion when our surgeon arrives, and we have reliable word that this will be in the next several days." (Exhibit 7, page GOY 1) Giddins felt that Vinay needed a definitive repair before the end of March. He indicated that if the operation could not be undertaken in Winnipeg then it would be necessary to transfer him out of province.

CONSENT

The Goyals went to the Heart Centre to meet Odim on March 1. Vipin Goyal specifically recalled that his wife asked Odim if he had done this type of procedure before, and was told that he had. Sheena Goyal recalled that Odim said to her that he would not touch a child if he had not done the operation before. Vipin Goyal recalled that he was upset and angry with his wife for asking Odim such a question. He admitted that he had a great respect for doctors and that he was not one to question what they told him.

Sheena Goyal said that she and her husband told Odim on more than one occasion that he was like God to them. Vipin Goyal recalled that Giddins had told him earlier that Odim was coming to Winnipeg from Boston and that he was one of the best. The Goyals also indicated that once the HSC had arranged to have a surgeon in Winnipeg, there was no discussion or suggestion from the VCHC that Vinay be sent out of province.

Odim said he told the Goyals about the risks of being on bypass (bleeding, organ dysfunction, pulmonary problems) and the risk of the procedure (removing the shunts). Odim testified that the longer the bypass time, the higher the probability of problems with these issues, but he said he did not explain that to the Goyals. He only told them that the procedure would take six to eight hours. Odim said he told the Goyals this was a moderate risk case, and that out of a hundred babies, ten might not make it. He also told them about problems with non-fatal complications, and what would happen if Vinay did not have the operation.

There was some discussion as to whether or not the operation should be performed in Winnipeg, and the Goyals asked Odum about his experience. Odum testified that he told them that this was his first position, but that he had trained in centres that had done cases like Vinay's. He also said that he had been intimately involved in both the pre-operative and post-operative care of those types of patients. Odum testified that he did not elaborate to them what he meant by intimately involved. Nor did he actually say that he had been involved in the intra-operative or surgical part of the care of patients like Vinay. When asked of his own experience, he said, "from the operative point of view of issues of doing shunts and doing the procedure, I had experience with a number of cases like Vinay." (Evidence, page 24,318) He testified, however, that he had never placed this type of VSD patch as a primary surgeon. However, he did not provide the Goyals with this information.

The Goyals provided their consent to the procedure. The operation was scheduled for March 17.

Vinay's case was one of some complexity. Odum testified that when the decision was made to perform Vinay's operation in Winnipeg, he did not formally or informally invite other members of the team to raise concerns or to discuss whether or not they felt the team was ready to proceed with this patient. Vinay's case was presented on February 21. However, Giddins and Odum were the only doctors in attendance. In a letter dated March 1, Odum wrote to Giddins, "It is clear the progressive course of cyanosis in this child and his palliated condition require surgical correction. We plan to bring the family and child to clinic for preliminary discussions and evaluations." (Exhibit 7, page GOY 4)

PRE-OPERATIVE CONDITION

Vinay was admitted to the Children's Hospital at 1145 hours on Wednesday, March 16, 1994 for surgical correction of his condition. On examination, Vinay was cyanotic with clubbed fingers. Since March 9 he had been treated with an antibiotic for an upper respiratory tract infection. In Vinay's pre-operative assessment, a physiotherapist heard breath sounds present throughout all lung fields, with a slightly harsh sound, especially in the left upper lobe.

At 1600 hours, Dr. H. Grocott, the anaesthesia resident, examined Vinay's chest and determined that his air entry was clear. He noted the child had had a mild upper respiratory-tract infection a week earlier with a runny nose, but no cough or fever. He assigned Vinay an anaesthetic class of ASA IV and noted that he was fit for anaesthesia. Swartz, the attending anaesthetist, also saw Vinay pre-operatively. She reviewed his history and tried to examine him. Both Grocott and Swartz made entries on the chart that the examination was difficult because Vinay was unco-operative. Swartz listed anticipated problems: arrhythmias (irregular heart rhythm), coagulopathy and right ventricular failure post-operatively. She also assessed the child as ASA IV.

A chest X-ray taken on March 16 indicated that Vinay's lungs appeared essentially normal. The heart remained slightly enlarged, with evidence of right ventricular hypertrophy.

THE OPERATION—MARCH 17

On Thursday morning, Vinay underwent a complete repair of a double outlet right ventricle and Tetralogy of Fallot. The operating team is set out in the accompanying chart.

TABLE 6.3: Persons involved in the operation on Vinay Goyal, March 17, 1994

<i>OR team member</i>	<i>Persons involved</i>
Surgeon	J. Odum
Surgical assistants	B.J. Hancock, I. Al-Githmi (resident)
Anaesthetists	J. Swartz, H. Grocott (resident)
Scrub nurses	C. Youngson, S. Scott
Circulating nurses	C. Weber, B. Zulak, C. McGilton
Perfusionists	M. Maas, T. Koga

In 1992 Dr. Kim Duncan had indicated in a letter to Collins that his long-term plan for Vinay called for a homograft reconstruction of the pulmonary valve in two to three years. A homograft reconstruction involves using cadaver heart tissue to reconstruct the valve. The approach Odum took was a transannular reconstruction. In this procedure, the annulus or ring of the valve is sliced open to widen it and a pericardium patch (a patch taken from the patient's own heart sac) is sutured over the slice to keep the passageway enlarged.

Over time, Vinay's pulmonary valve had become atretic (or non-functional). Odum therefore also performed a pulmonary valvectomy—this involves removal of the atretic pulmonary valve leaflets. Odum explained that he chose not to perform a valve replacement such as Duncan had planned because Vinay's anatomy and physiology would not tolerate the resulting transannular repairs and the regurgitation that might result. As well, Odum said that putting in a valve in a small child meant that the child would have to undergo repeated operations as he grew.

In addition, Odum placed a Dacron patch over the VSD, cut away the muscle in the right ventricle, closed the patent foramen ovale and removed the Blalock-Taussig shunts that Duncan had placed in Vinay.

No witness to this Inquest suggested that there was anything inappropriate in the diagnosis or in Odum's surgical plan.

TABLE 6.4: Length of phases of the operation on Vinay Goyal, March 17, 1994

<i>Phase of the operation</i>	<i>Time taken</i>
Induction	1 hour 13 minutes
Total Bypass	4 hours 19 minutes
Aortic cross-clamp	1 hour 33 minutes
Total surgical time	8 hours 7 minutes
Total operating-room time	10 hours 5 minutes

Fifty-five minutes of partial bypass was required before Vinay was completely weaned from the CPB machine. (Partial bypass is used to support the circulation until the heart functions well enough to allow complete separation from bypass.) It took two attempts and use of inotropic drug support before Vinay could be weaned.

An intra-operative echocardiogram led Giddins to conclude that there was good ventricular performance and an intact VSD patch. However, when transferred to the PICU, Vinay was receiving infusions of three inotropic agents: amrinone, epinephrine and dopamine. The doses of amrinone and epinephrine were moderately large, while the dose of dopamine was relatively low. The use of three inotropes was a sign of the weakened condition of Vinay's heart.

Hudson believed that during the operation there was evidence that the patch had not been successfully applied. One piece of evidence came from the intra-operative measurements of oxygen saturations in various parts of the heart. These measurements showed that the oxygen saturation in the pulmonary artery was ten per cent lower than the level in the right atrium. Such a difference was a sign of a possible leak, leading to shunting. In his report, Hudson wrote:

The most likely site for shunting would be around the VSD patch, because the patent foramen ovale had been closed with sutures. (Exhibit 307, page 3.4)

Hudson also commented on a murmur heard on March 18 in the PICU that also indicated a residual shunt might be present. This murmur had not been heard the day before and was consistent with there being a leak around the patch.

POST-OPERATIVE COURSE

Overall condition

Vinay remained in the PICU for 31 days until he was taken back for a second operation that was required because of a leak in the patch over the VSD. That leak was not confirmed until two weeks after surgery. During Vinay's time in the ICU, his course was complicated and his condition fragile. He suffered recurring respiratory difficulties and, except for the week from March 23 to 30, he remained intubated and ventilated. A series of chest X-rays taken during his month-long stay in the PICU indicated that at various times Vinay was suffering from pulmonary edema (a fluid buildup into the lungs from the heart), atelectasis (a collapse of lung tissue) and/or pneumonia. Treatment of the pulmonary edema started to compromise his kidney function. He had episodes of heart block with a slow heartbeat, which required treatment with a pacemaker. (Heart block occurs when there is a blockage or interruption of the electrical impulses that regulate the heart beat.) He also had recurring fevers and infections that were treated with antibiotics.

Breathing problems

Shortly after Vinay was transferred to the ICU, the Goyals spoke with Odum. They were told that the two to three days immediately after surgery were the most difficult. After Vinay was extubated, he received oxygen by facemask. By March 25 the lower lobe of his left lung had collapsed and a special pressure mask was placed on his face to assist him with his breathing. Sheena Goyal testified that he looked very uncomfortable under this mask.

One day he was okay, and the next morning when I went in, he had that pressure mask on his face, and it was giving [him a] really hard time to breathe. So he couldn't sleep for four days and four

nights when the mask was on his face, and his tongue was out, like he was wanting me to take it out (indicating), but, like I was helpless, I couldn't do anything. I just sat there. (Evidence, page 936)

She asked if the decline in his condition meant that there were problems with the initial operation. According to her testimony, she was assured that all was well. Eventually her son again needed to have mechanical ventilation.

Heart problems

In time Vinay developed biventricular failure, where both ventricles failed to perform their pumping adequately, and required almost continuous inotropic support to sustain his struggling heart. Echocardiograms done on March 21 and March 25 showed a small VSD patch leak. While this leak was possibly tolerable, a March 29 echocardiogram and March 30 cardiac catheterization indicated there was a buckling of the VSD patch. There appeared to be two leaking sites in the VSD patch.

Vinay was suffering from what was termed volume overload—in this case, an excess of blood in his right ventricle. This excess of blood was likely coming from the VSD (which was not fully patched) and through Vinay's pulmonary valve opening. Blood could flow through that valve opening in the incorrect direction because the valve leaflets, which had not been properly formed, had been removed during surgery.

CONCERNS OF THE NURSES AND THE FAMILY

As matters progressed and as Vinay spent more and more time in the PICU without showing signs of improvement, both the nurses and the family became concerned. According to Feser, it was usual for VSD patients to be stable when they entered the PICU and to leave the unit after a two or three-day stay. She became alarmed when this did not occur with Vinay. The family also became more and more concerned as to the care that Vinay was receiving, as well as to whether or not he was improving adequately. At one point, the Goyals called a family friend who was a pediatric cardiologist in Toronto. Their friend called Odim and discussed the case, but there was no indication as to what came of that discussion.

DECISION TO REOPERATE

A heart catheterization showed that Vinay's problems had not been solved and his condition was deteriorating. The problem could be addressed only by either replacing the valve or fixing the leak. Odim chose the latter option. It was made clear to the Goyals that there was no option left but to re-operate on Vinay to correct the leaking patch. The fact that this was a high-risk operation was clear to them. There was no discussion about trying to transfer Vinay to another heart centre. Indeed, the evidence tends to suggest that he was in no condition to be transferred any great distance.

Nonetheless, one would have thought that the option would have been raised with the family. Furthermore, by the time the Goyals were being asked to provide consent to a second operation, which did not take place until April 18, a second child, Jessica Ulimaumi, had died following pediatric cardiac surgery at the HSC.

THE CASE OF JESSICA ULIMAUMI

ISSUES

Jessica Ulimaumi died on March 27, 1994, after undergoing pediatric cardiac surgery on March 24. Her case gives rise to the following issues:

- Was there an inappropriate delay between the time of her diagnosis and the date of the operation on her heart?
- Was Jessica's family provided with sufficient information to allow them to give informed consent to the procedure?
- Was Jessica healthy enough to undergo an operation?
- Did the length of surgery contribute to her death?
- Were the repairs properly carried out?
- Did irregularities in the process of weaning her from ECMO contribute to her death?
- What was the cause of death and was it preventable?
- Should this death have triggered a review of the program?

BACKGROUND AND DIAGNOSIS

Jessica Ulimaumi was an Inuk child born on August 18, 1993, at the Arviat Nursing Station in the Northwest Territories. Jessica had a normal delivery at full term, with no apparent complications. Assessment at birth gave no indication of any heart problems. At the request of her mother, Jessica was adopted by relatives, Emalee and John Ulimaumi.

During a September 3, 1993, medical checkup at the Arviat Nursing Station, an examining nurse heard a loud heart murmur in Jessica's chest. This was confirmed by the visiting general practitioner, Dr. Banach, who referred Jessica to Dr. D. Grewar, in the Department of Pediatrics at St. Boniface Hospital. Tests conducted there revealed enlargement of the heart, increased pulmonary blood flow, and a 10 millimetre (in diameter) ventricular septal defect.

Grewar referred Jessica to the Variety Children's Heart Centre. Accompanied by her mother and an interpreter, she was seen by Giddins on October 1. Jessica's length (54 centimetres) and weight (3.7 kilograms) were low for her age, placing her at the twenty-fifth percentile. Giddins found evidence of mild respiratory distress. Jessica was breathing rapidly at 55 breaths per minute. Her lungs appeared to be overinflated, and she had intercostal in-drawing. These were all signs of breathing difficulties. A heart murmur was heard. Giddins was able to palpate (or feel with his hand) Jessica's liver at a distance of three centimetres below the right costal margin. This was a sign of possible congestive heart failure. However, Jessica's colour and the circulation in her limbs were good.

She was diagnosed as having:

- a five-millimetre-diameter atrial septal defect with a left to right shunt

- mild tricuspid valve regurgitation
- enlargement of the left and right atria, as well as the right ventricle
- prominent right ventricular muscle bundles (which were non-obstructive)
- a nonrestrictive 7–8 millimetre ventricular septal defect with outflow extension and left to right shunting.

The fact that the VSD was nonrestrictive meant that the pressures in Jessica's left and right ventricles were equal, putting Jessica at risk of developing pulmonary hypertension.

In a letter to Grewar dated October 14, Giddins said, "In summary, Jessica is a six week-old infant with a heart which is currently required to work additionally hard due to left to right shunting present at both the atrial and ventricular levels." (Exhibit 13, page ULI 4) He also said he started Jessica on furosemide (Lasix), a diuretic, because she had mild respiratory distress and lived a long way from a hospital. He planned to see her again in early December or sooner, if symptoms of congestive heart failure developed.

In the letter, Giddins gave no indication that Jessica needed surgery. Nor was there any mention of getting Jessica stronger in preparation for possible future surgery. In fact, no specific medical plan was recommended, other than giving her a diuretic and reassessing her in December.

In his evidence as to why he concluded that Jessica did not need surgery at that time, Giddins pointed out, as he had in the Caribou case, that small ASDs and VSDs in young children often closed on their own without surgical intervention. Jessica was also not in congestive heart failure—a state where the heart is failing to meet the needs of the body—and so performing a surgical procedure on her at that time held more risk than doing nothing. It should be noted that evidence presented to this Inquest suggests that Jessica's defect was large, rather than small. Despite this, Cornel, in his testimony said that it was his practice not to operate on patients with a similar problem until it was making them ill. He said that this rarely occurred before six weeks of age and often not until the child was more than seven months old.

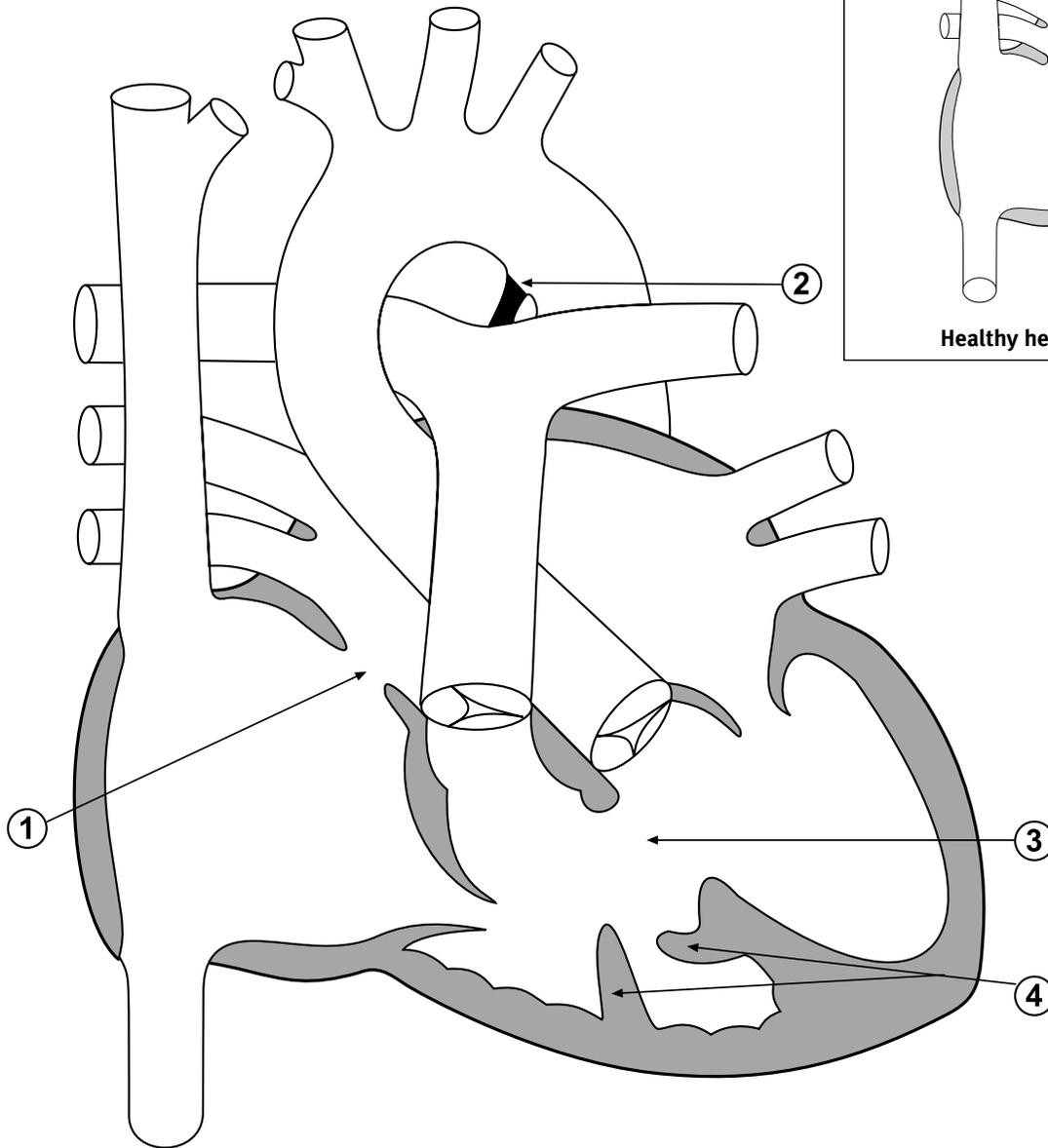
Giddins believed that, given the condition of Jessica's heart, it was essential that her condition be continuously monitored, since congestive heart failure could appear quickly and could be a prelude to death. For that reason, he sent a copy of the letter to Banach and the Arviat Nursing Station. However, Giddins did not specify what additional problems might arise. Jessica returned to Arviat.

In early November, Jessica was again taken to the Arviat Nursing Station. The nurses diagnosed her as having a rapid heart rate and respiratory distress. They arranged to have her seen by Grewar at the St. Boniface Hospital. He in turn referred her to Giddins, who saw her on November 15.

Giddins noticed she had been receiving a lower dose of furosemide than previously ordered and increased it to the amount that he had prescribed. On examination he found that Jessica had gained a pound in weight since her October visit. Her breathing was rapid at 65 breaths per minute, with mild to moderate in-drawing. Her liver span was normal, different from the first examination where it extended below the costal margin. The echocardiogram revealed that the previously noted right ventricular outflow tract musculature (the muscle bundles) was becoming obstructive, causing her heart to work even harder.

In a November 18 letter to Grewar, Giddins wrote, "Jessica continues to demonstrate findings of a considerable left to right shunt at ventricular septal defect level, but it would appear that her lungs are being protected somewhat from high pressures by the right ventricular outflow tract musculature. While she is relatively tachycardic [has a rapid heart beat] and tachypneic [is breathing rapidly], I do not believe she is sig-

Diagram 6.4 Jessica Ulimaumi – pre-operative heart



- 1 – Atrial septal defect
- 2 – Ligamentum arteriosus (former ductus arteriosus)
- 3 – Ventricular septal defect
- 4 – Abnormal right ventricular muscle bundles

nificantly compromised at this time.” (Exhibit 13, page ULI 15) He recommended an increase in her formula concentration and a liquid iron preparation to assist her growth. He indicated that with improved growth, her symptoms might diminish. He also encouraged the nurses at the Arviat Nursing Station to contact him with any concerns and suggested a reassessment appointment in February 1994.

When Jessica returned to Winnipeg in February, tests revealed that the VSD was not closing and that her problems were becoming more serious. She had a minimally restrictive, moderate to large VSD, with a large associated left to right shunt, a restrictive atrial septal defect and biventricular hypertrophy with reduced ventricular compliance (Exhibit 13, page ULI 78). (Her enlarged ventricles were not able to cope with the flow of blood as well as they ought to have.) However, on the Day Care Abstract for her heart catheterization, Giddins also wrote, “No significant ventricular outflow obstruction.” (Exhibit 13, page ULI 21) After seeing the results of the tests Giddins referred Jessica to Odium. By this point, Jessica had also been diagnosed with failure to thrive.

THE DECISION TO OPERATE

On March 1, Odium reviewed the heart catheterization report. In a letter to Giddins, Odium described Jessica as having a minimally restrictive ventricular septal defect, with elevated-end diastolic ventricular pressures (one of the earliest signs of the heart’s failing as a pump), and with no evidence of significant ventricular outflow tract obstruction. He wrote, “This ventricular septal defect clearly will not close on its own.” (Exhibit 13, page ULI 9)

In a separate letter to Giddins, Odium described meeting Jessica and Emalee Ulimami with an interpreter on March 1. He wrote, “I explained to the mother, via the interpreter, the importance of surgical repair of this ventricular septal defect. The mother appeared to understand the necessity for this intervention as well as the risks. We should plan to bring Jessica back within the next four to six weeks in order to repair this lesion. Hopefully by then she might have gained some additional weight.” (Exhibit 13, page ULI 10)

On March 18, Jessica was admitted to the Churchill Health Centre with nausea, vomiting, fever and diarrhea. A chest X-ray showed no signs of congestive heart failure. She was diagnosed as having gastroenteritis and continued to have diarrhea after discharge. Dr. Smith, in Churchill, spoke with Giddins about Jessica’s condition and arrangements were made for Jessica to be admitted to HSC on March 23 in preparation for surgery.

PRE-OPERATIVE CONDITION

Jessica was admitted to the HSC on Wednesday, March 23. The cardiology note written by Dr. Salvador described Jessica as being well hydrated with no congestive heart failure. However, she had lost 500 grams since her last examination at VCHC. He wrote, “She definitely looks wasted. Fit for the OR – need to observe for stools here.” (Exhibit 13, page ULI 54)

The pre-operative physiotherapy assessment indicated that Jessica had good air entry, with a clear chest. No pre-operative concerns were identified. Reimer, the anaesthetist, reviewed the chart and examined Jessica. He wrote, “Increased risk due to age, weight, CHF. Proceed as planned.” (Exhibit 13, page ULI 67)

A chest X-ray done that day showed an enlarged heart with a prominent increase in pulmonary blood flow (as compared with February 16). There were new added densities suggesting atelectasis and possibly some edema in the lung tissue. This was a sign of potential chest problems that could become more severe following surgery.

CONSENT

There are signed forms on the medical chart indicating that Emalee Ulimaumi gave her written consent to the admission of her daughter to the HSC and to her operation on the morning of March 24, 1994. There is also information on the file that an Inuk interpreter assisted Emalee Ulimaumi in understanding what was going on.

The Ulimaumi family did not participate in the Inquest proceedings. Therefore there is no information available from their perspective as to what they were told before signing the consent forms on the medical chart.

THE OPERATION—MARCH 24

The operation took place on Thursday, March 24. Jessica was to undergo a complete repair of the ventricular septal defect with a Dacron patch, suture closure of the atrial septal defect and ligation of the ligamentum arteriosus. The operating team is set out in the accompanying chart.

TABLE 6.5: Persons involved in the operation on Jessica Ulimaumi, March 24, 1994

<i>OR team member</i>	<i>Persons involved</i>
Surgeon	J. Odim
Surgical assistants	B.J. Hancock, I. Al-Githmi (resident)
Anaesthetists	H. Reimer, H. Grocott (resident)
Scrub nurses	C. Youngson, S. Scott
Circulating nurses	B. Zulak, S. Scott, C. Weber
Perfusionists	M. Maas, D. Smith

TABLE 6.6: Length of phases of the operation on Jessica Ulimaumi, March 24, 1994

<i>Phase of the operation</i>	<i>Time taken</i>
Induction	1 hour 12 minutes
Total bypass	8 hours 43 minutes
Aortic cross-clamp	2 hours 7 minutes
Total surgical time	13 hours 33 minutes
Total operating-room time	15 hours 5 minutes

Jessica was weaned from bypass at 1313 hours, after the initial repair. However, the operation was marked by the fact that this initial attempt to repair the VSD was unsuccessful, with evidence of a leak in the VSD patch first shown by the values for oxygen saturation in different parts of the heart. An intra-operative echocardiogram, performed at 1530 hours, demonstrated that there was a residual nonrestrictive left-to-right shunt under the right aortic valve cusp. This confirmed the suspicions that the patch closure of the VSD was incomplete. Odum had to attempt the repair a second time. The second attempt required an additional period of bypass of two hours and twenty-four minutes and an additional aortic cross-clamp time of forty-four minutes.

The total surgical time from beginning the incision to closure of the incision was thirteen hours and thirty-three minutes. Jessica was on bypass a total of six times, with a total CPB time of eight hours and forty-three minutes. She underwent aortic cross-clamping twice, for a total of two hours and seven minutes. The lengthy times were necessitated by the decision to redo the repair. In his report, Soder described the total bypass and cross-clamp times as very prolonged.

In his post-operative note Odum wrote that Jessica had a large VSD and that after the first repair, a large leak was still present. As a result, Jessica required a second period of CPB and aortic cross-clamping.

However, according to Youngson, Odum indicated that one of the problems with the repair was the type of suture that had been provided to him.

One of the comments that Dr. Odum made to me at that point in time was that if he had the right kind of suture material, this would never have happened. And I remember being very upset about that and disturbed by that comment, because I felt that he was blaming me for the fact that we had to go back and redo this repair. (Evidence, page 8,379)

There was no mention of the problems with sutures in the operative note. Also, whether Odum was correct or not in his assessment of the cause of the problem with the repair, it would appear that the time and place to have arranged for appropriate sutures was in February, when Youngson had sought his input.

Following the completion of the second corrective procedure, several unsuccessful attempts were made to wean Jessica from the bypass machine. During each attempt to wean her from the machine, Jessica's heart did not give an adequate response.

Jessica had very high pulmonary pressures that did not respond to the drugs that were administered. In addition, the anaesthetist had problems maintaining adequate ventilation of Jessica's lungs. During investigation of the problem, the endotracheal tube was dislodged from her throat. While reinserting the tube, Reimer had difficulty passing the tube below the vocal cords (Exhibit 13, page ULI 82).

A second intra-operative echocardiogram was done at 2015 hours. This showed no apparent ventricular outflow obstruction, a possible minor residual VSD shunt, a distended atria (with the right side more distended than the left) and mild to moderate tricuspid regurgitation. The lack of any obstruction focused attention on the other problems revealed by the echocardiogram. The possible VSD shunt indicated that the repair might still be incomplete. The distended atria indicated that the ventricles were struggling to pump blood. Hudson said: "The atrial distension indicates biventricular failure, right worse than left." (Exhibit 307, page 2.5) This meant that the ventricles were not capable of performing their proper function. This condition may have resulted from myocardial stunning, itself the result of the prolonged CPB and cross-clamp times.

The decision was made to transfer Jessica to the PICU and then to place her on another form of cardiopulmonary bypass, called an extra-corporeal membrane oxygenation (ECMO) machine. ECMO is a form of long-term cardiopulmonary bypass, which assists the heart in pumping and oxygenating blood. It is used in situations where a patient's heart cannot beat on its own but might recover sufficiently within a short time (up to a few days in length).

At the end of the surgical procedure, the nurses could not account for one suture needle. (This missing needle is of particular significance, since the autopsy report indicated that a needle was found near the cannulation site.) Losing a needle during the course of an operation is, surprisingly, a rather common event. During a cardiac operation, several hundred needles may be used. Cornel testified that it is not unusual for a needle to be dropped on the floor, to be lost in the drapes covering the patient, or even to get caught up in the surgeon's operating gown.

That is not to say that loss of a needle is a routine matter, for there is always cause for concern when this happens. However, the evidence established that needles are often misplaced during a lengthy operation. When a needle is lost and there is reason to suspect that it may have been inadvertently left or dropped inside a patient, a portable X-ray machine may be brought into the operating room to determine if the needle is indeed in the patient. An assessment is done to determine if it is necessary to retrieve the needle immediately or to leave it until the patient's condition has improved. As long as the surgeon is satisfied that the loss of the needle does not place the patient in jeopardy, matters will proceed normally.

In the OR, the nursing staff discovered that the needle was missing when they performed their needle count. At 2106 hours on the day of the operation, Celine Weber, the scrub nurse, filled out a general incident report form reporting a missing needle. She recorded, "Long case 0730 to 2200 hours many needles used (over 170). Surgeon notified, no X-ray done as is low priority at this time." The form was signed by Odim (Exhibit 19, Document 277B).

Odim's recollection was that, given Jessica's heavily compromised condition and the fact that there seemed to be no reason to believe that the needle was left inside her, he felt it was appropriate to send her to the PICU.

How Odim could have known that the needle was not left inside his patient is hard to determine. The evidence shows that the nurses had no idea where the needle was. If it had been inside the patient, an X-ray would probably have disclosed its location. However, while Odim should have ordered a chest X-ray in the operating room, his failure to do so does not seem to have had an impact on Jessica. There is some evidence to suggest that the needle was not left inside Jessica. Several post-operative chest X-rays were taken of her chest area in the PICU. None of them showed the presence of a needle near her heart before her death.

Thus, the OR nurses followed the proper procedure in completing an incident report about the fact that, at the end of the operation, they were unable to locate one needle. What happened to the needle that was lost during the operative procedure has never been resolved satisfactorily. The fact that the lost needle was recorded and reported to Odim was appropriate, and procedures in this regard were followed properly. The likely origin of the needle that was discovered by the autopsy will be dealt with in the discussion of the events surrounding Jessica's death.

POST-OPERATIVE COURSE

Jessica was admitted to the PICU at 2255 hours, accompanied by two anaesthetists, two perfusionists, an OR nurse and Odim. She was extremely pale and her extremities were cool. She had severe fluid retention—her body had retained an additional 1,280 millilitres of fluid while on bypass. The admitting nurse, Colleen Kiesman, recorded that Jessica's face was so swollen (another sign of fluid retention) that she could not open Jessica's eyes to check her pupils.

Jessica continued to experience bleeding problems throughout her stay in the PICU. Her urine had blood in it, and there was continuous bloody oozing from her sternum, which was a sign of a coagulopathy or clotting disorder. Coagulopathy problems can arise when a patient has been on bypass for a long time. Blood cells react differently when pushed through a bypass machine, as opposed to when they are normally pumped by the heart through the lungs. Thus, a lengthy bypass can damage the patient's blood cells and limit their ability to clot. For this reason, a wound that would normally clot quickly can turn into a serious site of bleeding following a prolonged period on bypass. Because ECMO is a type of bypass machine, it can also interfere with blood clotting.

On Friday, Jessica was still on ECMO, which was being operated by a perfusionist. She had continued to bleed from her chest into special drainage tubes. (Chest tubes are inserted post-operatively to drain fluid or air from around the lungs, thus allowing the lungs to expand.) While the blood drained through the chest tubes, the tubes were not the cause of the bleeding. That day, Jessica lost 525 millilitres of blood in six hours. To compensate for this loss, she was given blood transfusions. A chest X-ray showed that her edema and atelectasis were improving, but an echocardiogram showed that her heart was deteriorating. Jessica had increased left atrial and ventricular enlargement, decreased septal motion and a residual VSD shunt.

In an attempt to find a source of bleeding, Odim re-explored Jessica's chest in the PICU on Saturday at 2325 hours. He reported that she had a generalized coagulopathy, some leaking of blood from around the aortic cannula site (to which he added a second suture), and some blood within the mediastinum (the space around the top of the heart in the chest). The blood loss from the chest tubes continued to be enormous. Jessica lost a total of 2,732 millilitres in 24 hours. Numerous transfusions of blood and blood products were given.

On Sunday, March 27 there was still significant oozing of blood where the lines entered Jessica's body. The sternotomy site also continued to ooze, and the chest tube losses totalled 1,220 millilitres of blood over six hours. This means that over a 30-hour period, she lost eight times her blood volume. Odim was concerned about the lack of improvement in her ongoing coagulopathy. He considered it unlikely that her condition would improve while she remained on ECMO. Indeed, the longer she remained on the machine, the worse were her chances of recovery.

Odim decided to wean her from ECMO in the PICU, a decision that Kesselman agreed with, since Jessica was in too fragile a state to be moved to the OR. The decision to perform the procedure in the PICU was risky. In his testimony, Kesselman said that it had been never successfully done in the unit. In her testimony, Feser said that the PICU nursing staff were not familiar with weaning from ECMO or decannulating lines, one of the steps of the weaning process. "It is not something that you do on a basis of, you know, very

short notice.” (Evidence, page 29,947) The cardiac bins that the PICU staff had asked Odium to help them prepare were still not ready, as Odium had not yet responded to the request for a list of equipment.

Kesselman said that there was no discussion of requesting OR nursing assistance. Hancock scrubbed in to act as Odium’s assistant, while Kesselman and other PICU nurses were to perform essential monitoring functions. A perfusionist, Dave Smith, was present and continuing to provide perfusion services for the ECMO. There was no anaesthetist present, although an anaesthetist’s presence is required by policy for all surgical procedures at the HSC. Weaning from ECMO would appear to be a surgical procedure. An anaesthetist would have been able to provide assistance with ventilation, monitoring and relieving pain, providing other medications and treating blood problems.

Weaning Jessica from the ECMO machine should have been done in a more organized fashion, with a properly prepared surgical team. Odium seems to have failed to appreciate that fact. He proceeded without ensuring that there was appropriate staff in place to assist in the procedure. He did not direct that appropriately trained nurses be called in, although the evidence established that this assistance was available if requested.

The evidence suggested that once the procedure to remove Jessica from the ECMO machine started, matters quickly grew chaotic and critical. Jessica had been losing considerable amounts of blood before the procedure, and her condition was already badly compromised by her steady deterioration after the operation.

On removal of the inferior vena cava cannula, Jessica experienced a sudden and massive loss of blood. According to Odium and Hancock, the blood loss occurred through the opening at the cannula site. Odium could not staunch the flow of blood quickly or adequately. At Jessica’s bedside there were no Satinsky clamps (the type of clamp that is best suited for clamping such openings in a blood vessel). One of the ICU staff was sent to the OR supply room to get one. This took minutes to accomplish, during which time Odium attempted to decrease the loss of blood by pressing his fingers against the cannula opening.

Once the clamp arrived, Odium attempted to suture the site closed, but with the already-heavy loss of blood, his efforts proved futile. Jessica died before he could close the site completely. Had Odium responded earlier to Feser’s request for a list of equipment he needed in the PICU, the proper clamps would likely have been in place. The request for the clamps might also have alerted the PICU staff to the fact that Odium intended to undertake such procedures in the PICU.

Jessica was a small child. The available evidence established that the total amount of blood in her system would have been about 500 millilitres (half a litre). It would not have taken very long for her body to drain itself of all of its blood through a sustained opening such as a cannula site, in the absence of adequate pressure on the site.

However, what went unnoticed during the procedure was the fact that either the surgeon or his assistant had failed to clamp the inferior vena cava cannula line after removing it from Jessica. It is quite possible that Jessica bled to death through this unclamped line.

In the normal procedure for weaning a patient from bypass or ECMO, the surgeon announces that he or she is going to remove a venous cannula. At this point, the perfusionist will clamp the venous cannula line at the pump. The surgeon is expected to clamp the line at the patient’s end.

Odium did not clamp the line. This was an error for a number of reasons. Air can enter the unclamped line and, ultimately, the machine and then the patient, if it is necessary to go back on bypass. Blood that is in the

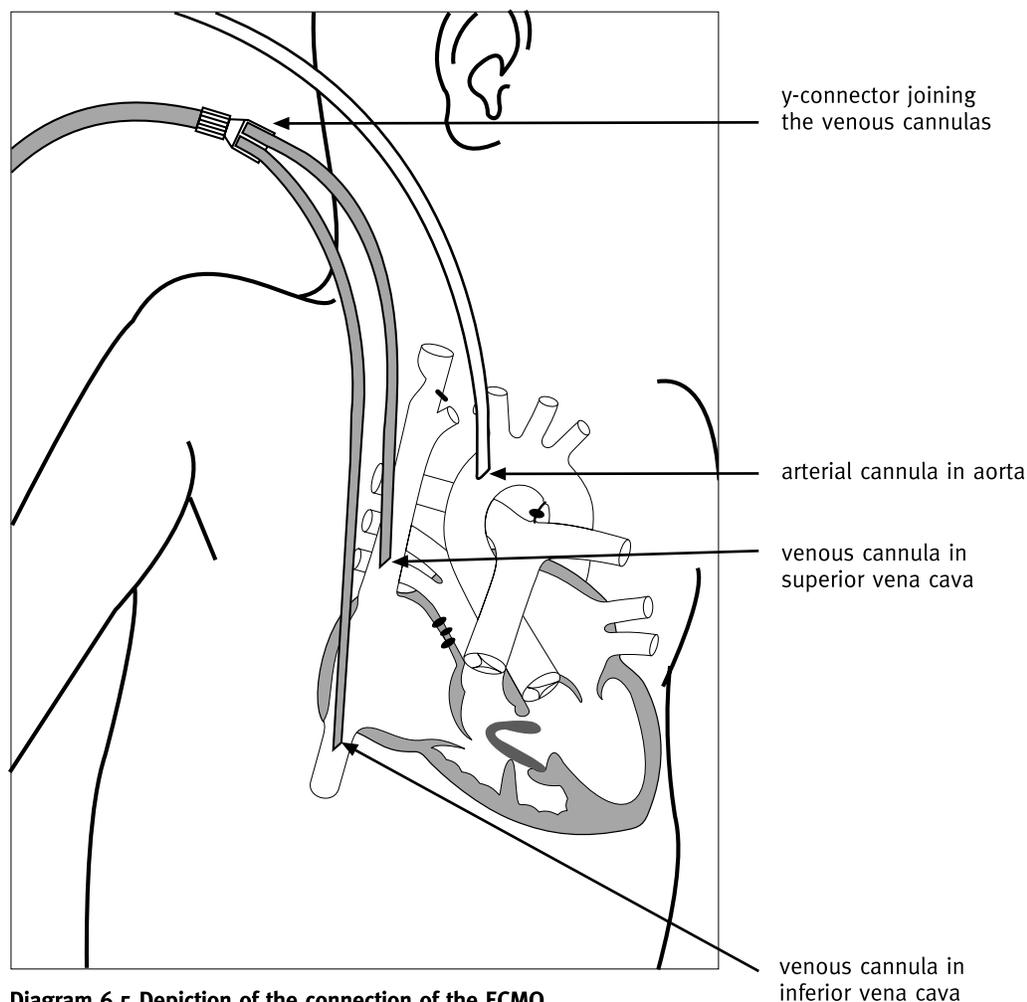


Diagram 6.5 Depiction of the connection of the ECMO lines to Jessica Ulimaumi.

line can be lost since it will simply drain out of the line. Finally, there is the danger that the patient can bleed to death. This danger arises from the fact that the lines from the inferior vena cava and the superior vena cava are joined together by what is termed a Y connector. From this connector, blood flows through a single line to the ECMO machine. If, as happened in this case, the line from the inferior vena cava is decannulated, while the line to the superior vena cava remains cannulated, blood can continue to flow from the child into the line from the superior vena cava. However, that blood can no longer flow into the ECMO machine if, as happened (quite appropriately) in this case, the line has been clamped at the ECMO end of the line. Instead, the blood can simply drain out of the unclamped line that had been connected to the inferior vena cava.

Perfusionist Dave Smith testified that once he heard a member of the team announce that the cannula had been removed, he noted a dramatic increase in the volume of blood he needed to transfuse into Jessica to maintain her pressure. He started to run out of blood to transfuse. “This was happening very quickly, the nurses were bringing blood from the blood bank, albumin. I was adding clear fluid just to keep going, keep the pressure up.” (Evidence, page 9,803) According to Smith, someone gave the order to go back on ECMO. Smith said he responded that he had no blood left. “And after that, at that point, they decided to quit I believe.” (Evidence, page 9,804)

Jessica went into cardiac arrest during this period. She could not be resuscitated and was pronounced dead at 1216 hours on March 27, 1994. While Odum went to speak to the family, Smith went to look at the child's body.

At that point, I noticed a venous cannula lying on the bed, beside the baby's chest. It was unclamped. I found that unusual, so I asked—Dr. Hancock was still there. She was across Jessica from Jonah and Murray Kesselman was at the head of the bed. I asked if this had ever been clamped, was this clamped at one time? And they said they didn't think so. They couldn't recall it being clamped. And they wanted to know why, so I proceeded to explain the physics of the situation. (Evidence, page 9,805)

Smith said that next to the cannula there was a flannel sheet that was soaked with blood.

In her testimony, Hancock stated that Odum took the cannula out and handed it to her. At that time Jessica started to bleed seriously.

I remember thinking, you know, that it wasn't clamped. But at the same time, the big problem was inside where she was bleeding from the inferior vena cava, and it was really just welling right up. (Evidence, page 20,648)

For this reason she said that she and Odum both turned their attention to the bleeding they could see. It was during this period that a nurse was sent for the Satinsky clamp. Odum testified that it was Hancock, not himself, who removed the cannula, under his instruction. He also testified that he was in the process of closing the bleeding site without a clamp. Odum testified that he heard the sound of the siphoning of blood from the heart and noted the decline in the heart's power. At that point he said he recognized that there could not be a clamp on the line. He concluded the major blood loss was from the cannula. Odum stated that the line was then clamped. He testified:

I don't recall who placed the clamp, whether Dr. Hancock placed it or myself. I just said, listen, we have to get a clamp on the line, and a clamp was got, and the line was clamped, the SVC cannula was clamped. I don't recall whether I did it or B.J. did it. We were sort of looking for a Kelly clamp and the clamp got applied. (Evidence, pages 24,205–24,306)

From Smith's testimony, it appears that Hancock might not have understood the dangers of not clamping the line. An experienced OR nurse might have noticed if the line was unclamped. However, the ICU nurses were not used to, or trained in, operating-room procedures, especially the procedures related to removal of a patient from bypass.

Smith did not complete an incident report about the event. In his testimony he indicated that he believed incident reports to be essentially a nursing responsibility. Smith was, however, quite upset by these events and reported them to Maas, his supervisor. Maas spoke with Odum the following day. He told Odum of the dangers in not clamping the line and the need to conduct these procedures in a manner that allowed the perfusionist a clear view of the lines. In his testimony, Maas said of Odum:

He acknowledged that a mistake had been made. He was quite straightforward and up front about it and that it wouldn't happen in the future and things would be done in orderly fashion. (Evidence, page 6,932)

Maas said that he did not fill out an incident report on the matter because:

We are not that familiar with incident reports, I will be quite honest. We don't fill them out because there are no incidents with us that we have ever experienced up to this point. Obviously this is an incident, and we felt the best route to go was a direct route. (Evidence, page 6,932)

It should be noted that the filing of incident reports did not preclude also speaking with Odim.

Odim's account of post-operative discussions differs considerably from the evidence provided by Smith and Maas.

I ventilated a little bit at the bedside when I recognized at the end that things weren't done as smoothly as things could have been done. Those were sort of my discussions with my team members at the bedside. I don't recall a later discussion with Mike. It's certainly possible that I might have had some words with him.

Q. Do I infer from your use of the word "ventilate" that you were angry with them?

Odim: At the whole, as I said I think there was a little bit of a break down, and I—nobody was sort of looking at the monitor, and we didn't know when the blood pressure was dropping from the monitor. We were all there. I said well, I am sitting tying a knot and trying to control bleeding, somebody needs to tell us, yell out what's going on, and that didn't happen very efficiently. I was a little concerned that there was a delay to put the clamp on and asked my assistant, when you take the cannula out, don't you always clamp it, and why wasn't that done? And I also, I asked Mr. Smith, that, you know, if the blood pressure goes down, you need to let us know so we go right back on ECMO. So, that was sort of the discussion I had with my team members as, you know, the person in charge to facilitate so that this would not happen again. (Evidence, pages 24,208–24,209)

In later testimony, Odim was presented with Maas's testimony to the effect that he had spoken to Odim about the incident and that in a straightforward manner Odim had acknowledged that a mistake had taken place. Odim said: "Unfortunately I don't recall the specifics of that conversation." (Evidence, page 24,243)

In his patient progress notes, Odim wrote that he had successfully weaned Jessica from ECMO with stable cardiac functions, although inotropic drugs were being administered, for approximately forty minutes. He wrote that she then developed severe bleeding following removal of the inferior vena cava cannula. Odim said that she was placed back on ECMO but could not be stabilized. This report does not capture the confused nature of events. This statement was also contradicted by Dave Smith, who said that Jessica was never successfully re-established on ECMO.

None of the medical staff made an entry in this child's chart indicating that a clamp had not been placed on the IVC venous cannula line, despite the clear importance that this would have had in determining the cause of the baby's death. This omission is a glaring one and bears comment. As noted in Chapter Three the chart or medical record is a crucial source of information. Failure to chart pertinent events would, for example, prevent the Chief Medical Examiner's office from reaching an appropriate conclusion as to whether or not an inquest should be held into a child's death.

Additionally, the medical record is a primary source of information for the family of a deceased child. The HSC as a matter of policy in these cases made the charts available to the families of the children who died in 1994. In this case, anyone reading the Ulimaumi chart would not have been able to determine what occurred in the PICU during the attempt to wean Jessica from the bypass machine, since not all of the material facts were disclosed in the chart. When asked why the clamp issue was not mentioned, Odim said:

I think the operative report states what happened in terms of the destabilization of the patient during decannulation. (Evidence, page 24,215)

On that point Odim was not correct. The operative report gives little indication of the events disclosed by the evidence.

AUTOPSY FINDINGS

A staff pathologist at the HSC, Dr. Joseph de Nanassy, performed the autopsy. He concluded that the immediate cause of death was “Cardiac arrest post cardiac surgery due to or as a consequence of coagulopathy and hemorrhage during weaning from ECMO.” (Exhibit 13, page ULI 22.) He noted that her superior vena cava had been narrowed by a suture. This likely was caused during the original surgery. There was also the presence of a needle near the cannula site.

Odim commented on the needle found in Jessica during the autopsy. He felt that this needle was in all likelihood one that was used during attempts at removing Jessica from the ECMO machine in the PICU. In his testimony, Odim said the needle was the needle “from my reinforcement, attempt to reinforce that suture line before I started to massage the heart and aborted that when the blood pressure and the cardiac action was going down.” (Evidence, page 24,211) The evidence suggests that the needle likely became lodged in Jessica during the attempt to wean her from ECMO in the PICU and played no role in her death.

The only item in de Nanassy’s report that has come under question is his conclusion that Odim’s second repair was intact. Two of the consulting witnesses who prepared reports for this Inquest disagreed with this finding. Drs. Walter Duncan and Glenn Taylor⁴ both reviewed the autopsy report, as well as the heart specimen. Duncan also reviewed a videotape of the heart echocardiogram done immediately after the second attempt at repairing the VSD. They both concluded that the VSD had not been successfully repaired at all. In other words, both the first and second attempts were not done properly.

Duncan and Taylor concluded that, rather than placing the patch across the hole in the septal wall, Odim had in fact sutured the patch to a muscle bundle that was attached to another part of the wall of the ventricle. As a result, blood continued to shunt through the opening in the septal wall in the VSD and heart performance remained poor.

Neither doctor could point to this factor as a cause of death, since the events that led directly to Jessica’s death related to the failed attempt at removal from the ECMO machine. Both were of the opinion, however, that the failed repair would explain why Jessica did not recover well enough after the operation to be weaned from the CPB machine in the operating room or be weaned from ECMO. Indeed, if the repair had not been properly done, it would have been impossible to wean Jessica from ECMO.

Duncan conceded that the heart specimen he reviewed was not in very good condition. As a result, it might not have reflected the true condition of the repair. However, he also reviewed the echocardiogram

⁴ Dr. Glenn Paul Taylor received his medical degree from the University of British Columbia in June 1976. He completed post-graduate training at Toronto General Hospital in 1976, as well as the University of British Columbia in 1977 and the University of Toronto in 1979. He was appointed a fellow of the Royal College of Physicians in Canada in anatomical pathology in December 1981. He was certified in anatomic pathology by the American Board of Pathology in June 1991 and awarded special qualifications in pediatric pathology in June 1992 by the same body.

A member of the hospital staff at the Toronto Hospital for Sick Children, he was also affiliated with the University of Toronto Department of Laboratory Medicine and Pathobiology, the University of Toronto Department of Pathology and the University of British Columbia Department of Pathology.

At the time of his evidence, Taylor was a staff pathologist with the Department of Pediatric Laboratory Medicine at the Hospital for Sick Children in Toronto as well as an associate professor in pathobiology, Department of Laboratory Medicine, at the same institution. He was also a consultant pathologist at the British Columbia Children’s Hospital.

Taylor has delivered several lectures, workshops and courses on pathology and has published extensively in the area. He was acknowledged as having special expertise in anatomic pathology and was permitted to give expert evidence to the Pediatric Cardiac Surgery Inquest in that area.

videotapes (something that he specializes in doing as a pediatric cardiologist) and concluded that the tapes confirmed his view that the repair was unsuccessful.

Duncan concluded that, because of the failed operation, the cannula site would have been exposed to very high blood pressures while Jessica was on ECMO. This would explain why there was so much damage to Jessica's cannulation site when the venous cannula was first removed. The increased pressure at this location would have resulted from the fact that the blood was not flowing properly, as a result of the failed repair. Duncan therefore concluded that the failed repair had a direct bearing on what occurred in the PICU during the ECMO weaning process.

De Nanassy thought that Taylor and Duncan had reached their conclusions from assessments made on the study of a dissected heart specimen. He stood by his initial report, which was based on examination of the heart shortly after death. However, Duncan's evidence, based on his viewing of the echocardiogram tapes, is persuasive. This evidence clearly suggests that the VSD was not properly repaired at the time of Jessica's initial operation.

POST-MORTEM EVENTS

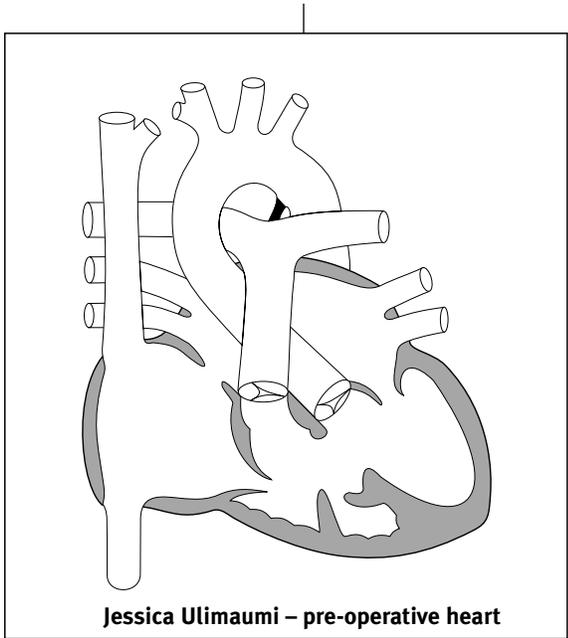
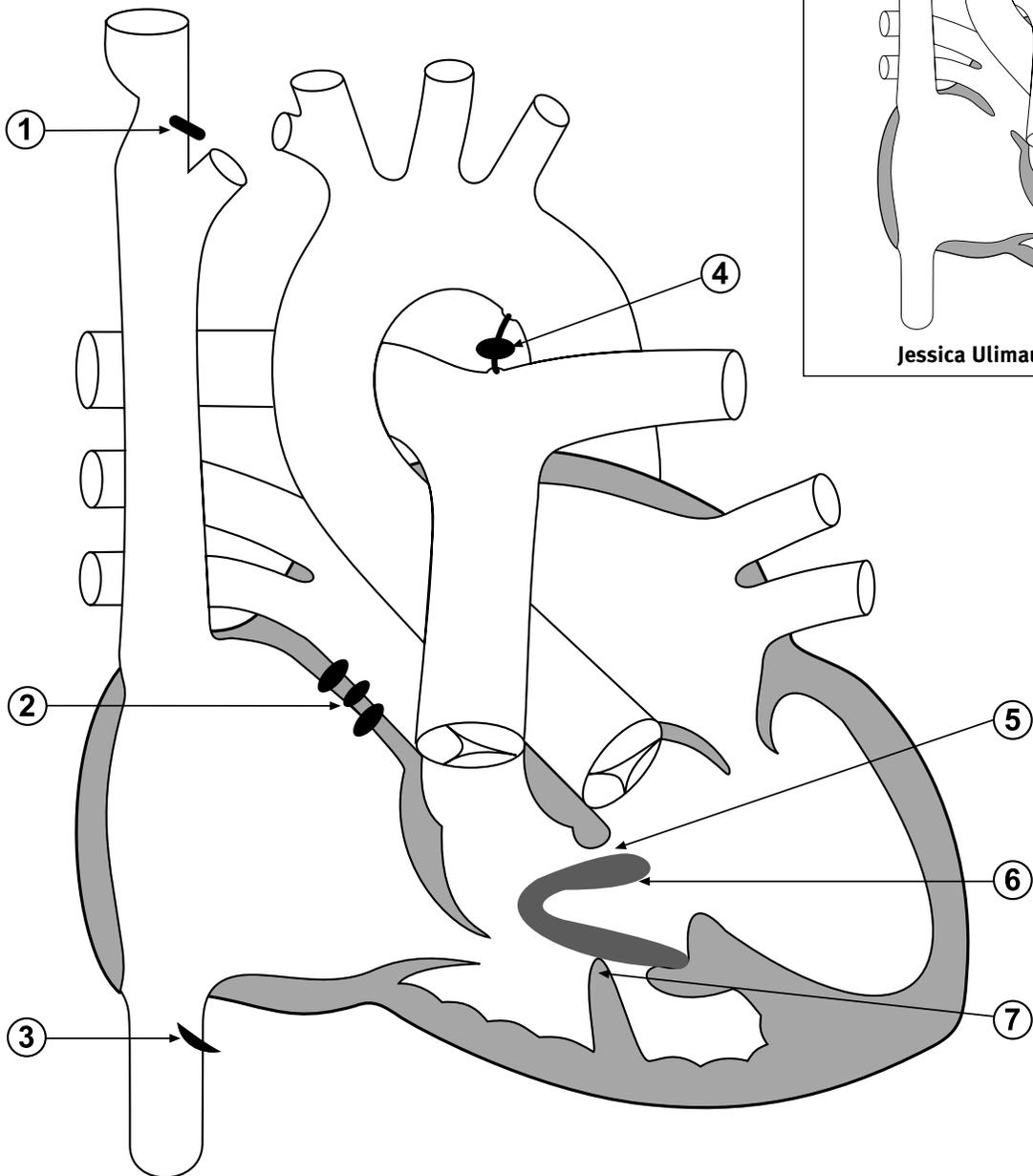
During the course of proceedings it was revealed that the HSC Department of Pathology had retained Jessica's heart following the autopsy. It is not known if this fact was ever revealed to the family. There is no explicit written consent allowing the HSC to retain the heart. While this question did not become an issue during the course of the Inquest, it has been a focus of public concern in other jurisdictions.

The authorization that parents sign when giving consent to an autopsy is an unrestricted authorization. However, parents can, if they choose, place restrictions on the autopsy, and in at least one case, the parents of a child whose death is under examination by this Inquest did so. Despite this, there is nothing in the consent form that provides parents with the knowledge that their child's heart may—and, indeed, probably will—be retained by the hospital.

Some cultures place an emphasis on dealing with the entire body when a person dies. Such cultures may require that limbs that are amputated, organs that are removed, the after-birth, and even hair cuttings must be treated with the same respect as one's body is after death. Even in cultures that do not have such traditions, parents may experience significant stress and anger on discovering that their child's heart was not buried with the rest of their child's body, but was retained in the facility where their child died.

It is recognized that the HSC did not retain the hearts of children who underwent autopsies for capricious reasons. These hearts were used in teaching and were in fact examined as a part of this Inquest. However, the rights of the parents to make an informed decision about what is to become of their child's body cannot be ignored. That gives rise to a recommendation at the end of this report.

Diagram 6.6 Jessica Ulimaumi – post-operative heart



- 1 – Suture constriction of superior vena cava
- 2 – Suture closure of atrial septal defect
- 3 – Surgical needle, inferior vena cava
- 4 – Ligation of ligamentum arteriosus (former ductus arteriosus)

- 5 – Portion of VSD not closed by surgery
- 6 – Patch closure of portion of ventricular septal defect
- 7 – Patch sutured to right ventricle muscle bundle as opposed to septal wall

FINDINGS

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

- Was there an inappropriate delay between the time of Jessica Ulimaumi's diagnosis and the date of the operation on her heart?
- Was Jessica's family provided with sufficient information to allow them to give informed consent to the procedure?
- Was Jessica healthy enough to undergo an operation?
- Did the length of surgery contribute to her death?
- Were the repairs properly carried out?
- Did irregularities in the process of weaning her from ECMO contribute to her death?
- What was the cause of death and was it preventable?
- Should this death have triggered a review of the program?

This case brought to the fore many of the issues that are central to this Inquest. They include questions of inexperience and competence, lack of preparation, failure in team building and communication, and a failure to undertake a proper review following an operation.

Was there an inappropriate delay between the time of her diagnosis and the date of the operation on her heart?

■ Findings

Once Giddins made a decision to wait to see if Jessica's septal defects would heal themselves, it is unclear if the information essential to determine if this course was working was shared with the Churchill Health Centre, where Jessica was hospitalized.

Her condition did not improve significantly between the time of her diagnosis and her visit to the Variety Children's Heart Centre in February 1994. If anything, there is evidence that her condition worsened. By February 1994, Jessica was diagnosed as having a larger VSD than in October 1993, when she had first been seen. Her shunt had worsened. She was also experiencing congestive heart failure by then and was diagnosed with failure to thrive, a condition closely associated with congestive heart failure.

As was stated in the Caribou case, waiting for a septal defect to close seems to be an acceptable course of action in such cases, and it is hard to fault Giddins for this decision.

However, if the plan was to give Jessica an opportunity to develop further and gain size and strength, not only should such information have been shared with the medical personnel treating Jessica in Arviat, but a plan for that development should have been developed and put into action. That does not appear to have been the case.