Report of the Panel reviewing the events surrounding the death of Róisín Ruddle

February 2005

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Section 1 – Introduction

1.1 On 23rd July 2003, Mr Micheál Martin TD, the then Minister for Health and Children, convened a Review Panel to conduct an independent review of the events surrounding the death of Róisín Ruddle. The terms of reference of the Panel were:

- To consider the report of the Eastern Regional Health Authority (ERHA) in relation to the events of 30th June 2003 at Our Lady's Hospital for Sick Children, Dublin and to make such further enquiries and conduct such interviews as the Panel considers necessary;

- To address the questions raised by the family;

- To examine protocols and procedures relevant to this incident having regard to prevailing standards of best practice, and to examine their application in this case;

- To report to the Minister and to make such recommendations as it sees fit.

1.2 The Minister indicated that the report of the Review Panel, together with the ERHA report, would be published.

1.3 The following persons were appointed as members of the Review Panel:

- Mr David Hanly (Chairman)
- Ms Kay O'Sullivan, Director of Nursing at Cork University Hospital
- Dr Shakeel Qureshi, Paediatric Cardiologist at Guy's and St Thomas's Hospital, London

Ms Mary Hogan, Assistant Principal Officer at the Department of Health and Children, acted as Secretary to the Panel. She was assisted by Mr Fergal Flynn, Higher Executive Officer at the Department of Health and Children.

1.4 Further to paragraph 2 of the terms of Reference, the Panel met Róisín's parents, Mr Gerard Ruddle and Mrs Helen Quain-Ruddle (who were accompanied by Róisín's maternal grandfather, Mr Danny Quain) to establish the questions the family wished to raise.

1.5 The Panel held preliminary meetings with the Deputy Chairman of the Committee of Management (the Board) and the then Acting Chief Executive of Our Lady's Hospital for Sick Children, Crumlin (Our Lady's Hospital), and with relevant staff of the Eastern Regional Health Authority.

1.6 The Panel was provided with a copy of Róisín's medical records, and met with members of the consultant medical and nursing staff at Our Lady's Hospital, as well as with administrative personnel at the Hospital. The Panel also met with some former members of staff. A list of the people from the ERHA and the Hospital who were interviewed by the Panel is at **Appendix 1**.

1.7 The Panel retained legal advisers to assist it in ensuring that fair procedures were followed at all stages of the review process. A Memorandum on Procedures was prepared and made available to the persons who were interviewed by the Panel. A copy of the Memorandum is at **Appendix 2**. The questions raised by the Ruddle family, insofar as they were relevant to each individual, were also made available to the persons concerned.

1.8 A Glossary of some of the technical terms used in this Report is at **Appendix 3**.

1.9 The Report is structured as follows:

Section 2	Background to the establishment of the Review
Section 3	Executive Summary
Section 4	Consideration of the ERHA Report
Section 5	Specific questions raised by the Ruddle family
Section 6	Examination of relevant protocols and procedures
Section 7	Findings
Section 8	The current position
Section 9	Recommendations

Section 2 – Background to the establishment of the Review

2.1 On 27th March 2003, Róisín Ruddle was placed on the elective cardiac surgery list at Our Lady's Hospital for the insertion of a Glenn shunt. Her surgery was scheduled for 30th June 2003.

2.2 Róisín was admitted to Our Lady's Hospital on 25th June 2003 for her pre-operative investigations, and discharged home on the 26th. She was re-admitted on Sunday 29th June in preparation for her planned surgery the following day.

2.3 On Monday 30th June, Róisín's operation was deferred because there was no staffed intensive care bed available for her following her surgery. Róisín and her parents left the hospital at approximately 12 noon on 30th June and returned home. Róisín died at home in the early hours of Tuesday 1st July 2003.

2.4 Mr Micheál Martin TD, the then Minister for Health and Children, was informed of Róisín's death and immediately requested the ERHA to urgently prepare a report on the events of 30th June. This report was presented to the Minister on 14th July 2003. A copy of the report was also provided by the ERHA to Róisín's parents. Having considered the report, Mr Ruddle and Mrs Quain-Ruddle felt that further questions needed to be answered and asked the Minister to establish an independent inquiry into the matter. Following discussions with Róisín's parents, the Minister convened a Review Panel to conduct an independent review of the events surrounding Róisín's death.

Section 3 – Executive Summary

3.1 Róisín Ruddle was born on 16th May 2001 at Limerick Regional Hospital. She was transferred to Our Lady's Hospital on the same day. She was diagnosed as having an extremely complex cyanotic congenital heart defect. This consisted of pulmonary atresia, multiple ventricular septal defects in unusual positions, and a small hypoplastic right ventricle. This is a very unusual combination of defects. Following initial investigative procedures, Róisín underwent an operation to insert a modified right Blalock-Taussig shunt on 21st May 2001.

3.2 Róisín's condition continued to be managed by the consultant cardiologists at Our Lady's Hospital, and she underwent a number of investigative procedures during the following months. The management of her cardiac condition was discussed at the Hospital's Joint Cardiology / Cardiothoracic Conference (Joint Conference) on a number of occasions and the options for her treatment were considered. In March 2003, it was agreed that Róisín should undergo cardiac catheterization with a view to a Glenn shunt procedure.

3.3 Róisín was due to undergo the Glenn shunt procedure on 30th June 2003. This procedure was a palliative operation which was part of a staged strategy in the management of Róisín's cardiac condition. She underwent the normal pre-operative investigations on 25th/26th June 2003 and was discharged, to be re-admitted on 29th June for planned surgery the following day. On 30th June, however, her surgery was deferred because there was no staffed intensive care bed available for her post-operatively. Róisín was discharged from the Hospital on 30th June and she returned home with her parents. Róisín died at home in the early hours of Tuesday 1st July 2003.

3.4 The autopsy indicated that Róisín's death was due to acute cardio-respiratory failure associated with the presumed development of a cardiac arrhythmia. This view was supported by the medical opinion presented in the course of the Review, and by the Review Panel's medical expert.

3.5 If the Glenn shunt procedure had gone ahead as planned on 30th June, it would most likely have improved Róisín's oxygen saturations, and this may have reduced the likelihood of an arrhythmia. However, the reasons for the occurrence of arrhythmias in patients with congenital heart defects are complex and, despite an improvement in oxygen saturations, fatal arrhythmias can still occur. Nevertheless, it is the view of the Panel that if Róisín's operation had gone ahead as planned on 30th June, the likelihood of her survival would have been greater.

3.6 Róisín's parents told the Panel that it was their view that the ERHA Report contained some inaccuracies. Having examined these matters, the Panel is satisfied that, with one exception (see Section 4.6), the ERHA Report accurately reflects the facts relating to Róisín's treatment and care at Our Lady's Hospital.

3.7 Róisín's parents raised a number of questions relating to the clinical care Róisín received in Our Lady's Hospital. Having examined Róisín's medical records and interviewed the clinical staff involved in her care, the Panel is satisfied that the clinical care Róisín received while a patient in Our Lady's Hospital was appropriate.

3.8 The reason for the deferral of Róisín's surgery on 30th June was that there was no staffed intensive care bed available in the Intensive Care Unit to accommodate her post-operatively.

3.9 The Intensive Care Unit (ICU) at Our Lady's Hospital comprises a total of 21 fully-equipped beds. The beds are divided into two units, the Main ICU and St Patrick's ICU. The Hospital has not been in a position to utilize the full complement of beds in ICU because of a shortage of appropriately trained nursing staff. The main ICU, which caters for all cardiac patients, has 8 fully-equipped beds, but has only sufficient nursing staff to operate 7 of these.

3.10 There is, and has been for some time, a worldwide shortage of paediatric ICU nursing staff. Our Lady's Hospital reported difficulties in recruiting such staff as far back as 1996, although it appears that the problem became more acute in or around 1998.

3.11 Given the centrality of the ICU to the operation of the Hospital as a whole, the Panel considers that the shortage of nurses to staff the Unit does not appear to have been seen by Hospital management at the time as a priority issue warranting significant management attention. From the evidence presented, it is clear to the Panel that the problems relating to the recruitment and retention of specialist nursing staff were considered matters to be addressed solely by the Director of Nursing and her staff. Although aware of the problems, there is no evidence that Hospital management or the Committee of Management gave any active support, other than the approval of financial resources, to helping the Director of Nursing with the problem-solving initiatives that were clearly needed to address the recruitment issues for this highly critical area of the Hospital's activities.

3.12 In the opinion of the Panel, insufficient focus was placed by Our Lady's Hospital management and the Committee of Management on the resolution of the issue and, as a consequence, there was a lack of urgency in applying and distributing available resources to resolving the problem or at least trying to do so. That said, the Panel feels that it is important to point out that, despite significant efforts made by the

Hospital in more recent times, the Hospital is still not in a position to staff its full complement of ICU/HDU beds.

Section 4 – Consideration of the ERHA Report

4.1 At their meeting with the Panel, Róisín's parents said that it was their view that there were some inaccuracies in the ERHA Report, and these are addressed in the following paragraphs. (The Section references that follow the quotes indicate the Sections in the ERHA Report from which the quotes are taken.)

4.2 ***"The Authority is advised that all relevant clinical staff involved in the care of the child were consulted and were involved in the compilation of the information returned by [Our Lady's Hospital]"*** (Section 1)

The family said that a number of junior medical staff at the Hospital were involved in Róisín's care but are not mentioned as having had an input into the Report.

The Panel is satisfied that it was appropriate that the senior medical staff at the hospital were consulted in relation to the compilation of the information contained in the Report, and that they were the relevant clinical staff in this context.

4.3 ***"24th March 2003: As per plan the patient was re-admitted for elective cardiac catheterization which was carried out by a Consultant Paediatric Cardiologist on 25th March 2003"*** (Section 3)

The family does not believe that there was any plan in relation to Róisín's care.

Róisín's diagnosis and treatment are examined in Section 6 of this Report. The Panel found that Róisín's cardiologists and surgeon formulated and followed an appropriate plan of management for her treatment.

4.4 ***27th March 2003: The case was discussed at a Cardiac Conference and a decision was made to list the child for Cardiac Surgery (Bi-Directional Glenn Shunt)"*** (Section 3)

Róisín's parents told the Panel that they knew on 25th March that Róisín would be having this procedure.

The Cardiologist who carried out the cardiac catheterization procedure on 25th March discussed the results with the family; at that stage it was clear that a bi-directional Glenn shunt would be the appropriate option. However, a final decision in relation to surgery was not taken until

Róisín's case was discussed with the other Cardiologists and the Cardiothoracic Surgeons at the Joint Conference on 27th March.

4.5 ***"The child was deemed medically fit for discharge by the Cardiology and Cardio Thoracic team"*** (Section 5)

The family says that nobody physically examined Róisín before she was discharged.

This matter is dealt with in Sections 5.10 and 5.11 of this Report. The Panel heard that, while Róisín did not undergo any physical examination prior to her discharge, her Cardiothoracic Surgeon was satisfied that she was fit for discharge, and so discharged her.

4.6 ***"[Mrs Quain-Ruddle] was informed that surgery was re-organised for Monday, 7th July 2003"*** (Section 4)

"An alternative date of Monday, 7th July 2003 was given for surgery" (Section 5)

Mrs Quain-Ruddle said that she was not given any definite alternative date for Róisín's surgery before she and her family left the Hospital on 30th June.

This matter is dealt with in Section 5.14 of this Report. The Panel found that these statements contained in the ERHA Report were inaccurate and that a confirmed alternative date for surgery was not given to Mrs Quain-Ruddle before she and her family left the hospital on 30th June.

4.7 The Ruddle family also told the Panel that there were some inaccuracies in the Report concerning the times of Róisín's admissions to the Hospital. The Panel did not feel it necessary to address these because, in its view, they are not material in the context of the overall review of the events surrounding Róisín's death.

4.8 With the exception of the statements discussed in paragraph 4.6, the Panel found that the ERHA Report accurately reflects the facts relating to Róisín's treatment and care at Our Lady's Hospital.

Section 5 – Specific questions raised by the Ruddle family

Further to paragraph 2 of the Terms of Reference the Panel met Róisín's parents, Helen Quain-Ruddle and Gerard Ruddle (who were accompanied by Róisín's maternal grandfather, Danny Quain), on 14th October 2003 to establish the questions they wished to raise. They raised a number of questions and concerns relating to the care Róisín received at Our Lady's Hospital. The Panel discussed these questions and concerns with the relevant medical, nursing and administrative staff at Our Lady's Hospital, and the responses are set out below. Where the questions and concerns are addressed in more detail in a later Section of the Report, that Section is referenced.

5.1 The Ruddle family say that Dr Adrian Moran (Consultant Cardiologist) expressed concern in October 2002 about Róisín's low oxygen levels. Could this have indicated a possibility of needing earlier treatment, or of cardiac arrhythmia, and, if so, was this mentioned, or should it have been mentioned, at consultations with the family?

5.2 The Ruddle family say that they were informed in January 2003 by the liaison nurse at Crumlin hospital that Dr Moran believed that Róisín's right ventricle had grown sufficiently to allow for two-ventricle repair. Was there ever a possibility of Róisín undergoing this procedure?

5.3 What was the basis for a change in the decision on Róisín's treatment pathway, which the Ruddle family believes was made before the cardiac catheterization on 25th March 2003, that she was to have the Glenn shunt procedure?

These matters are addressed in Section 6 of the Report.

5.4 Róisín's parents met with Mr A.E. Wood (Consultant Cardiothoracic Surgeon) in his private clinic subsequent to the cardiac catheterization procedure. Was this normal procedure?

The Panel discussed this question with Mr Wood. He told the Panel that, after a patient's clinical management has been discussed at the Joint Conference, and it has been agreed that elective surgery is required, it is normal practice for him to see the patient and the parents either in his outpatients' clinic or in his private rooms. This is necessary in order for Mr Wood to be satisfied that the parents understand the natural history of the condition, the risks and benefits of the proposed surgery, and the implications and prognosis for the future.

The Panel is satisfied with this response.

5.5 What is the usual mechanism for putting patients on the surgical waiting list? Do parents see the surgeon to discuss treatment before agreeing to have their child placed on the waiting list? If so, where would the child normally be seen? What is the usual method for scheduling cardiac surgery operations? How are cases reviewed and prioritised? How regularly is this done?

The Panel was advised that the normal procedure for placing patients on the cardiac surgical waiting list is that, following discussion at the Joint Conference wherein a patient is referred for surgery, the cardiothoracic surgeon sees the parents and the child either in his outpatients' clinic or in his rooms. It is only after he sees the parents and receives their agreement to the proposed surgical treatment that the patient is officially listed. The cardiac surgery schedule is prepared four weeks in advance. Priority is given to those patients waiting longest, those whose condition is highlighted by the cardiologists or the referring paediatricians as deteriorating, or in-patients who are considered too ill to be discharged home. The list is reviewed every Monday, and again after the Joint Conference on a Thursday.

The Panel is satisfied with this response.

5.6 Róisín's parents say that at their meeting with Mr Wood, he told them to contact his secretary to obtain a preliminary date for Róisín's operation. The Ruddle family indicate that they contacted Mr Wood's secretary twice in April, once in May and once in June. They were informed when Mr Ruddle rang on 18th June of the date for the operation. Does such regular contact on the part of the parents expedite the scheduling of an operation?

In the course of his meeting with the Ruddle family on 27th March, Mr Wood asked them to contact his secretary approximately two weeks later. Mr Wood told the Panel that this is his standard practice as a double-check to ensure that no patient is omitted from the waiting list. It also provides the parents with a direct access pathway in order that Mr Wood can be notified of any change or deterioration in the medical condition of the child. The parents of children on the surgical waiting list are encouraged to ring Mr Wood's secretary regularly. This does not, however, expedite the scheduling of an operation unless there is a medically-supported indication of deterioration in the child's condition.

The Panel accepts that the communication protocols described above are operated by the Cardiothoracic Surgeon in order to ensure (a) that no patient is omitted from the waiting list and (b) that parents have a facility to urgently communicate any concerns regarding the health status of their child to the surgeon.

5.7 Róisín's parents believe that their daughter was upset during the pre-operative procedures during 25th and 26th June 2003 and that

she had a bad allergic reaction to a cream applied to her arms. Can you comment on this?

The Panel was advised that a local anaesthetic cream is generally applied prior to procedures which require the insertion of a needle. While the nurse who was particularly responsible for Róisín's care at the relevant time cannot remember applying the cream to Róisín during her pre-operative procedure, she told the Panel that it is not uncommon for children to suffer a reaction to the cream and that the procedure in such instances is to reassure the parents that the reaction is common and will usually disappear within a couple of hours. The nurse told the Panel that if Róisín's reaction had been anything more than what was commonly seen, she would have recorded it and drawn it to the attention of a doctor.

On the night of 29th June, at the request of Róisín's parents, local anaesthetic cream was not used prior to Róisín's cannula being inserted.

The Panel accepts this response.

5.8 Róisín was admitted to Crumlin hospital sometime after 5 pm on Sunday 29th June. Her parents believe that Róisín was the third patient on the list for elective operations the following day. They also say that they were informed on the morning of 30th June, by the father of the child who was first on the list for surgery, that he had been told the previous night (29th June) that emergencies had come in and that it was unlikely that his child would be operated on. Is it correct that it was apparent on Sunday night, 29th June, that Róisín would not be operated on the next day? If so, was it appropriate that she be prepared for the operation?

The Panel discussed these issues with medical and nursing staff in the ICU, and with Mr Wood. The environment in the ICU is unpredictable; the conditions of patients in the Unit can alter, for better or worse, very quickly. It was not until approximately 10.30am on Monday 30th June that Mr Wood was in a position to decide that Róisín's surgery would have to be deferred. At that stage he went to St Brigid's Ward to inform Róisín's parents of the situation. It was appropriate, therefore, that Róisín was prepared for the operation.

The Panel accepts this response.

None of the medical or nursing staff interviewed by the Panel was able to explain how the parent of the other child was apparently told on the night of the 29th June that surgery deferrals were likely the following day because of emergency admissions to the ICU. The Panel is not in a position to make a finding on this particular point.

5.9 Róisín was placed on an intravenous drip on the night of 29th June until 11 am on 30th June. What were the contents of this drip? Were the nurses made aware before 11am that Róisín was not going to be operated on and, if so, ought the drip to have been removed at an earlier stage?

The Panel discussed this with Mr Wood and with the nurses on St Brigid's Ward. The drip contained Dextrose 5% (intravenous fluids of an isotonic nature) to keep Róisín hydrated while she was fasting prior to surgery. Her weight was 11.3 kgs, and she was given 42 mls per hour. The nurses were made aware that Róisín's surgery had been deferred when Mr Wood came to St Brigid's Ward sometime between 10.30am and 11am, shortly after the decision to defer had been made. Mr Wood told the Panel that it would not have been appropriate for the drip to have been removed at an earlier stage.

The Panel is satisfied with this response.

5.10 Who deemed Róisín medically fit for discharge on the morning of 30th June?

5.11 What checks, if any, were done to deem Róisín medically fit for discharge before she left the hospital on 30th June?

The Panel discussed these issues with Mr Wood. He told the Panel that Róisín had been admitted electively for surgery in a stable medical condition. Her pre-operative tests, performed on 25th/26th June, were satisfactory. No new medical problem had arisen after her re-admission on 29th June and it was not considered necessary to carry out any further checks before discharging her home. On this basis, Mr Wood discharged Róisín home on 30th June as there was no medical reason to keep her in hospital.

The Panel also discussed these issues with other members of the medical staff, who all agreed with the approach taken.

The Panel is satisfied with this response.

5.12 Given that Róisín had fasted from the evening of 29th June, ought she or her family have been offered food for her, particularly as she was about to undertake a long car journey home?

The Panel discussed this question with the nursing staff on St Brigid's Ward. They all advised the Panel that it was normal practice on the ward to offer food for a child who had been fasting. They were also of the view that the parents of children on the ward, particularly those who were familiar with hospital routine, would have known that food was available. The nurse who was particularly responsible for Róisín's care on 30th June told the Panel that she did offer food for Róisín to Róisín's mother, who said she would give Róisín a yoghurt. The nurse said that

she went to the kitchen and got two yoghurts. Mrs Quain-Ruddle took one of them, saying that Róisín would never eat two. None of the nurses knew whether Róisín had actually eaten the yoghurt.

Mrs Quain-Ruddle told the Panel that she had to request food for Róisín, as none was offered. The Panel is not in a position to make a finding as to whether she was or was not offered food. The Panel is of the view that it should be standard procedure for a child in Róisín's position to be offered some food as a matter of course, particularly if the child is about to embark on a long car journey, and that the parents should be advised about the importance of keeping the child hydrated.

5.13 Róisín's parents say that Róisín would not eat throughout 30th June. Could the pre-operative preparation have been the cause of this, taking into account any distress that Róisín may have suffered as a consequence?

It was the view of the relevant medical staff that the fluids contained in the intravenous drip would not have been the cause of Róisín refusing to eat. The Panel was told that Róisín had previously tolerated her pre-catheterization preparations without difficulty, and these would have been similar to the pre-operative preparation. None of the medical staff was in a position to say what might have been the cause of Róisín's diminished appetite that day.

The Panel accepts this response.

5.14 The Ruddle family say that they were not given a definite date for the rescheduling of Róisín's surgery before they left the hospital on 30th June. They say that the first they heard of a definite date was when the liaison nurse rang to sympathise with them after Róisín's death.

The Panel discussed this question with Mr Wood, and with relevant members of the nursing staff. Mr Wood told the Panel that when he spoke to Mrs Quain-Ruddle to explain that Róisín's surgery had been deferred, he told her that the surgery would probably be rescheduled for the following Monday, 7th July, but that before confirming this he would have to review his surgical waiting list. He told Mrs Quain-Ruddle that when he had done this his secretary would ring her to confirm the date of Róisín's re-scheduled surgery. His secretary intended to ring the family the following morning (1st July) to confirm the date, but learned of Róisín's death before she could do so. The cardiac liaison nurse knew that the date for Róisín's rescheduled surgery had been confirmed, and referred to this when she rang the family to sympathise with them.

The Panel is satisfied with this response.

5.15 Is it appropriate that Róisín undertook a lengthy car journey home after her discharge on 30th June? In this regard, the Ruddle family point to a survey done by the Coombe hospital which found that a healthy baby's oxygen levels and heartbeat drop after one hour of travelling in a car seat.

The Panel discussed this with the relevant medical staff, who were of the view that the journey home would not have affected Róisín's physical condition. They told the Panel that Róisín had undertaken similar journeys to and from the Hospital on several occasions without difficulty. The Panel was advised that other patients with complex congenital heart disease and oxygen saturations equivalent to Róisín's have travelled greater distances to and from the Hospital, and have travelled to the United Kingdom and the United States by plane without experiencing any difficulties.

In addition, if the journey had affected Róisín's condition, the concern would have been that she had become dehydrated, in which case it would have been expected that her shunt would have been blocked. The autopsy examination found that this was not the case.

None of the medical staff was aware of the survey said to have been undertaken by the Coombe Hospital. When contacted by the Panel, the Coombe Hospital said that it was not aware of any such study having been undertaken at the Hospital.

The Panel accepts this response. However, the Panel is of the view that frequent long journeys are not ideal for patients with heart conditions, and has made a recommendation on this issue (see Section 9.1).

5.16 Could any stress associated with Róisín's pre-operative treatment, the cancellation of her operation and two lengthy car journeys have contributed to her death by cardiac arrhythmia? Could she have died of the heart condition which the cancelled surgical procedure sought to treat? Could or should the operation have been carried out at an earlier stage?

The medical staff with whom the Panel discussed these issues considered it very unlikely that the deferral of Róisín's surgery, her pre-operative treatment or her journey home by car precipitated a cardiac arrhythmia. They believe it is likely that Róisín's death was due to an unexpected fatal cardiac arrhythmia associated with her congenital heart defect.

The Panel was told that the scheduled surgery, a bi-directional Glenn shunt, was a palliative operation which was part of a staged strategy in the management of Róisín's cardiac condition. The fatal arrhythmia could have occurred at any time post-operatively, and the medical

opinion at the Hospital was that there was no medical indication to carry out the procedure any earlier than planned.

The Panel accepts this response. These issues are dealt with in more detail in Section 6 of the Report.

5.17 Why are only Mondays set aside for elective surgery for children with heart defects? Is it appropriate that only one day is set aside for these procedures? Does the fact that these operations are scheduled immediately after the weekend mean that there is a greater chance of postponement? Why can postponed elective surgeries not be scheduled for the following day or days rather than a week or weeks later?

5.18 When Mr Wood was on sick leave in 2003, approximately 5 operations for children were postponed. Could this have been avoided? Is there cover for Mr Wood while he is on vacation, and, if not, does this contribute to a lengthening waiting list?

At present there are two cardiothoracic surgeons operating in Our Lady's Hospital, Mr Wood and Mr Redmond. Elective cardiac surgery is currently performed on Mondays by Mr Wood and on Wednesdays by Mr Redmond, and Róisín's parents would have been aware of this. This scheduling of the service is necessary as other surgical specialties also require planned access to the ICU. In addition, the Cardiac Department must allow for the provision of services to emergency cases. The two surgeons provide emergency cover for each other for annual leave, study leave and sick leave. Each surgeon operates an individual surgical waiting list for elective patients, and it would not be normal practice for patients to be transferred from one list to the other except in cases of emergency. The Panel understands that arrangements are in train for the provision of additional cardiac surgery procedures at Our Lady's Hospital (see Section 8.2).

The Panel accepts this response. The Panel did not find any evidence that there is a greater chance of an operation being postponed if it is scheduled to be performed immediately after the weekend.

5.19 The Eastern Regional Health Authority Report indicates that 7 other cardiac surgical postponements took place in 2003. How late were these postponements and were the patients involved treated any differently from Róisín?

Mr Wood told the Panel that all seven of the cardiac surgery cases referred to above were deferred on the day of the scheduled operation. These operations were rescheduled within the following one to five weeks without any harmful effects. The cases in question were not dealt with any differently to Róisín's case.

The Panel accepts this response.

5.20 Are you satisfied that the practices and procedures in Our Lady's Hospital are optimized in favour of the patient?

The medical and nursing staff told the Panel that, given the constraints under which they operate, they believe that the practices and procedures in Our Lady's Hospital are optimized in favour of the patients. The constraints referred to were the availability of operating theatre space, insufficient experienced ICU nurses, and infrastructural deficiencies.

The Panel accepts this response. The availability of operating theatre space, the shortage of experienced Intensive Care nurses, and the infrastructural deficiencies are dealt with in more detail in Sections 7 and 8 of the Report.

5.21 Mr Ruddle and Mrs Quain-Ruddle say that Dr Oslizlok (Consultant Cardiologist), speaking to them after Róisín's death stated that "there won't be any changes, we will continue as before". They took this to mean that Róisín's death would not have an effect on hospital management or procedure. Is this correct?

Dr Oslizlok told the Panel that his comment was made in response to Róisín's parents saying that they hoped that this Review would have the effect of ensuring that what happened to Róisín would not be allowed to happen again. Dr Oslizlok took this to mean that procedures would be put in place to ensure that a child's cardiac surgery would never again be deferred. He believes he told the Ruddle family that surgical cancellations, although hopefully rare, would always arise and that, given the nature of congenital heart disease, unfortunately there would always be cases of tragic unpredictable sudden death and that the two events may occasionally coincide. Dr Oslizlok said he felt it was necessary to be realistic about what medicine and society could and could not achieve.

Having discussed this with Dr Oslizlok, the Panel believes that he was misunderstood in relation to the comment he made. The Panel is satisfied that he and his colleagues are constantly striving to improve the services provided to patients and to minimize cancellations of this nature.

Section 6 – Examination of relevant protocols and procedures

6.1 Róisín's medical condition

6.1.1 The Panel was provided with copies of Róisín's medical records which give details of her medical condition and her medical management while in the care of Our Lady's Hospital.

6.1.2 Róisín was born with a complex congenital heart defect comprising hypoplasia of the right ventricle, pulmonary atresia, multiple ventricular septal defects, and patent arterial duct. This means that Róisín's right ventricle was quite small, the pulmonary valve was blocked, there were at least two holes in the wall between the two main pumping chambers of the heart, and the arterial duct was patent. The result of this combination of defects was that blood could not pass from the right ventricle to the lungs for oxygenation through the pulmonary valve, but had to reach the lungs through the arterial duct.

6. 2 Treatment options

6.2.1 If the right ventricle is of normal size, and there is only one ventricular septal defect, a complete corrective operation may be possible following an initial Blalock-Taussig shunt operation. The Blalock-Taussig shunt involves the creation of an artificial channel between the aorta and the pulmonary artery. The corrective operation, a Rastelli operation (bi-ventricular repair), would involve closing the ventricular septal defect and joining the right ventricle to the pulmonary artery with a tube, or conduit.

6.2.2 When the patient's right ventricle is very small, a three-stage operation is usually required. The first operation involves the creation of a Blalock-Taussig shunt. The second operation, called a Glenn shunt, involves joining the vein carrying blue (de-oxygenated) blood from the upper part of the body (superior vena cava) to the right pulmonary artery. This operation is usually carried out when the patient is between six and 24 months old. The third operation is called a Fontan procedure, and involves joining the vein carrying blue blood from the lower half of the body (inferior vena cava) to the pulmonary artery. This three-stage approach results in the diversion of the blue (de-oxygenated) blood from the body to the lungs for oxygenation, and the red (oxygenated) blood is passed around the body, as in normal circulation.

6.2.3 Róisín's combination of heart defects was rare, and fell into neither of these categories.

6.3 Prognosis

6.3.1 The prognosis for a patient with Róisín's particular combination of defects is not known, as the combination is an uncommon one. The long term results of surgery and the prognosis depend on the size of the patient's right ventricle and pulmonary artery.

6.3.2 In cases such as that described in paragraph 6.2.1 above, the first operation (the Blalock-Taussig shunt) carries a mortality risk of less than 5%, and the later corrective operation has a mortality risk of approximately 5%. The prognosis for such patients is good, although further operations may be required to replace the conduit as the patient grows. This treatment option is unlikely to lead to the patient requiring a heart transplant in the future.

6.3.3 In cases such as that described in paragraph 6.2.2 above, each of the three operations carries a mortality risk of approximately 5% or less, resulting in a long term survival rate of about 85%. A significant proportion of such patients may deteriorate 20 to 30 years after the final operation, to the stage where they require a heart transplant.

6.3.4 It is likely that Róisín's prognosis would have been closer to that described in paragraph 6.3.3 above, than to that described in paragraph 6.3.2.

6. 4 Medical Management

6.4.1 The following paragraphs set out the sequence of Róisín's medical management at the Hospital. They are, of necessity, technical in nature. The Panel's comments on the medical management are shown in italics.

6.4.2 Róisín was born in Limerick Regional Hospital on 16th May 2001. She was noted to be cyanosed at approximately 15 hours of age, failed the hyperoxia test and was started on prostaglandin infusion. Because of suspicion of cyanotic congenital heart defect, she was transferred to Our Lady's Hospital on the same day.

6.4.3 At Our Lady's Hospital, she was evaluated by Dr Paul Oslizlok (Consultant Cardiologist), who performed an echocardiogram. This confirmed the diagnosis of pulmonary atresia, with at least two ventricular septal defects (VSD). Both of these were moderately large; one was apical and one mid-trabecular. The ascending aorta arose from the left ventricle and there was a patent arterial duct supplying confluent pulmonary arteries. There was no overriding of the aorta because of the unusual location of the VSDs.

6.4.4 On 17th May 2001, cardiac catheterization and angiography were performed by Dr Kevin Walsh (Consultant Cardiologist). Angiography confirmed the diagnosis suspected on echocardiography. There was

duct-dependent pulmonary circulation, and in addition there was a possibility of mild stenosis of the left pulmonary artery at the entry point of the arterial duct. A balloon atrial septostomy was carried out during the cardiac catheterization.

6.4.5 On 21st May 2001, Mr A.E. Wood (Consultant Cardiothoracic Surgeon) performed a modified right Blalock-Taussig shunt procedure using a 5mm Impra graft. The post-operative course was complicated by significant but transient renal dysfunction. Róisín was discharged home on 6th June 2001.

Róisín's initial management, the investigative procedures and the decision-making which led to the insertion of the Blalock-Taussig shunt are considered by the Panel's medical expert to have been appropriate.

6.4.6 Róisín was reviewed by Dr Walsh in the cardiac clinic on 28th June 2001. It was decided to perform a repeat cardiac catheterization in order to consider balloon angioplasty of the left pulmonary artery.

6.4.7 Róisín was re-admitted on 17th July 2001 for cardiac catheterisation, which was performed on the same day. This confirmed the previous anatomy, the Blalock-Taussig shunt was patent, and the left pulmonary artery stenosis was mild. This did not require balloon angioplasty and she was discharged home on 18th July 2001.

The decision to perform a second cardiac catheterization, the purpose of which was to assess the Blalock-Taussig shunt and to evaluate the left pulmonary artery stenosis, was appropriate. The catheterization showed the left pulmonary artery stenosis to be mild and not to warrant any treatment.

6.4.8 On 14th September 2001, Róisín was reviewed in the cardiac clinic by Dr Oslizlok. His view was that the surgery should be deferred for at least one year and that Róisín should be reviewed in three months. The reason for deferring surgery was in the hope that a bi-ventricular repair might be possible. To this end, Róisín's case was discussed again at the Joint Conference on 20th September 2001. It was agreed to defer surgery pending further review. Róisín was reviewed in the cardiac clinic on 21st December 2001, 22nd March 2002 and 4th October 2002. When Róisín was reviewed on 4th October 2002 by Dr Moran, he expressed concern about Róisín's oxygen saturation levels. In his view, the echocardiographic study carried out at that visit showed a good-sized right ventricle. He instigated further discussions on Róisín's case which took place at the Joint Conference on 7th November 2002. The possibility of device closure of the apical muscular VSD, followed by the insertion of a conduit between the right ventricle and the pulmonary artery, was considered. Róisín's haemoglobin level was 18.5 g/dl on 22nd December, 2002.

The discussions at the Joint Conferences, including the discussions about possible changes in treatment strategy, highlight the difficult and complex nature of Róisín's heart defect and its management options. The decision to delay the surgery to a later date, in order not to exclude the possibility of a bi-ventricular repair in the future, was reasonable. Bi-ventricular repair, whenever possible, is considered a better option than a Fontan procedure.

6.4.9 Róisín was reviewed on 11th January 2003 by Dr Oslizlok. She was stable and active with only occasional episodes of cyanosis. Her oxygen saturation level was 72%. Because of some increase in cyanosis, Dr Oslizlok thought that her name should be placed on the waiting list for device closure of the VSDs by catheter technique, followed by a Rastelli operation.

6.4.10 Róisín's condition was discussed again at the Joint Conference on 6th March 2003. On this occasion, it was suggested that she should undergo cardiac catheterization and trans-oesophageal echocardiography with a view to proceeding with a bi-directional Glenn shunt. The echocardiography was required to confirm that the Glenn shunt was the correct treatment plan. A 1½ ventricle repair was also considered, but was thought to be a limited option.

Aiming for a single ventricle repair required carrying out a Glenn shunt initially, with the intracardiac anatomy being left untouched. This would have necessitated a further operation (a Fontan procedure) a few years later. This was the most realistic and the safest option in the long term for treating Róisín's heart defects.

6.4.11 On 24th March 2003, Róisín was re-admitted for cardiac catheterization. The oxygen saturation on admission was 76%. A detailed echocardiogram was performed by Dr Moran. He confirmed a large mid-muscular VSD of about 15mm and a moderate sized 7 mm posterior muscular VSD. There was moderate hypoplasia of the right ventricle and good left ventricular function. Cardiac catheterization was performed by Dr Walsh on 25th March 2003. A left ventricular angiogram showed two muscular VSDs, one posterior and one anterior. The right ventricle was moderately hypoplastic. The pulmonary arteries were confluent and of good size. Róisín's condition was discussed at the Joint Conference of 27th March 2003. It was agreed that she should be placed on the waiting list for a bi-directional Glenn shunt, to be performed in June 2003. Róisín was discharged home on 26th March 2003.

The cardiac catheterization and echocardiography confirmed that the size of the right ventricle and the size and location of the VSDs were such that it was much safer to proceed with a Glenn shunt operation.

6.4.12 Róisín was re-admitted on 25th June 2003 for pre-operative assessment and was seen by the Cardiothoracic Senior House Officer.

It was noted that Róisín had been energetic up to the previous few weeks, when it had been noted by her mother that Róisín became tired quickly and asked to be carried after climbing the stairs. Mrs Quain-Ruddle had also noticed that Róisín was more cyanosed and slightly short of breath on these occasions. Her haemoglobin level on 26th June was 18.4 g/dl. Róisín was discharged home on 26th June 2003.

6.4.13 Róisín was re-admitted on 29th June 2003 for planned surgery the following day. On 30th June she was prepared for theatre in the normal way, but surgery was postponed because of the lack of a staffed ICU bed. Mr Wood explained the situation to Róisín's mother and Róisín was discharged home on 30th June 2003.

On pre-operative assessment, Róisín's haemoglobin level, while indicating the need for further surgery to improve oxygenation, did not indicate a very severe lack of oxygen to a level where emergency surgery was required. Róisín was, therefore, considered as an elective case and this was an appropriate categorisation.

6.4.14 On 1st July 2003 the Hospital was informed by Róisín's General Practitioner that Róisín had unexpectedly deteriorated and died during the early hours of that morning. She had awoken her parents at about 12.30am and approximately 50 minutes later she had suddenly developed seizures and become rigid and pale. Her GP arrived five minutes later and tried without success to resuscitate her. Róisín was pronounced dead at approximately 1.45am.

6.4.15 The autopsy confirmed the heart defects, but it is important to note that the Blalock-Taussig shunt was found to be patent. It was, therefore, thought that Róisín may have died from an intractable arrhythmia.

If Róisín had been suffering from dehydration, this might have produced a thrombosis and subsequent occlusion of the Blalock-Taussig shunt. However, the autopsy showed that the shunt was patent and so the function of the shunt could not have contributed to Róisín's death.

It is possible that undertaking several car journeys between Our Lady's Hospital and her home may have been detrimental to Róisín's health. However, there is no medical evidence to support this possibility in Róisín's case.

Cardiac arrhythmias can occur in any form of cyanotic or acyanotic congenital heart defects, and on occasions can result in death. In cases of complex heart defects, arrhythmias may occur prior to any corrective surgery, and susceptibility to arrhythmias may remain even after corrective surgery has been performed. It is likely that Róisín's death was the result of a cardiac arrhythmia.

6.5 Nursing Care

At their meeting with the Review Panel, Róisín's parents expressed concerns in relation to certain aspects of the nursing care provided to Róisín while she was a patient in Our Lady's Hospital, and these concerns are reflected in Sections 5.7, 5.9 and 5.12 of the Report.

The Panel discussed these concerns with the relevant nursing staff, and their responses are recorded in Section 5. Following these discussions, the Panel is satisfied that correct protocols and procedures were applied in relation to the nursing care provided to Róisín while she was a patient in Our Lady's Hospital.

6.6 The Intensive Care Unit

6.6.1 Paragraph 2.2 of the ERHA Report provides an overview of the Intensive Care Unit at Our Lady's Hospital, as follows:

> ***Intensive Care is provided in Our Lady's Hospital for Sick Children for critically ill children with a wide variety of medical and surgical conditions covering all medical specialties.***
>
> ***There are 21 fully equipped intensive care beds at the Hospital. These are divided into two units – the Main ICU and St Patrick's ICU. The Main ICU consists of 8 beds and this caters for all post-operative open heart surgery cases in addition to other intensive care patients. Complex cardiac cases are concentrated in the Main unit in order to maintain the specialised nursing skills required for these patients.***
>
> ***St Patrick's ICU consists of 13 beds, five of which function as High Dependency beds. St Patrick's ICU deals with all types of intensive care cases with the exception of complex cardiac cases. St Patrick's Intensive Care Unit does not admit post-operative open heart cardiac surgery patients as the nursing skill mix to care for these patients is located in the Main Intensive Care Unit.***

6.6.2 In the course of its meetings with Hospital staff, the Panel was told that, although the Intensive Care Unit at Our Lady's Hospital has a physical capacity of 21 beds, the Hospital has not been able to recruit sufficient intensive care nurses to open all of the 21 beds. The main ICU, which caters for all cardiac patients, has 8 fully-equipped beds, but has only sufficient nursing staff to operate 7 of these. In June 2003, the Unit as a whole was staffed for between 14 and 16 beds, depending on the case mix between intensive care and high dependency patients. (Patients requiring intensive care are nursed on the basis of one nurse

per patient; patients requiring high dependency care are nursed on the basis of one nurse per two patients.)

6.6.3 In the early morning of 30th June 2003, there were 14 patients in the Unit, seven in the Main ICU and seven in St Patrick's ICU. All 14 patients required intensive care nursing. Intensive Care Unit staff established that the only bed available was a high dependency bed in St Patrick's ICU. This bed was available because an intensive care patient was going to be extubated and would no longer require one-to-one nursing. The availability of this bed allowed the first surgical case to proceed, as that patient did not require intensive care nursing post-operatively.

6.6.4 Following the completion of the first case on the list, Mr Wood went to the ICU to check the position regarding the other two patients on his surgical list (one being Róisín), both of whom would require an intensive care bed post-operatively. There was no intensive care bed available at that time, but there was a possibility of transferring one intensive care patient out of the ICU. Arrangements were subsequently made to transfer this patient to a neonatal unit in another hospital. No other patient was fit to be transferred out of the Unit, either onto a ward within the Hospital, or to an ICU in another hospital. There was, therefore, only one intensive care bed available for the two cardiac surgical cases on the list. Mr Wood had to decide which of the two cases would proceed, and which would have to be deferred. Mr Wood and his team made a clinical decision to defer Róisín's surgery because it was deemed to be less urgent.

Following its meetings with the relevant clinical staff, including consultants and nurse management in the ICU, the Panel is satisfied that every effort was made to make beds available in the ICU for the cases on the cardiac surgical list for 30th June. Unfortunately, despite all these efforts, it proved necessary to defer Róisín's surgery, as there was no staffed intensive care bed available to accommodate her post-operatively.

Section 7 – Findings

7.1 Was Róisín's medical management appropriate?

The Panel is of the view that, of the various treatment options considered for Róisín, the Glenn shunt followed by the Fontan procedure was the most appropriate, and that the other strategies were unlikely to become feasible in her case. Given the rarity and complexity of Róisín's medical condition, the Panel finds that her clinical management was appropriate.

7.2 Was the deferral of Róisín's surgery a contributory factor in her death?

7.2.1 The results of the autopsy showed that the Blalock-Taussig shunt was patent and, therefore, the most likely cause of death was an arrhythmia. This view was supported by the medical opinion presented in the course of the Review, and by the Review Panel's medical expert.

7.2.2 If the Glenn shunt procedure had gone ahead as planned on 30th June, it would most likely have improved Róisín's oxygen saturation, and this may have reduced the likelihood of an arrhythmia. However, the reasons for arrhythmias occurring are complex and, despite an improvement in oxygen saturations, fatal arrhythmias can still occur. Nevertheless, it is the view of the Panel that if Róisín's operation had gone ahead as planned on 30th June, the likelihood of her survival would have been greater.

7.3 The reasons behind the deferral of Róisín's surgery

7.3.1 The Panel finds that the fundamental reason behind the deferral of Róisín's surgery was the inability of Our Lady's Hospital to recruit / retain sufficient experienced ICU nursing staff to support the available ICU beds.

7.3.2 Among the factors contributing to the shortage of paediatric ICU nurses was a change in the system of nurse education in the mid-1990s. Up to that time, qualification as a registered sick children's nurse (RSCN) was achieved through (i) the completion of a three year certificate course leading to registration as a sick children's nurse, (ii) the completion of a four year integrated certificate course leading to dual registration as both a sick children's and a general nurse, or (iii) nurses already registered could pursue a post-registration course in sick children's nursing leading to registration as a RSCN. RSCNs who wished to qualify as specialist paediatric ICU nurses could undertake a six month certificate course after a minimum of six to twelve months work experience within the paediatric ICU setting.

At that time, therefore, becoming a sick children's nurse took a minimum of three years, and becoming a fully trained paediatric ICU nurse took a minimum of four years.

7.3.3 Since 1996, the only route to becoming a sick children's nurse is to pursue a post-registration Higher Diploma programme over 18 months (nurses undertaking this programme revert to the salary scale of a first year staff nurse for the duration of the programme). It currently takes four years training to obtain registration as a general nurse, which means it takes a minimum of 5.5 years to qualify as a sick children's nurse. If a RSCN then wishes to qualify as a specialist paediatric ICU nurse, he/she must first obtain a minimum of six months work experience in paediatric ICU and then complete a further Higher Diploma in Nursing Studies (Clinical Practice – Paediatric Critical Care) over one year (full time) or two years (part time).

It now, therefore, takes a minimum of seven years to become a fully trained paediatric ICU nurse.

7.3.4 The numbers of students seeking to pursue the sick children's nursing post-registration programme have been falling steadily, leaving a much smaller pool of nurses qualified to undertake the paediatric ICU course. A further disincentive to nurses pursuing a qualification as paediatric ICU nurses is that, although additional specialist qualification allowances are payable in respect of (i) a sick children's nursing qualification and (ii) a paediatric ICU qualification, only one allowance (whichever is the greater) is payable at a time.

7.3.5 The protracted training period, the salary/allowance disincentives, the high acuity and stress associated with paediatric intensive care nursing, and the cost of living in Dublin (where the paediatric ICUs are located) are all contributory factors to a decrease in the numbers of sick children's nurses and, consequently, the numbers of specialist paediatric intensive care nurses.

7.3.6 Given the changes in the system of nurse education from 1996, future staff shortages were predictable. The Panel has seen copies of intra-Hospital correspondence, and minutes of a meeting between representatives of the hospital and the Department of Health in 1996, wherein the difficulty of recruiting ICU nurses is alluded to. The Panel heard that the difficulty became more acute in or around 1998.

7.3.7 The Panel tried to ascertain the steps that were taken by Our Lady's Hospital before 1998 to manage the problem, but no evidence was presented to suggest that the Hospital made any significant efforts to identify initiatives that might have been taken to address the issue. The Panel was particularly concerned to note that, in circumstances where crucial ICU nurses were in short supply, there was no one person in Our Lady's Hospital who had full-time responsibility for nursing recruitment.

7.3.8 There is evidence that, in 1998, a number of initiatives were introduced by the then Director of Nursing to try to improve the level of recruitment and retention of critical nursing staff, and that these were successful to some degree, although the situation deteriorated again in 2000. In that year, the Hospital, with the support of the ERHA, began to recruit nurses from overseas.

7.3.9 The Panel accepts that significant efforts have been made by the Hospital in more recent times to try to resolve the issue.

7.3.10 The Panel is aware that there is, and has been for some time, a worldwide shortage of paediatric ICU nurses. Given that Our Lady's Hospital is the only centre for paediatric cardiac services in the country, and that ICU nurses are central to the provision of these services, the Panel is of the view that the shortage of such specialized nurses, predictable from the mid-1990s, does not appear to have been seen by Hospital management at the time as a priority issue warranting significant management attention. From the evidence presented, it is clear to the Panel that the problems relating to the recruitment and retention of specialist nursing staff were considered matters to be addressed solely by the Director of Nursing and her staff. Although aware of the problems, there is no evidence that Hospital management or the Committee of Management gave any active support, other than the approval of financial resources, to helping the Director of Nursing with the problem-solving initiatives that were clearly needed to address the recruitment issues for this highly critical area of the Hospital's activities. The problem may have been compounded by the fact that, during the relevant period, there were several changes of personnel in the Director of Nursing post, and periods where the post was filled in an acting capacity.

7.3.11 The Panel is aware of hospitals in the United Kingdom where various initiatives were taken over the years to try to lessen the risk of surgical cancellations due to the non-availability of ICU staff. Some hospitals were more successful in this regard than others.

7.3.12 In the opinion of the Panel, insufficient focus was placed by Our Lady's Hospital management and the Committee of Management on the resolution of the issue and, as a consequence, there was a lack of urgency in applying and distributing available resources to resolving the problem or at least trying to do so. That said, the Panel feels that it is important to point out that, despite the significant efforts that have been made by the Hospital in more recent times, the Hospital is still not in a position to staff its full complement of ICU/HDU beds.

Section 8 - The current position

8.1 Governance and Management Structure

The Review Panel heard that a consultancy firm is currently preparing a report on the governance and management structure of Our Lady's Hospital, and that it is anticipated that the report will recommend changes in the current structure. In the meantime, arrangements are being made to put a Clinical Bed Manager in place. Arrangements are also in train to designate responsibility for issues relating to nursing recruitment and retention to one person. This post, which will be a full-time nurse manager post, will be positioned within the Hospital's Human Resources Department.

8.2 Cardiac Surgery

A new Operating Department at Our Lady's Hospital, comprising (*inter alia*) five replacement operating theatres and two new operating theatres, has been built and equipped. The five replacement theatres were commissioned in 2003, and funding has recently been approved for the commissioning of the two new theatres. In the meantime, the Hospital has sought and obtained additional funding from the ERHA to utilize some of the capacity provided by the two new theatres for the provision of additional cardiac surgery procedures. A third cardiothoracic surgeon has been appointed and is due to take up post shortly.

8.3 Intensive Care Unit Capacity

8.3.1 The Panel heard that management at Our Lady's Hospital is optimistic in relation to recruiting the additional ICU nursing staff necessary to allow the Hospital to operate its full complement of ICU beds.

8.3.2 The Council for Children's Hospitals' Care was established in 1999, primarily to assist the three Dublin paediatric hospitals to work with each other and with the ERHA to plan and develop acute paediatric services on a co-ordinated basis in the functional area of the Authority. It also, as necessary and appropriate, facilitates co-operation and liaison with other agencies providing acute paediatric services throughout the country. The Panel heard that the Council as part of its brief has been working with the three Dublin paediatric hospitals to establish formal arrangements among ICU units in those hospitals to ensure optimum utilization of the available paediatric ICU/HDU beds in the ERHA region. Under this initiative, an electronic mail transfer system has been put in place between Our Lady's Hospital and the Children's University Hospital in Temple Street so that each unit is aware of the other's capacity on a daily basis. The work of this

committee is ongoing, and it is anticipated that further information systems will be put in place to ensure that the needs of children requiring intensive or high dependency care will be responded to appropriately and as quickly as possible.

8.3.3 In addition, the Council is working with the ERHA and clinical staff and management at Our Lady's Hospital and the Children's University Hospital in Temple Street to develop an initiative whereby long-term ventilated patients in ICU might be transferred to a unit more appropriate to their needs, thus optimizing ICU bed availability.

8.4 Redevelopment of the Hospital

The Panel is aware that the Minister for Health and Children has approved the establishment of a Project Team to plan for the future development of the facilities at Our Lady's Hospital. An Outline Development Control Plan, which will set the context for future capital developments on the site, has been prepared and, having been endorsed by the Hospital, has been submitted to the ERHA and the Department of Health and Children for approval to advance the development process.

8.5 Nurse Education

The Panel is aware that, further to the recommendations of the Report of the Paediatric Nurse Education Review Group, the Minister for Health and Children has established an Expert Group to develop a comprehensive strategy for the future of midwifery and paediatric nurse education. This Group is currently exploring the feasibility of offering both a direct entry integrated sick children's / general nursing degree programme, and continuing post-registration programmes.

Section 9 – Recommendations

9.1 The Panel found no evidence to suggest that the stress of the travel to and from Our Lady's Hospital on 29th and 30th June, so soon after her previous journeys on 25th and 26th June, was a contributory factor in Róisín's death. However, it is the Panel's view that frequent long journeys are not ideal for children with heart conditions. The Panel noted that children due to undergo cardiac surgery on Wednesdays are admitted for their pre-operative procedures on the Monday beforehand. Children due to undergo cardiac surgery on Mondays are admitted for their pre-operative procedures on the previous Wednesday, discharged on the Thursday, and re-admitted on the Sunday for planned surgery the following day. It is likely that many families would wish to travel back to their own homes rather than avail of any accommodation facilities on-site when there was no medical reason to do so.

The Panel recommends that relevant persons in Our Lady's Hospital should consider ways to avoid the necessity of such patients and their families having to undertake two journeys in quick succession, particularly where the distance to be travelled is significant. If it is necessary to carry out operations on a Monday, facilities should be available to carry out the necessary pre-operative procedures in the Hospital at weekends.

9.2 The Panel is aware that it is intended that a full-time nurse manager post be created within Our Lady's Hospital to manage nursing recruitment and retention issues, and that this post be positioned within the Hospital's Human Resources Department. The Panel recommends that this post be created as soon as possible so that the appropriate time and resources are concentrated on ensuring, insofar as possible, the ongoing availability of experienced nursing staff within the ICU.

9.3 The Panel is aware that Our Lady's Hospital intends to appoint a Clinical Bed Manager. The Panel recommends that this appointment be made at the earliest possible date to ensure the efficient and effective use of resources in accordance with best practice.

9.4 The Panel is aware that arrangements are in train to review the governance and management structure within Our Lady's Hospital. The Panel recommends that, whatever management structure is put in place, it should facilitate arrangements whereby critical issues are brought to the attention of senior management and to the Committee of Management (or its successor) at the earliest possible date, so that any measures intended to resolve those issues can be monitored and evaluated at an appropriate level.

9.5 The Panel acknowledges the enhanced efforts made by Our Lady's Hospital in more recent times to attract and support paediatric nurses

who do not possess a paediatric ICU qualification but who are willing to work in ICU. The Panel also acknowledges the increased efforts that are being made, especially the co-ordinated approach with other ERHA health service employers to recruit ICU nurses from overseas.

The Panel recommends that the issue of attracting and retaining suitably qualified or experienced nurses in ICU be kept under constant review and that further creative ways of addressing the problem be explored on an on-going basis.

9.6 International best practice dictates that the planning of a paediatric ICU service should be done on the basis of an average 75% occupancy rate. The Panel recommends that this occupancy rate should be factored in to future facilities and staffing plans for paediatric ICU at Our Lady's Hospital.

9.7 The Panel recommends that nursing staff turnover in the ICU at Our Lady's Hospital be closely monitored to ensure optimum forecasting of nurse staffing turnover patterns and nurse workforce planning.

9.8 The Panel recommends that Our Lady's Hospital should consider the feasibility of establishing a standby (on-call) roster for ICU nurses, given the critical nature of the services provided by such staff.

9.9 The Panel was advised that Our Lady's Hospital does not have a recruitment website. Given the difficulties in recruiting appropriately qualified nursing staff, the Panel recommends that the Hospital develop as soon as possible an attractive recruitment website in order to maximize recruitment opportunities in respect of all disciplines within the Hospital.

9.10 The Panel acknowledges that the number of places available in Our Lady's Hospital for nurses undertaking the Higher Diploma in paediatric ICU nursing has increased in recent years. The Panel recommends that the number of places available on this course be kept under constant review, and adjusted in accordance with service needs.

9.11 The Panel recommends that all necessary steps be taken to encourage higher numbers of students to pursue registration in sick children's nursing, to try to ensure that there is a sufficient pool of nurses qualified to undertake the specialist paediatric ICU nursing course. The Panel also suggests that the overall training period required to become a fully-qualified paediatric ICU nurse (currently a minimum of seven years) be re-examined.

9.12 The Panel is aware that the Council for Children's Hospitals' Care has established a sub-committee, comprising representatives from the three Dublin paediatric hospitals, to improve communication systems among the available intensive care units for the benefit of children who require these facilities, both within the ERHA region and nationally. The

Panel recommends that this sub-committee be given every support to ensure the achievement of its objective.

9.13 The Panel is of the view that Our Lady's Hospital, as the National Paediatric Cardiac Centre, would benefit from establishing links with similar institutions internationally to facilitate the sharing of knowledge and experience in dealing with any problems arising, such as a shortage of specialized nursing staff, that may be common to such institutions generally, and recommends that the Hospital should proceed to establish such links.

Acknowledgements

The Panel would like to thank the Ruddle family for their co-operation with the Review. The members of the Panel and Secretariat wish to express to the family their deepest sympathies on the loss of Róisín.

The Panel would also like to acknowledge the co-operation of the Eastern Regional Health Authority and of the staff (including former staff) of Our Lady's Hospital. We feel it appropriate to mention the genuine sympathy for the Ruddle family expressed by all those whom we met in the course of the Review.

Finally, the Panel would like to express its appreciation of the support it received from the Secretariat.

APPENDIX 1

Meetings with relevant persons

The Review Panel met the following individuals during the course of its work:

Eastern Regional Health Authority

Mr Jim Breslin, Director of Planning, Commissioning and Change
Ms Mo Flynn, Senior Commissioner
Mr Willie Rattigan, Service Planner

Our Lady's Hospital for Sick Children, Crumlin

Governance and Administration

Mr Frank Feely, Deputy Chairman of the Committee of Management of Our Lady's Hospital

Ms Moira McQuaid, General Manager (then Acting Chief Executive)

Mr Gerry O'Dwyer, Chief Executive

Medical

Dr Pat Doherty, Consultant in Anaesthesia and Intensive Care

Dr David Mannion, Consultant in Anaesthesia and Intensive Care

Dr Jacinta McGinley, Consultant in Anaesthesia and Intensive Care

Dr Brendan O'Hare, Consultant in Anaesthesia and Intensive Care

Dr Paul Oslizlok, Consultant Cardiologist

Mr Mark Redmond, Consultant Cardiothoracic Surgeon

Dr Kevin Walsh, Consultant Cardiologist

Mr A.E. Wood, Consultant Cardiothoracic Surgeon

Nursing

Ms Fiona Brennan, Clinical Nurse Manager I

Ms Aileen Connolly, Assistant Director of Nursing

Ms Jackie Cogan, Clinical Nurse Manager II

Ms Kathleen Crumlish, Clinical Nurse Specialist (Cardiology)

Ms Eithne Farrell, Clinical Nurse Manager II

Ms Tara Galligan, Clinical Nurse Manager I

Ms Rachel Kenna, Clinical Nurse Manager III

Ms Geraldine Moore, Staff Nurse

Ms Helene Murchan, Clinical Nurse Specialist (Cardiology)

Ms Michelle O'Gorman, Staff Nurse

Ms Linda Phelan, Staff Nurse – Intravenous Team

Ms Geraldine Regan, Director of Nursing

Ms Ann Spillane, Staff Nurse

Ms Caroline Thomas, Staff Nurse

Others

Mr Paul Kavanagh, former Chief Executive of Our Lady's Hospital

Ms Emily Logan, former Director of Nursing at Our Lady's Hospital

Dr Adrian Moran, former Consultant Cardiologist at Our Lady's Hospital *

* The discussion with Dr Moran, who now works in the United States, was held via a voice-conference link

Written submissions were received from Professor Brendan Drumm (Department of Paediatrics, UCD), Heart Children Ireland, and The New Crumlin Hospital Group. These were noted by the Panel.

APPENDIX 2

Memorandum on Procedures

1. Status

1.1 This Review Panel was convened by Micheál Martin TD, Minister for Health and Children to conduct an independent review of the events surrounding the death of Roisin Ruddle.

1.2 In order to carry out its work, the Panel depends on the voluntary co-operation of those who are in a position to assist it.

2. Membership

2.1 The members of the Panel are:

Mr David Hanly (Chairman)

Ms Kay O'Sullivan, Director of Nursing at Cork University Hospital

Dr Shakeel A. Qureshi, Paediatric Cardiologist at Guy's and Thomas's Hospital, London

3. Terms of Reference

3.1 The Terms of Reference of the Panel are:

- To consider the report of the ERHA in relation to the events of 30 June 2003 at Our Lady's Hospital for Sick Children, Dublin and to make such further enquiries and conduct such interviews as the Panel considers necessary;

- To address the questions raised by the family;

- To examine protocols and procedures relevant to this incident having regard to prevailing standards of best practice, and to examine their application in this case;

- To report to the Minister and to make such recommendations as it sees fit.

- Following the Review, both Reports will be made available.

3.2 The Panel is presently aware of three questions raised by Roisin's parents, Mr and Mrs Ruddle, as follows:

- Was Roisin seen by a Consultant on the morning of 30 June before the decision was taken to cancel her surgery?

- Why was Roisin (who had been fasting) not given a meal before her discharge?

- What was the impact of travelling to-from home on Roisin's state of health?

3.3 It is the Panel's intention to meet with Roisin's parents in the course of the Review and if further questions are raised by the family at that stage those questions will fall within its terms of reference and will receive due examination (subject to the requirements of fair procedures being observed and the constitutional and other rights of all concerned being protected).

3.4 In the event that any additional questions raised by the Ruddle family extend beyond those set out in paragraph 3.2, all relevant parties will be notified.

4. Procedures

4.1 In carrying out its functions the Panel will ensure that fair procedures are followed in the carrying out of its functions, and that the constitutional and other rights of all individuals and bodies concerned are protected.

4.2 The Panel will invite persons who may be in a position to assist its work to meet with the Panel. At this time, the Panel intends to meet the following persons:

Our Lady's Hospital for Sick Children

Mr A. E. Wood, Consultant Cardiac Thoracic Surgeon
Mr Mark Redmond, Consultant Cardiac Thoracic Surgeon
Dr P. Oslizlok, Consultant Cardiologist
Dr Kevin Walsh, Consultant Cardiologist
Dr Adrian Moran, Consultant Cardiologist
Dr D. Mannion, Consultant Anaesthetist / Intensivist
Dr J. McGinley, Consultant Anaesthetist / Intensivist
Dr B. O'Hare, Consultant Anaesthetist / Intensivist & Director of the Paediatric Intensive Care Unit
Dr P. Doherty, Consultant Anaesthetist / Intensivist

Mr Frank Feely, Deputy Chairman of the Board at Our Lady's Hospital
Ms Moira McQuaid, Acting Chief Executive

Ms Geraldine Regan, Director of Nursing
Ms Aileen Connolly, Assistant Director of Nursing
Ms Rachel McKenna, CNMIII, Intensive Care Unit

Ms Helene Murchan, Cardiac Liaison Nurse
Ms Kathleen Crumlish, Cardiac Liaison Nurse
The nurse in charge of recruitment of ICU nursing staff

Nursing staff on St Bridget's Ward who had direct dealings with Roisin Ruddle between 3pm on Wednesday 25th June 2003 and 4pm on Thursday 26th June 2003

Nursing staff on St Bridget's Ward who had direct dealings with Roisin Ruddle between 5pm on Sunday 29th June 2003 and 12.30pm on Monday 30th June 2003

Eastern Regional Health Authority

Mr Jim Breslin, Director of Planning, Commissioning and Change

The Panel may in the course of its enquiries decide to invite other people to meet with the Panel, if it considers that it may assist the Panel to do so. An updated list of interviewees will be made available to all relevant parties.

4.3 The Panel intends that its meetings with relevant personnel will be non-adversarial and fact-finding, and that the proceedings will be as informal as is practicable.

4.4 Persons meeting the Panel will be entitled to have a legal adviser, a union official or any other appropriate person present at meetings with the Panel. However, the Panel has no powers to cover the costs of such representation. The attendance by any such persons at meetings with the Panel does not confer the right on such persons to intervene in the interview process.

4.5 The Panel does not intend to be legally represented at meetings with relevant personnel. However, if in the course of any meeting the Panel considers it would be appropriate to do so, the meeting will be adjourned to allow the Panel to take legal advice.

4.6 Meetings with relevant personnel will be recorded, with the prior consent of the individual concerned.

4.7 If, following any meeting, the Panel wishes to raise a further matter with the person concerned or to clarify a matter that was discussed at the meeting, the Panel intends to raise that matter with the person concerned in writing rather than convene another meeting. The Panel will ensure that interviewees are given an opportunity to respond to matters relevant to them. If significant matters are raised which might affect the reputation and good names of individuals or bodies, the Panel reserves the right to deal with these consistent with the rights of the parties involved and commensurate with its terms of reference.

APPENDIX 3

Glossary

Acyanotic

The opposite of cyanotic (q.v.).

Angiogram / angiography

Angiography is the method used to x-ray the blood vessels and chambers of the heart. The angiogram is the result produced.

Aorta

The main artery carrying oxygenated blood away from the heart.

Apical

The area of the dividing wall between the two ventricles which is at the bottom of the wall.

Balloon angioplasty

The stretching and opening of a narrowed vessel using a balloon.

Balloon atrial septostomy

A procedure in which a hole is made in the dividing wall between the upper two chambers of the heart to allow better mixing of oxygenated and de-oxygenated blood.

Bi-ventricular repair

A repair which involves having two ventricles pumping blood to the two separate circulations, the right ventricle pumping blood to the lungs and the left ventricle pumping blood to the brain and the rest of the body. See also Rastelli operation.

Blalock-Taussig shunt

Artificial channel created between the aorta and the pulmonary artery to allow an increase in blood flow to the lungs to pick up oxygen.

Cardiac arrhythmia

A variation from the normal regular rhythm of the heart beat.

Cardiac catheterization

A procedure to diagnose congenital heart disease, in which a tube is inserted into a blood vessel and passed through to the chambers of the heart to produce angiograms and to take blood samples to measure oxygen levels in different chambers.

Congenital heart defect

A heart defect that is present from birth.

Cyanotic, cyanosed, cyanosis

A state in which the skin, usually of the face and extremities, turns a bluish tinge. It indicates that the blood is not adequately oxygenated in the lungs due to reduced blood flow to the lungs caused by the congenital heart defect, and therefore the blood reaching the brain and the rest of the body is de-oxygenated.

Duct-dependent

Blood flow to the lungs is dependent on the arterial duct remaining open.

Echocardiogram / echocardiography

Echocardiography is the use of ultrasound techniques for the purpose of examining the heart. The echocardiogram is the result produced.

Extubated

The removal of the tube that is used to assist a baby's ventilation.

Fontan procedure

The creation of an artificial channel between the inferior vena cava and the pulmonary artery in addition to the Glenn shunt, such that all the de-oxygenated blood bypasses the heart chambers and is directed into the lungs.

Glenn shunt

Artificial channel created between the superior vena cava and the pulmonary artery to allow de-oxygenated blood from the upper half of the body to reach the lungs directly.

Haemoglobin

The substance in blood that acts as the carrier of oxygen from the lungs to all the tissues of the body.

Hyperoxia test

A test in which a baby is given 100% oxygen by mask, and measurements are taken of the oxygen levels in the arteries. If the oxygen level remains low, this indicates the presence of a congenital heart defect.

Hypoplasia

Excessive smallness of an organ arising from imperfect development.

Impra graft

A tube of synthetic material used to create a Blalock-Taussig shunt.

Isotonic fluid

A fluid that can be mixed with the body's fluids without causing any disturbance.

Mid-trabecular, mid-muscular

The area of the dividing wall between the two ventricles which is in the middle of the wall.

Occlusion

The obstruction or blockage of a blood vessel.

Oxygenation

The process of oxygen transfer from the lungs to the blood passing through the lungs.

Oxygen saturations

The level of oxygen in the blood.

Patent

Open, not blocked.

Patent arterial duct

A normal structure present before birth which connects the aorta (the main artery carrying oxygenated blood to the brain and the rest of the body) to the pulmonary artery (the artery carrying de-oxygenated blood to the lungs).

Prostaglandin infusion

Infusion of a substance to keep the arterial duct open.

Pulmonary artery

The main artery carrying de-oxygenated blood to the lungs.

Pulmonary atresia

A condition in which the pulmonary valve has not developed and is thus completely blocked, preventing any blood from entering the lungs.

Rastelli operation

Operation involving the closure of the ventricular septal defect in such a way as to allow oxygenated blood to pass from the left ventricle to the aorta, and the insertion of a conduit to join the right ventricle to the pulmonary artery.

Renal dysfunction

Impairment of the function of the kidneys.

Septal defect

A congenital abnormality of the heart in which there is a hole in the dividing wall between the left and right sides of the heart.

Stenosis

An unnatural narrowing in the vessels of the heart.

Thrombosis

The formation of a blood clot within the blood vessels of the heart.

Trans-oesophageal echocardiogram

An ultrasound scan in which the ultrasound probe is passed through the oesophagus into the stomach in order to scan the heart.

Ventricle

The term applied to the two lower cavities of the heart.