

An inadequate care process

An investigation into the quality and safety of the cardio-surgical care chain for adults at St Radboud UMC, Nijmegen

24 April 2006

Table of contents

Glossary.....	III
Summary.....	5
1 Introduction.....	6
1.1 Background.....	6
1.2 St Radboud UMC's response to the Health Care Inspectorate.....	6
1.3 Agreements reached between St Radboud UMC and the Health Care Inspectorate.....	8
1.4 Remit of the external committee.....	8
2 Organisation of the cardio-surgical care chain.....	10
2.1 General organisational structure of St Radboud UMC.....	10
2.2 Organisation of the Cardio-Pulmonary Centre.....	10
2.3 Protocols.....	14
2.4 Record-keeping.....	15
2.5 Consultation.....	15
2.6 Current policy developments.....	15
3 Investigative methodology.....	17
3.1 Introduction.....	17
3.2 Comparison with other Dutch centres.....	18
3.3 CUSUM mortality analysis.....	18
3.4 Study of mortality case histories.....	19
3.5 Morbidity analysis.....	20
3.6 Interviews.....	20
4 Results: evaluation of the Cardio-surgical care chain.....	21
4.1 Mortality.....	21
4.2 Morbidity.....	26
4.3 Interview summaries.....	26
5 Observations and discussion.....	37
5.1 Introduction.....	37
5.2 Assessment of risk profile and complexity of care.....	37
5.3 Mortality.....	37
5.4 Morbidity.....	39
5.5 Conclusions of the case record reviews.....	39
5.6 Causes of the elevated mortality and morbidity.....	39
6 Concluding remarks.....	46
References.....	47
Appendix 1. Available mortality data and their evaluation by St Radboud UMC in response to enquiries made by the Health Care Inspectorate.....	48
Appendix 2. Composition of the External Investigation Committee (EIC).....	50
Appendix 3. Departmental consultation arrangements.....	51

Glossary

A10, A11, A12	Nursing wards
Additive EuroSCORE	Scoring system used prior to open-heart surgery to calculate the mortality risk associated with the procedure
AGNIO	<i>Assistent Geneeskundige Niet In Opleiding</i> (a junior doctor who has completed training)
AOV	Department of Thoracic and Cardiac Surgery ('A' building, lower floor)
AV	Aortic valve
BHN	<i>Begeleidingscommissie Hartchirurgie Nederland</i> (Dutch Cardiac Surgery Supervision Committee)
BOL	<i>Beroepsopleidende leerweg</i> (professional training path)
CABG	Coronary Artery Bypass Graft;
CAIO	<i>Cluster Centrale Sterilisatie, Anesthesiologie, Intensive Care en Operatiekamers</i> (Central Sterilisation, Anaesthesiology, Intensive Care and Operating Theatre Cluster)
CCV	Cardiac monitoring
CLA	Collective Labour Agreement
CORRAD	CORonary Artery Surgery Database St RADboud, St Radboud UMC's thoracic and cardiac surgery databank
CUKZ	Nijmegen University Children's Hospital Cluster
CUSUM	CUMulative SUMmation, an analytical technique
CVA	Cerebral vascular accident (stroke)
ECC	Extracorporeal Circulation
EIC	External Investigation Committee
EuroSCORE	European System for Cardiac Operative Risk Evaluation. Scoring system used prior to open-heart surgery to calculate the mortality risk associated with the procedure
H20	General Intensive Care Unit (seven beds)
H35	General Intensive Care Unit with isolation facilities (eight to ten beds)
IC	Intensive Care
ICU	Intensive Care Unit
IGZ	<i>Inspectie voor de Gezondheidszorg</i> (Health Care Inspectorate)
IIC	Internal Investigation Committee
MC	Medium Care
MV	Mitral valve
NICE	National Intensive Care Evaluation
NVA	<i>Nederlandse Vereniging voor Anesthesiologie</i> (Netherlands Association for Anaesthesiology)
OT	Operating Theatre
SMT	Small Management Team
STS	Society of Thoracic Surgeons
ULCD	<i>Universitair Longcentrum Dekkerswald</i> (Dekkerswald University Pulmonary Centre)
UMC	University Medical Centre

Summary

Conclusion

In 2004, mortality among patients undergoing cardiac surgery at St Radboud UMC was abnormally high. In addition, surgery carried out in the period 2003 to 2005 was associated with a high to very high incidence of follow-up surgery necessitated by haemorrhaging and cardiac tamponade. Elevated levels of postoperative organ failure were also recorded.

The elevated rates of mortality and morbidity were attributable primarily to shortcomings in the care chain. These shortcomings included lack of coordination, insufficient use of protocols, an insufficiently multidisciplinary approach, a lack of operational uniformity, inadequate review arrangements and lack of leadership.

There is no evidence that the complexity of the caseload handled by St Radboud UMC gave rise to the above-average mortality and morbidity rates; if anything, the centre's caseload should have had the opposite effect. Nor can the high levels of mortality and morbidity be attributed to failings on the part of any individual or group involved in the provision of cardio-surgical care. Numerous matters need to be addressed in the short term in order to rectify the problems in the cardio-surgical care chain; particular priority should be given to the provision of strong leadership and the reorganisation of the cardio-surgical care process along clearly defined lines. It is the responsibility of the hospital management to expedite implementation of appropriate changes and of the Health Care Inspectorate to closely monitor the process of change.

The investigation

On 9 September 2005, a policy meeting attended by all the disciplines concerned with the treatment of cardiac surgery patients took place at St Radboud UMC. The aim of this gathering was to formulate effective improvement programmes for the Cardio-Pulmonary Centre. At the policy meeting, mortality and morbidity data were presented. These data subsequently found their way into the public domain through e-mail correspondence, leading to considerable publicity and disquiet.

The statistics themselves and the public outcry they provoked prompted St Radboud UMC's Board of Governors and the Health Care Inspectorate (IGZ) to take a number of initiatives. These initiatives had two objectives: to provide greater clarity regarding the accuracy of the published data and the seriousness of the situation, and to establish whether the cardio-surgical care chain was substandard and, if so, what should be done to rectify the situation.

In this context, St Radboud UMC's Board of Governors and the IGZ together set up an External Investigation Committee (EIC), consisting of external experts in the various disciplines involved in the cardio-surgical care chain. Each of these experts was nominated by his or her professional association, and the committee was chaired by the Inspectorate. The EIC's remit was to assess the accuracy of the mortality and morbidity data, to establish whether the rates of mortality and morbidity were indeed elevated, to seek to identify the possible causes and to recommend improvements.

The EIC studied material made available by the hospital, interviewed roughly fifty members of the medical staff, cardio-surgical care chain workers and referring cardiologists, and – working independently and in conjunction with an internal committee – reviewed the case histories of patients who died in 2004 and 2005. It was on the basis of these investigations that the EIC arrived at the conclusion set out above.

1 Introduction

1.1 Background

On 9 September 2005, a policy meeting attended by representatives of all the disciplines involved in the care chain took place in the Cardio-Pulmonary Centre¹ at St Radboud UMC. One of the subjects discussed at this meeting was treatment outcome data for cardiac surgery patients, collected in the context of the National Intensive Care Evaluation (NICE) system. St Radboud UMC has been participating in this system since the start of 2004. The NICE system provides for the continuous, comprehensive registration of data on all patients admitted to participating units for intensive care.

According to the data presented at the meeting, the rate of mortality associated with thoracic and cardiac surgery at St Radboud UMC in 2004 was more than twice the national average (6.7 per cent versus 2.7 per cent).

The data prompted the recently appointed Professor of Cardio-Surgical Anaesthesiology (who had taken up his post on 1 September 2005) to e-mail his staff, urging them to raise performance levels. In his e-mail, the Professor made reference to an unacceptably high rate of mortality associated with heart valve surgery and said that he himself 'would not be willing to undergo surgery in this centre'. This e-mail was subsequently forwarded to the Health Care Inspectorate by an anonymous informer and published in the press.

In response, the Health Care Inspectorate (IGZ) asked St Radboud UMC's Board of Governors to provide it with more information. In particular, the Inspectorate wished to know:

- whether the mortality rate associated with heart valve surgery was indeed unacceptably high;
- whether the situation was sufficiently serious to warrant the suspension of surgical activities;
- what action had been taken following the policy meeting; and
- whether action had been taken to raise the standard of cardio-anaesthesiological care.

1.2 St Radboud UMC's response to the Health Care Inspectorate

The policy meeting

In its written response, which is summarised below, St Radboud UMC reported that the policy meeting had been organised with a view to facilitating focused analyses and defining effective improvement programmes for implementation in the context of a chain-based approach, which was seen as the key to successful quality improvement. At the policy meeting, three conclusions had been drawn regarding the NICE data for 2004:

- *"There has been a considerable shift in the patient mix, with the number of low-risk patients falling relative to the number of high-risk patients.*
- *The complication and mortality rates need to be reduced by collective effort.*
- *There is currently too much emphasis on a single-step logistic approach within the chain; improvements should preferably involve the whole chain or at least several links."*

¹ With effect from 1 January 2005, St Radboud UMC's Cardiac Centre was merged with the Pulmonary Diseases Department to form the Cardio-Pulmonary Centre. In this report, consistent use is made of the title 'Cardio-Pulmonary Centre'.

Various initiatives had been set in motion for the second half of 2005: the improvement of preoperative screening, the restructuring of the multidisciplinary complication and mortality review and the definition of a clinical path (complete with performance indicators) for cardiac surgery patients as a group.

Following a more detailed discussion of the mortality figures, the policy meeting had concluded that the high rate of mortality in 2004 was attributable partly to the high-risk patient group. The meeting had also taken the view that no single factor was clearly responsible for the high rate of mortality.

With regard to the e-mail, St Radboud UMC indicated to the Health Care Inspectorate that the phrase ‘unacceptably high rate of mortality’ should be interpreted as an informal expression used with a view to stressing that absolutely everything should be done to bring about an improvement. St Radboud UMC reasoned that when the professor had said that he himself ‘would not be willing to undergo surgery in this centre’, he was seeking dramatic emphasis in order to convey a sense of urgency.

Mortality figures

The reported rates of mortality for 2004 and 2005 were supported by all the data sources available to St Radboud UMC, i.e. the records maintained by the unit’s own Department of Thoracic and Cardiac Surgery, the NICE database and the figures recorded by the Dutch Cardiac Surgery Supervision Committee (BHN). All relevant personnel within the Cardio-Pulmonary Centre were in agreement concerning the absolute mortality figures, which were above the Dutch average. Every effort was being made to get the rate below the national average.

The unit’s performance over the previous eight years was subsequently analysed more closely by St Radboud UMC, using the EuroSCORE system (one of the international standards for evaluating the quality of cardiac surgery centres by reference to mortality figures). To this end, patients were categorised as high, medium or low-risk (see Appendix 1). On the basis of this analysis, St Radboud UMC concluded

“that the results of the Cardio-Pulmonary Centre are consistent with European figures for overall mortality among cardiac surgery patients in general and among the individual risk groups.”

However, the figure for high-risk patients undergoing mitral heart valve surgery formed an exception in this regard, being well above the Expected Mortality Rate. St Radboud UMC explained this by saying that St Radboud UMC also accepted for surgery patients who represented a very high risk.

Conclusions reached by St Radboud UMC

St Radboud UMC concluded that the performance of the Cardio-Pulmonary Centre

“ ... may be regarded as qualitatively normal on the basis of the internationally accepted standard. The conclusion is that the above-average rate of mortality, insofar as not explained by the patient population having a higher-than-average risk profile, is multifactorial in its origin.”

St Radboud UMC added that it remained committed to realising continuous improvement and to securing a place among the top three centres in the Netherlands.

The Centre argued that the key to securing further improvement was focused chain analysis.

Plans were in place to build on the targeted quality drives of recent years by pursuing the following initiatives within the hospital in the near future:

1. Detailed chain analysis was to be accelerated. To this end, suitably qualified additional personnel were to be recruited.
2. To give further impetus to the chain analysis strategy, the Board of Governors was to establish an (international) external consultation group, complementing the personnel already deployed and soon to be deployed within the Centre.
3. All disciplines were to focus more (concentrate more expertise) on the care given to cardiac patients, which was expected to enhance the expertise of the specialists concerned.
4. A focused analysis was to be made in the short term of all complications and all mortality since 1 January 2004.
5. The regular multidisciplinary complication and mortality review system was to be optimised within the Cardio-Pulmonary Centre in order to ensure that lessons were learnt quickly from recent experience.
6. Stricter definitions of the circumstances under which surgery was indicated for patients in the high-risk groups were to be introduced where possible.

1.3 Agreements reached between St Radboud UMC and the Health Care Inspectorate

Since no simple explanation could be given for the high mortality figures in the main risk groups, particularly patients undergoing mitral valve surgery, St Radboud UMC and the Health Care Inspectorate both concluded that further analysis was in order. Following discussion of St Radboud UMC's written response, the IGZ and St Radboud UMC's Board of Governors decided to establish an external investigation committee to consider the quality and safety of the cardio-surgical care chain at St Radboud UMC's Cardio-Pulmonary Centre.

In addition, St Radboud UMC set up an internal project group to look at the development of the cardiac surgery care chain for adults and an internal committee to study the case histories of patients who died in the centre's care (the Internal Investigation Committee, or IIC). It was decided that the internal project group and the IIC should report to the Board of Governors, while the external committee should report to both the Board of Governors and the IGZ. St Radboud UMC's Board of Governors and the IGZ also concluded that a much more cautious approach should be taken to determining whether surgery was indicated for very high-risk patients (those with a EuroSCORE of 10 or higher) exhibiting mitral valve pathology.

1.4 Remit of the external committee

The aims of the external committee's investigations were defined as follows:

- To identify features of the cardio-surgical care chain that might be detrimental to the quality and safety of care, and, where possible, to make proposals regarding a programme of improvement for the care chain for cardiac surgery patients at St Radboud UMC.
- To assess the accuracy of the reported mortality and morbidity figures.
- To determine the extent to which the elevated rate of mortality could be attributable to the characteristics of the patient population, and/or to the treatment provided at the hospital.

The investigation was to involve the following activities:

- A. A systematic analysis of the cardio-surgical care chain as a whole, including the associated mortality and morbidity rates.
- B. Studies of the working methods at St Radboud UMC by individual EIC members focusing on their particular fields of expertise.
- C. Targeted follow-up examination by the Health Care Inspectorate of certain elements of the quality system, to be selected at a later date.

It was agreed that the external committee should be chaired by the Health Care Inspector. The IGZ was also represented on the committee by an emeritus cardiologist, who acted as vice-chairman. Other members of the external committee included specialists in thoracic and cardiac surgery, intensive care, anaesthesiology and nursing. At the request of St Radboud UMC, these committee members were nominated by the relevant professional associations. The IGZ's nominee was approved by the Association of Cardiologists.

St Radboud UMC's Staff Director for Medical Affairs acted as an adviser to the external committee and attended the meetings when nothing confidential was being discussed. The members of the committee are listed in Appendix 2.

The committee's investigation methods are described in section 3. First, however, the organisation of the Cardio-Pulmonary Centre is briefly described. The results of the investigation, its conclusions and the associated proposals are set out in sections 4 to 6.

2 Organisation of the cardio-surgical care chain

2.1 General organisational structure of St Radboud UMC

In principle, St Radboud UMC is structured on four levels:

Board of Governors

Cluster

Business unit

Workstation

St Radboud UMC's core activities – patient care, research and training – are organised on a decentralised basis, in clusters. Each cluster has its own cluster management team, consisting of a Team Leader (typically a professor), an Operations Manager and, where clusters that include nursing wards and outpatient clinics are concerned, a Care Manager (typically someone with a nursing background). The clusters are supported by the business units and staff units. The Board of Governors, acting on behalf of and under the supervision of the Board of Governors of the Catholic University Foundation, is ultimately responsible for the performance of St Radboud UMC.

Each cluster is made up of a number of business units. A business unit is a group of workstations in or associated with a medical department. A workstation is the smallest business and organisational unit involved in the performance of operational activities and the development of policy in connection with one or more core activities. Each such unit is managed by a medical staff member and a Nursing Manager.

In October 2005, the Cardio-Pulmonary Centre was divided into the organisational units described below.

2.2 Organisation of the Cardio-Pulmonary Centre

The Cardio-Pulmonary Centre is an alliance of the business units Thoracic and Cardiac Surgery, Cardiology, Paediatric Cardiology and Pulmonary Disease. Paediatric Cardiology is part of the CUKZ (Nijmegen University Children's Hospital Cluster). The business units Thoracic and Cardiac Surgery, Cardiology and Pulmonary Disease are part of the Specialist Surgery Cluster (CSS). Each business unit has its own management team, on which all workstations and disciplines are represented. A number of parties involved in the thoracic and cardiac surgery chain are part of the CAIO Cluster (Central Sterilisation, Anaesthesiology, Intensive Care and Operating Theatres).

2.2.1 Thoracic and Cardiac Surgery

In addition to its Departmental Head (the Professor of Cardiac and Thoracic Surgery), the Department of Thoracic and Cardiac Surgery has seven medical staff members, two trainee junior doctors, three ‘agnios’, one permanent general physician and two trainee physician assistants², seven secretarial workers and one Cardio-Pulmonary Centre Manager. Three medical staff members work exclusively in paediatric cardiac surgery and congenital cardiac defect correction surgery. Two medical staff members perform both cardiac surgery and pulmonary surgery, which is undertaken at the Dekkerswald University Pulmonary Centre (ULCD). Day-to-day medical care at the ULCD is provided by pulmonologists, who refer to the two thoracic and cardiac surgeons in cases where surgery may be appropriate.

In 2003, the Department of Thoracic and Cardiac Surgery established a preoperative outpatient clinic for patients requiring follow-up surgery, elderly patients and high-risk patients. In the middle of 2004, at the initiative of the Department of Thoracic and Cardiac Surgery, the preoperative outpatient clinic was relaunched following a period of sporadic activity. The aims were: personal contact with the patient, information provision, the determination of indications and more precise risk stratification. About five or six patients a week underwent preoperative assessment at the clinic. The preoperative outpatient clinic is organisationally part of the Cardiac Centre Outpatient Clinic and Function Department. This department has a workstation management team consisting of a Nursing Manager and a cardiologist. Ultimate medical responsibility for the preoperative outpatient clinic lies with one of the thoracic and cardiac surgeons.

Approximately 1,100 surgical procedures a year are performed at the Cardio-Pulmonary Centre. The breakdown of these procedures by type is presented in Tables 1 and 2.

Table 1. Breakdown of surgical procedures³

Patient group	Type	Procedures in 2003	Procedures in 2004	Procedures in 2005
Adults	Open-heart surgery	659	639	583
	Closed-heart surgery and other procedures	141	155	128
	Pulmonary surgery (excl. Dekkerswald)	51	44	43
	<i>Total</i>	<i>851</i>	<i>838</i>	<i>754</i>
Children < 18 year	Open-heart surgery	170	167	154
	Closed-heart surgery and other procedures	95	91	68
	Pulmonary surgery (excl. Dekkerswald)	11	17	4
	<i>Total</i>	<i>276</i>	<i>275</i>	<i>226</i>
Total	Open-heart surgery	829	806	737
	Closed-heart surgery and other procedures	236	246	196
	Pulmonary surgery (excl. Dekkerswald)	62	61	47
	<i>Total</i>	<i>1127</i>	<i>1113</i>	<i>980</i>

Source: CORRAD

² Physician Assistants are health care workers who are allowed to practise medicine under the supervision of a fully qualified physician.

³ The number of procedures undertaken has fallen sharply since September 2005, when the elevated mortality rates at St Radboud UMC became known.

Table 2. Breakdown of adult surgical procedures into the main categories

Type	Procedures in 2003	Procedures in 2004	Procedures in 2005
Coronary surgery	386	354	342
Aortic valve surgery, possibly in conjunction with CABG	141	139	151
Mitral heart valve surgery, possibly in conjunction with CABG	45	51	26
Aorta and Mitral heart valve surgery possibly in conjunction with CABG	15	10	6
Other	72	85	58
Total	659	639	583

Source: CORRAD

2.2.2 Extracorporeal Circulation

Organisationally speaking, the Extracorporeal Circulation Department (ECC) forms part of the Thoracic and Cardiac Surgery Business Unit. The Departmental Head answers to the CSS Cluster Care Manager (as do all Nursing Managers within CSS). Thirteen people work in the department.

2.2.3 Dekkerswald University Pulmonary Centre

The Dekkerswald University Pulmonary Centre has been part of St Radboud UMC since 1 January 2005. Dekkerswald is used for the performance of pulmonary surgery, usually on Mondays and Wednesdays. Two of the surgeons attached to the Department of Thoracic and Cardiac Surgery focus primarily on pulmonary surgery. A comprehensive range of pulmonary procedures is undertaken at Dekkerswald, including thoracic wall corrections.

2.2.4 Cardiology

The Cardiology Department has eleven medical staff members, including two cardiologists who specialise in thoracic and cardiac surgery. These individuals help to treat cardiac surgery patients, whom they see both before and after surgery.

2.2.5 Anaesthesiology

St Radboud UMC has a group of approximately fifty anaesthesiologists. In addition, there are about fifty junior doctors working in Anaesthesiology, some of them trainees and some of them qualified. Sixteen of the anaesthesiologists work exclusively in cardiac surgery. The Anaesthesiology Management Team consists of the Departmental Head/Professor (Team Leader), the Chef de Clinique, the Head of the Palliative Care Knowledge Centre, Anaesthesiology Staff Foreman and the Head of Managerial Affairs. The present Departmental Head has been in post since 2003. In 2005, a new Professor of Cardiac Anaesthesiology was appointed.

The Anaesthesiology Department is not involved with the Department of Thoracic and Cardiac Surgery's preoperative outpatient clinic.

2.2.6 Intensive Care (IC)

The Intensive Care Unit has a total of forty-one beds, divided between four workstations:

- H20: General Intensive Care (seven beds)
- H35: General Intensive Care with isolation facilities (eight to ten beds)
- N12: Neurosurgical Intensive Care (six beds)
- AOV: Thoracic Surgery (twelve beds: nominally five of them for children and seven for adults, but this split can be adjusted as necessary)
- Q3C: Paediatric Intensive Care, eight beds in the Q building.

The medical staff working in Intensive Care have primary responsibility for the treatment of all patients in IC. The medical staff complement is roughly twenty FTEs: eleven intensivists, two of whom are part-time surgeons, two part-time anaesthesiologists, and eight to ten trainee intensivists. There are also roughly twenty junior doctor FTEs training to become internists, surgeons and anaesthesiologists. The junior doctors provide direct patient care in the IC Unit, under the supervision of the trainee intensivists. A trainee intensivist is required to work for three months as a junior doctor before taking on supervisory responsibilities. The trainee intensivists are in turn supervised by the intensivists. In the evening, at night and at the weekend, one or two trainee intensivists and one intensivist are available to care for all adult IC patients (totalling up to thirty). The Paediatric IC Unit operates its own shift system. The intensivist is responsible for the care provided. The intensivist is often on site overnight, and otherwise can be on site within ten minutes.

The IC Management Team consists of the Departmental Head/Professor (Team Leader), the Head of Managerial Affairs and a representative of each workstation MT, with a good balance between medical and nursing personnel. Each workstation MT consists of a Workstation Medical Manager and a Nursing Manager. The present Departmental Head has been in post since 2003.

During the day, admissions to all IC departments are coordinated by a single intensivist. Cardiac surgery patients are usually admitted to AOV, which is close to the operating theatre.

2.2.7 Operating Theatre (OT)

The OT Business Unit is an independent organisational entity, acting as a 'third party' with responsibility for the OTs (operational and other matters) and positioned adjacent to the surgical business units within the surgical clusters and the Anaesthesiology Business Unit (part of the CAIO Cluster). The OT Management Team is organised on a duplex principle and consists of a Medical Manager and a General Manager. OT is made up of several units, one of which is devoted to thoracic and cardiac surgery. Each OT unit has a workstation MT, consisting of an anaesthesiologist who acts as formal Team Leader, a Chef de Clinique/Planner for the relevant surgical disciplines, and (group) heads representing the relevant surgical assistants, anaesthesiology personnel and Post-Operative Recovery Room personnel. There is also an OT User's Panel, which advises the Management Team when considering and implementing decisions regarding surgery, the implications for OT of developments in the field, capital expenditure, OT procedures, etc.

2.2.8 Nursing wards

Each nursing ward has its own workstation MT, consisting of a Nursing Manager and a medical specialist.

Nursing ward A10 is devoted to thoracic and cardiac surgery and urology. In early 2004, work started on a six-bed MC Unit to support the Thoracic and Cardiac Surgery Department (three beds) and the General Surgery Department (three beds).

Medical supervision of the thoracic and cardiac surgery section of the MC Unit is provided by the two cardiologists and trainee cardiologists specialising in cardiac surgery and the thoracic and cardiac surgeons; on the thoracic and cardiac surgery section of the nursing ward, supervision is provided by the thoracic and cardiac surgeons. Day-to-day medical care on the thoracic and cardiac surgery section of the MC Unit and on the thoracic and cardiac surgery section of the nursing ward is provided by thoracic and cardiac surgery junior doctors, who are in turn under the supervision of the thoracic and cardiac surgery staff. Nursing ward A00/Cardiac Monitoring, which has roughly seventy personnel, is part of the Cardiology Business Unit.

2.2.9 Referring centres

Approximately 80 per cent of patients undergoing thoracic or cardiac surgery at St Radboud UMC's Cardio-Pulmonary Centre are referred there by other centres. The cardiology centres referring the largest numbers of cases are the Canisius Wilhelmina Hospital in Nijmegen, Koningin Beatrix District Hospital in Winterswijk and the Slingeland Hospital in Doetinchem (see Table 3).

Table 3. Referrals by centre

Centre	2003		2004		2005	
	Referrals	%	Referrals	%	Referrals	%
St Radboud UMC	147	23	151	24	148	26
Canisius Wilhelmina Hospital, Nijmegen	186	29	167	27	175	30
Doetinchem	89	14	76	12	107	19
Winterswijk	78	12	94	15	28	5
Ede	45	7	7	1	4	1
Zevenaar	31	5	32	5	32	6
Boxmeer	16	2	9	1	9	2
Arnhem	31	5	45	7	45	8
Zutphen	15	2	27	4	10	2
Other referring centres	11	2	18	3	17	3

2.3 Protocols

Each department follows various specially developed thoracic and cardiac surgery protocols. A "clinical path" for the cardiac surgery patient is currently under development as part of the Adult Cardiac Surgery Care Chain Development Project launched in November 2005. A clinical path for IC has been under development somewhat longer, and entered use early in 2006. The protocols followed at St Radboud UMC are managed using the QUINT (Quality on INTranet) system. This system provides for the management, publication and retrieval of both hospital-wide and department-specific information. Most of the protocols relevant to the thoracic and cardiac surgery chain relate to nursing care. There are no anaesthesiology protocols specific to thoracic and cardiac surgery. An anticoagulant protocol was drawn up in 2003, but has never been properly implemented.

The main protocols and work instructions used are as follows:

Preoperative:

- Nursing Work Instruction concerning Preoperative Patients admitted to Nursing Ward A10 prior to Cardiac Surgery
- Preparatory Nursing Care of Preoperative Patients prior to Cardiac Surgery
- Agreements Regarding Standards for the Acceptance of Cardiac Surgery Patients (August 2004)

Intraoperative:

- OT Procedure for Thoracic and Heart Surgery
- Procedure for the Replacement of an Aortic or Mitral Valve (nursing work instruction)
- CABG Procedure (nursing work instruction)

Postoperative:

- Nursing Work Instruction A11/12 concerning Nursing Care for Postoperative Patients following Cardiac Surgery
- Transfer of Patients from the Post-Operative Recovery Room to Medium Care Unit A13
- Admission of Adult Cardiac Surgery Patients (implemented)

- Path for Thorax-Cardiac IC Patients to Discharge or Transfer. Aim: to ensure a uniform approach to the transfer of patients from IC to Medium Care and Low Care on A10, up to the point of discharge or transfer.
- Nursing Work Instruction concerning the Discharge of Patients Receiving Postoperative Care on Nursing Ward A11/A12 following Cardiac Surgery
- Fluid Registration/Balance Maintenance for and Daily Observation of Thorax-Cardiac Patients on the A11/12 Day List
- The Issue of Medication Instructions and the Administration of Medication to Thorax-Cardiac Surgery Patients on Nursing Ward A11/A12
- Protocol concerning the Prevention of Decubitus in Adults following Cardiac Surgery by Positional Variation
- Skin and Wound Treatment and Evaluation
- IC: protocols for glucose regulation, intravenous phosphate suppletion and intravenous potassium regulation, and variance reporting

2.4 Record-keeping

Each department (Cardiology, Intensive Care, Thoracic and Cardiac Surgery, Perfusion, Anaesthesia) maintains its own (paper) patient records. In addition, an electronic record is kept of each patient's anaesthesiological history. Some patient data, such as lab test and radiology results, are recorded in the Electronic Patient Dossier. Cardiology and Thoracic and Cardiac Surgery have made considerable progress with the digital processing of patient data, and make use of a digital CariOPACS, digital ultrasound scans, etc. In addition to keeping traditional medical records, the Department of Thoracic and Cardiac Surgery has operated the CORRAD data registration system since 1987. The CORRAD databank contains administrative, pre-, per-, and postoperative (hospitalisation) data and annually gathered follow-up data on adult cardiac surgery patients. Once a year, the data is summarised in the department's annual report. Finally, the IC Unit makes use of an application called ICWeb, which was developed in house to record information such as patients' medication records.

2.5 Consultation

Consultation within the cardio-surgical care chain at St Radboud UMC is organised predominantly on business unit-specific and workstation-specific basis (see Appendix 3, 'Departmental consultation arrangements', as reported by the departments). In the period 2003 to 2005, a monthly multidisciplinary meeting was held to discuss complications in cardiac surgery cases. The meetings were attended by the departmental heads, medical staff and junior doctors from Cardiology, Thoracic and Cardiac Surgery, Anaesthesiology, Intensive Care and Paediatric Cardiology. Meetings were chaired and supervised by the Head of the Department of Thoracic and Cardiac Surgery, and each was prefaced by a junior doctor.

2.6 Current policy developments

Within St Radboud UMC, particular emphasis is currently being placed on chain-oriented care and the development of multidisciplinary treatment profiles and/or clinical paths for specific patient groups. Following publication of the reports by the Ruys-Van den Broek Committee (see subsection 4.3), Cardiology, Thoracic and Cardiac Surgery, Pulmonary Disease, Paediatric Cardiology, Anaesthesiology and IC drew up a policy plan in July 2005 for the further development of the Cardio-Pulmonary Centre. The objectives defined for thoracic and cardiac surgery in the next few years included the following (Policy Plan of the Department of Thoracic and Cardiac Surgery 2005-2010):

- Optimisation of standard thoraco- and cardio-surgical care, involving the further reduction of mortality and morbidity and further differentiation and innovation within the field.
- Close collaboration among all parties involved in the surgical chain. Expansion of step-down capacity (monitored post-IC care) and implementation of the fast-track care plan for accelerated progression along the post-operative monitored care path.
- Increased throughput of patients to MC, the Post-Operative Recovery Room and/or the nursing ward.
- Effective dialogue with health insurers and referrers and promotion of referrer-loyalty through competitive turnaround times and quality of care.
- Concentrated effort to ensure the performance of a thousand open-heart procedures a year.
- Operational quality assurance through the use of tools such as performance indicators.
- Proper incorporation of training and research into the academic duties of the cardio-thoracic surgeon and detailed specification of the cardio-thoracic surgeon's academic profile.

3 Investigative methodology

3.1 Introduction

It is possible to scientifically measure performance in the field of medical intervention by determining the cost-benefit balance for a procedure and comparing it with alternative treatment options or the non-provision of treatment. The cost of a medical treatment is determined by medical factors (e.g. premature mortality and premature morbidity) and by economic factors (e.g. occupational disability, and the direct cost to the patient and the community). The performance of a medical care chain can be properly assessed only if account can be taken of the long-term benefits as well.

Poor performance in the care chain will result in increased costs for the patient and the community. Only a few cardiac surgery centres around the world have a comprehensive data structure that can shed light on long-term performance and thus help to shape day-to-day policy. In its assessment of the performance of the cardio-surgical care chain at St Radboud UMC, the EIC has confined itself to an analysis of premature mortality and premature morbidity, since structured follow-up data concerning the care chain is unavailable (as indeed it is for all such centres in the Netherlands).

Observation interval

The observation interval that is best used for the assessment of premature mortality and morbidity depends on the pathology type. Scientifically, the interval is determined by levelling off the risk function to a level that remains constant over an extended period. Where coronary surgery is concerned, the interval determined in this way is three months, for valve replacement or repair it is six months and for surgery to correct congenital defects it is twelve months. For the reasons set out above, the EIC has confined itself to consideration of mortality and morbidity at St Radboud UMC. Ideally, mortality and morbidity at facilities providing after-care to patients who have undergone surgery at the centre should also be taken into consideration. However, it is very difficult to correlate mortality and morbidity at such facilities to the performances of St Radboud UMC. In view of these analytical shortcomings, the EIC recognises that the rates of mortality and morbidity associated with St Radboud UMC must in fact be higher than indicated in this report.

Outcome parameters: premature mortality and morbidity

The EIC interprets premature mortality and morbidity as mortality and complications or symptoms that develop following a procedure. Such mortality and morbidity may be a consequence of the procedure, the pre-, per- and post-operative conditions and/or the policies pursued at St Radboud UMC. Morbidity is an undesirable occurrence following cardiac surgery. Morbidity usually precedes mortality, and morbidity that is not a precursor to mortality involves temporary or permanent harm to the patient. The development of renal insufficiency necessitating dialysis, for example, has far-reaching implications for the patient, but also has economic and social consequences. Morbidity may therefore be considered a valid outcome parameter for use along with mortality. In this report, a given patient may be included in the figures presented in several morbidity tables and in the mortality figures.

The standard applied

Patients and the wider community believe that medical procedures should not result in premature mortality or morbidity. However, no cardiac surgery centre in the world is able to meet the public's expectations in this regard. Nevertheless, there is considerable variation in the performance of such centres.

Within the thoracic and cardiac surgery discipline, peer review-based systems have been developed, in the context of which it is possible to define a standard level of performance. However, such systems have serious limitations:

- Certain variations in the condition of the patient prior to surgery are not taken into account, because they are relatively uncommon.
- The standard is defined within a particular socio-economic setting, and is not necessarily valid in the context of another socio-economic setting.
- A standardisation model should be assessed on the basis not only of its discriminatory capacity (ability to discriminate between the expectation and non-expectation of mortality) but also of the accuracy of the risk evaluations (effective usable risk percentage) across the entire spectrum of treated patients.

Therefore, although the EIC has made use of standardisation models (e.g. the additive EuroSCORE, described in the next subsection), it has been careful to take account of the limitations of such models. Use has also been made of systems in which standardisation models play a role, such as the CUSUM analysis system described below. It should also be noted that, while an individual case of mortality may be attributable to a particular error or circumstance, the EIC considers it much more important to identify patterns over an extended period on the basis of data relating to as many patients as possible.

3.2 Comparison with other Dutch centres

Scope for the comparison of mortality figures for the various Dutch cardiac centres is limited, due to a paucity of data corrected for variations in patient characteristics. The NICE Foundation maintains a database, which is used partly for the comparison of participating centres. This database contains information concerning all patients admitted to IC in the centres concerned. Since all cardiac surgery patients who leave the operating theatre alive are admitted to IC for further treatment, the database covers almost all the patients in whom the EIC was interested. The recorded data are aggregated and record treatment durations and mortality rates both for Intensive Care and for the hospital as a whole. The models used by NICE to predict mortality have not been validated for the cardiac surgery patient group. However, it is possible to deduce the seriousness of patients' conditions on admission to IC by referring to the APACHE III scores. Hence, St Radboud UMC's mortality figures for each APACHE III category can be compared with the corresponding aggregated national figures. To enable comparison of the Nijmegen data with average data for other Dutch centres, St Radboud UMC made the NICE data for 2004 available to the EIC. The data in question were supplied in the form of the Centre's annual report for 2004, which was also discussed among the professional groups involved with cardiac surgery in September 2005. The NICE data for 2005 were not yet available.

3.3 CUSUM mortality analysis

The mortality figures were analysed using the CUSUM (CUMulative SUMmation) technique, on the basis of the additive EuroSCORE system. This is a scoring system used prior to open-heart surgery to calculate the mortality risk associated with a given procedure. Using this system, a score was calculated for each patient by the summation of weightings for seventeen separate risk factors (including age and sex)⁴.

In the context of a CUSUM analysis, each treated patient is presented sequentially over time.

⁴ A variant of the EuroSCORE system is also available: the logistic EuroSCORE system. This involves using a logistic regression model to determine the mortality risk for each individual patient on the basis of the weightings for the seventeen risk factors.

If the patient survives the procedure, the responsible care chain is awarded a performance score corresponding to the risk forecast derived from the additive EuroSCORE (1999), expressed in 'life units'. So, for example, if the forecast risk is 4 per cent, survival results in 0.04 life units being added to the performance score. If the patient dies during or following surgery, one life unit minus the forecast risk is deducted from the performance score. In the example given above, the deduction would be 0.96 life units (1.00 life unit - 0.04 life units = 0.96 life units). Thus, a CUSUM analysis was performed on the CORRAD database for the years 2003 to 2005. The EIC was provided with data on 2380 successive patients treated within the cardio-surgical care chain at St Radboud UMC in the years 2003, 2004 and 2005.

CORRAD stands for CORonary Artery Surgery Database St RADboud: the cardiac surgery databank maintained by St Radboud UMC. The CORRAD system has been in operation since 1987. The databank records mortality, morbidity and EuroSCORE information for all patients treated at the centre.

In order to make analysis possible, a number of assumptions had to be made. In all cases, the assumptions made were *favourable* to the Cardio-Pulmonary Centre. They were:

- Patients still undergoing treatment would not die in the hospital.
- Patients transferred to another facility would not die there.
- Patients undergoing a second procedure should be discounted.

Analyses were performed for all the cardiac surgeons collectively and for each (anonymous) cardiac surgeon individually.

Additive EuroSCOREs of more than 10 are not considered reliable. The CUSUM analysis was therefore performed using data for a selection of patients whose EuroSCOREs were 10 or less. Assessment of the results of the CUSUM analysis has been based on the general principle that a Dutch cardiac centre should at least achieve a neutral performance score (no net gain or loss of life units). This report presents both uncorrected and corrected mortality data. Uncorrected data are figures that have not been adjusted to reflect variations in patient characteristics, e.g. age, ventricle function, history of insulin-treated diabetes, vascular pathology or CVA, and that do not exclude data for patients whose EuroSCOREs are more than 10. Such data are poor predictors of mortality. The EIC wishes to emphasise that it would be scientifically unjustified to base conclusions on the uncorrected data. This point is consistently reiterated when such data is presented.

3.4 Study of mortality case histories

The EIC reviewed the study of mortality case histories undertaken by the Internal Investigation Committee. To this end, the EIC looked at a selection of the case histories studied by the internal committee. This selection consisted of:

- All cases that the internal committee had adjudged to involve sub-optimal actions, events or procedures
- The first and every fifth subsequent case on the full list of mortality cases for each year
- All cases involving a complicating CVA

On this basis, twenty-four mortality cases from 2004 and 2005 were reviewed.

Each case review involved discussion by the collective EIC membership, on the basis of:

- A case summary provided by the IIC
- Tabulated data concerning all patients, again provided by the IIC
- The full case files, as maintained by Thoracic and Cardiac Surgery, Cardiology and IC, made available by St Radboud UMC at the Inspectorate's written request

Following independent review by the EIC, conclusions were formulated in consultation with the internal committee. The two committees both fully support the analytical methods used and the associated findings.

3.5 Morbidity analysis

The morbidity analysis was based on frequency tables for the years 2003, 2004 and 2005, extracted from the CORRAD system by the Department of Thoracic and Cardiac Surgery. The NICE database does not record specific morbidity data. Benchmarking is not possible where morbidity data is concerned, since no corresponding national data are available. Morbidity frequencies at Nijmegen were therefore compared with figures reported in the medical press. Particular use was made of the STS Fall 2005 Report, which gives US mortality and morbidity data for the preceding ten years, accompanied by expert commentary.

3.6 Interviews

Each member of the EIC, together with the committee's chairman (except in one case, where a deputy nominated by the IGZ accompanied the member in question), interviewed departmental heads, medical staff members, nursing staff members and, where appropriate, other key figures (e.g. referrers) active in his or her specialist field, with a view to forming a picture of the working methods at St Radboud UMC. The interviews took place between December 2005 and March 2006. It was made clear to each interviewee that the process was confidential, i.e. that the findings would be made known to the EIC, but not to the adviser, the Staff Director for Medical Affairs of St Radboud UMC. A draft version of each interview report was sent to the relevant interviewee to allow for the correction on factual inaccuracies. The report now before you reflects the content of the finalised interview reports, incorporating corrections requested by the interviewees.

The interviews were based on a specially compiled list of themes and topics, but a significant degree of flexibility was adopted with regard to the discussion matter. In all cases, the direction of the interview was significantly influenced by the input of the interviewee. All the interviews except those with nursing staff members took place at neutral locations, away from the interviewee's own department. To support the interview process, EIC members were given tours of IC and the nursing wards. Reference was also made to documentation provided by various interviewees, including protocols, annual reports and policy documents. A total of approximately fifty interviews were held.

4 Results: evaluation of the Cardio-surgical care chain

4.1 Mortality

4.1.1 Case record reviews

The Internal Investigation Committee reviewed sixty-six mortality cases in depth. All involved adult patients who underwent open-heart surgery at St Radboud UMC in 2004 (n = 51) or in the first half of 2005 (n = 15) and who died while hospitalised. As much information as possible was collated regarding the patient's prior history, the preoperative examination results, the nature of the surgical procedure undertaken, the progression of the surgery and the post-operative progression of the patient's condition.

The internal committee classified a case of mortality as potentially "avoidable" if, in the light of current medical knowledge, the documented facts were indicative of one or more normal forms of care being omitted, or being provided incorrectly or tardily, thus contributing to the patient's death. In other words, the focus was on identifying cases from which lessons could be learnt that could help to reduce future rates of mortality in the relevant patient group.

It will be apparent that the benefit of such an analysis depends on a number of factors, including the following:

1. The quality of the process itself
2. The quality of the reporting
3. The expertise of the committee members performing the analysis
4. The interpretation of what it is reasonable to expect in the context of normal care

It is important to bear these dependencies in mind when considering the results of the analysis. Conclusions cannot be drawn concerning the quantitative significance of the analytical findings, since no comparable studies have been reported in the academic press. There is no value in asking whether the number of "avoidable" deaths was particularly high or low; rather, the emphasis has to be on identifying from the reviewed cases points in the care chain where organisational changes or new/updated protocols can or should be introduced with a view to reducing future mortality.

The ultimate conclusion of both investigation committees was that seven of the sixty-six cases examined involved "avoidable" death, as defined above (10.6 per cent; 95 per cent RI 4.4 – 20.6 per cent).

The shortcomings identified by the review process included the following:

- Lack of a standardised procedure for anticoagulant control
- Lack of clear agreements as to who had control in multidisciplinary situations
- Lack of preoperative multidisciplinary agreements on the selection of appropriate surgical procedures
- The use of off-pump CABG, even though the procedure had not been standardised and little experience had been gained with it
- Lack of a standardised method for checking the patency of a graft
- Lack of a procedure for testing changes to a multidisciplinary decision
- Lack of a standardised method for checking cannula position
- Poor communication between the perfusionist, anaesthesiologist and cardiac surgeon during surgery
- Lack of clear arrangements for the instruction of perfusionists
- Lack of a clear preoperative anticoagulant policy
- Lack of clear management arrangements in Medium Care

- Lack of standardised per- and postoperative monitoring in connection with the pacemaker policy
- Lack of protocols governing response to potential complications
- Lack of standardised and controlled peroperative monitoring arrangements

4.1.2 Analysis of mortality figures: Uncorrected figures

The additive EuroSCORE for the years 2003 to 2005 predicts 105.2 mortality cases during hospitalisation. This equates to an average forecast mortality rate of 4.42 per cent. The EIC accordingly concludes that the patient population treated at St Radboud UMC during the period under review was relatively low-risk compared with the average for a University Hospital. In fact, 135 patients died while hospitalised at St Radboud UMC during the period in question. Hence, the observed mortality is 1.25 percentage points higher (28 per cent higher in relative terms) than might have been expected. **However, these percentages are uncorrected, and therefore an unsuitable basis for assessment (see subsection 3.3).**

4.1.3 Analysis of mortality figures: Figures corrected for high-risk cases

For the reasons explained earlier, an analysis has also been performed after excluding data relating to patients with an additive EuroSCORE of more than 10. This resulted in a study population of 1725 patients. Following the exclusion of high-risk patients, one would expect the observed risk associated with the cardio-surgical care chain to be lower than the forecast risk. The additive EuroSCORE suggests that, during hospitalisation, there should have been 70.4 deaths in this group of patients, equating to an average forecast mortality rate of 4.08 per cent. In fact, eighty-three patients died while at St Radboud UMC. Hence, the observed mortality is 0.8 percentage points higher (18 per cent higher in relative terms) than might have been expected. The EIC therefore concludes that, even after limiting the observation interval and correcting for shortcomings in the standardisation model, mortality was abnormally high during the study period.

4.1.4 Trend analysis

A trend analysis of the data on the basis of the CUSUM principle is more instructive. Figure 1 indicates that, in 2003 (up to and including patient 601), the performance of the care chain was consistent with the forecast additive EuroSCORE: the CUSUM score on 1 January 2004 was minus 3.74 life units. This may certainly not be described as a good performance, since one would have expected a performance that was distinctly better than the norm.

In 2004 (from patient 602 to patient 1197, inclusive), the Centre's performance deteriorated unmistakably relative to the norm. The CUSUM score on 1 January 2005 was minus 17.9 life units. The EIC takes the view that performance during this period fell short of any acceptable standard.

In 2005 (from patient 1197), the CUSUM score ceases to deteriorate, and actually recovers slightly to end at minus 12.6 life units. In the final six months of 2005, the CUSUM score rose from minus 16 to minus 12, but remained well below the norm.

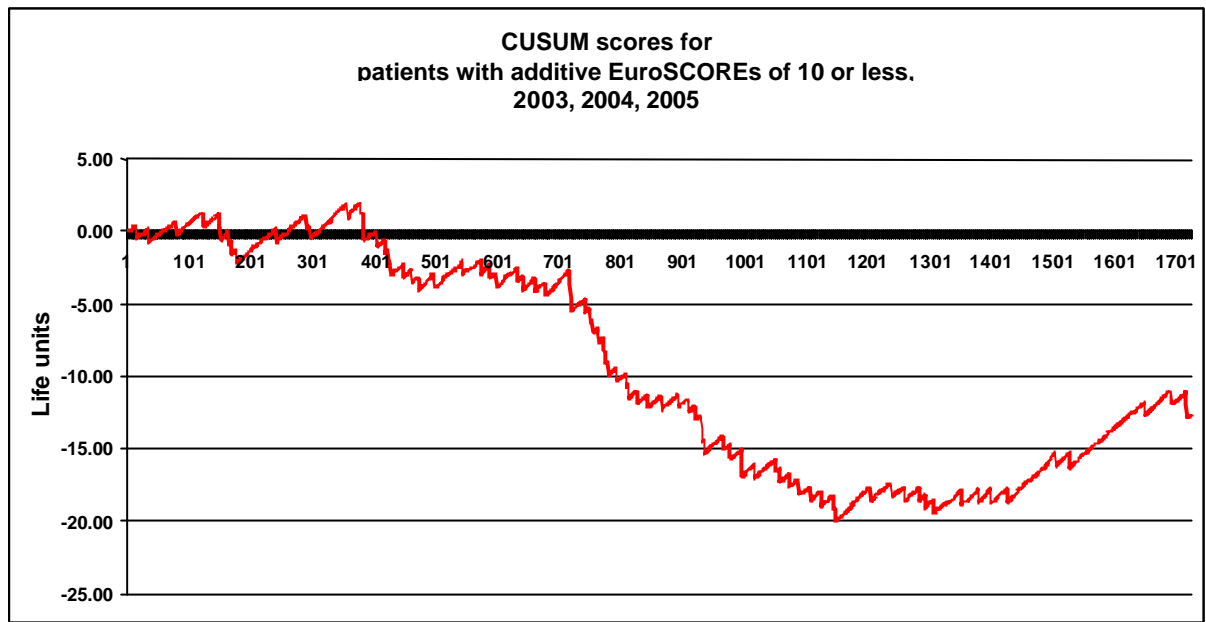


Figure 1: Cumulative representation of mortality during hospitalisation among patients with additive EuroSCOREs of 10 or less in 2003, 2004 and 2005

4.1.5 Analyses for individual surgeons

Trend analyses were also performed for the individual surgeons, revealing no major differences from one surgeon to another. The EIC decided not to include the findings of these analyses in this report. One of the reasons being that the analysis method is truly valid only if a sufficiently large number of patients can be included. Within the observation period, the number of procedures performed by each surgeon was fairly small. During the three-year period, the total number of procedures per surgeon that involved cases where the additive EuroSCORE was 10 or less was 172 ± 151 (distribution 5 to 373).

4.1.6 Analyses for individual care programmes

The EIC obtained data on the mortality associated with the four most common care programmes in the period 2003 to 2005 (see Table 3).

Table 3. Mortality per care programme

Programme	Year	Number of patients	Mortality	% (95% RI)
CABG	2003	386	11	2.8
	2004	354	13	3.5
	2005	331	10	3.0
	Total	1071	34	3.17 (2.4-4.7)
AV replacement (with or without CABG)	2003	141	13	9.2
	2004	139	17	12.2
	2005	146	10	14.6
	Total	426	40	9.38 (7.2-13.4)
MV replacement (with or without CABG)	2003	45	7	15.6
	2004	51	5	9.8
	2005	25	3	12
	Total	121	15	12.39 (7.2-19.8)
AV + MV replacement / repair (± CABG)	2003	15	3	20
	2004	10	3	30
	2005	6	0	0
	Total	31	6	19.35 (7.4-37.5)

The data presented above are uncorrected. **It would therefore be unjustified to draw any conclusions from the above data without taking account of their inherent limitations (see subsection 3.2).**

The EIC does not have additive EuroSCOREs for the individual care programmes. The report *Overzicht Patiënten Hartchirurgie Volwassenen 1997-2004 UMC St Radboud* (Statistics concerning Adult Cardiac Surgery Patients at St Radboud UMC, 1997-2004) does, however, provide some information on the risk profile per care programme. The EIC has therefore been able to make a comparison between the average risk profile per care programme in the period 1997 to 2004, and the average mortality rate for the period 2003 to 2005. The observed risk has also been compared with the “STS Fall 2005 Report”, which provides US mortality figures for the various care programmes over the last ten years. The results are presented in Table 4.

For the CABG care programme, the average risk profile was 2.9 ± 2.6 per cent. In the context of a university hospital, this is an extremely low forecast level of risk. The observed mortality rate was 3.2 per cent; statistically speaking, this figure is within the 95 per cent reliability interval. The STS database figures indicate a mortality rate of 2.7 per cent in 2000, falling gradually to 2.2 per cent by 2004. Observed mortality at St Radboud UMC is therefore on the limit of that predicted using the additive EuroSCORE system but above the STS level.

For the aortic valve replacement care programme (including both cases involving and cases not involving coronary revascularisation), the average risk profile was 5.6 ± 2.4 per cent. Again, therefore, the patient population may be deemed low risk by university hospital standards. The observed mortality was 9.4 per cent (well above the 95 per cent reliability interval). The STS data indicates a mortality rate of 3.8 per cent in 2000, declining gradually to 2.9 per cent by 2005 for the patients requiring isolated aortic valve replacement. For the patients requiring such valve replacement in combination with coronary reconstruction, the STS mortality figure was 6 per cent in 2000 and 5 per cent in 2005. The split between isolated replacements and replacements in combination with coronary reconstruction is not known to the EIC, but a classic distribution is assumed. The observed mortality at St Radboud UMC was therefore higher than mortality predicted using the additive EuroSCORE system and above the STS level.

For the mitral valve replacement or repair care programme (including both cases involving and cases not involving coronary reconstruction), the average risk profile was 5.5 ± 2.7 per cent. Once more, the patient population may therefore be deemed low risk by university hospital standards. The observed mortality was 12.4 per cent, well above the 95 per cent reliability interval. The STS data indicates that the mortality associated with mitral valve replacement in the US ranged from 6.2 per cent in 2000 to 5.2 per cent in 2005; for mitral valve repair, the figures were 1.6 per cent in 2000 and 1.2 per cent in 2005. Where valve replacement was performed in combination with coronary revascularisation, mortality was higher: 12.2 per cent in 2000, and 10.3 per cent in 2005. Where valve replacement was performed in combination with coronary reconstruction, mortality was also higher: 9.0 per cent in 2000, and 7.2 per cent in 2005. The split between isolated valve repairs/replacements and repairs/replacements in combination with coronary reconstruction is not known, but a classic distribution is assumed. The observed mortality at St Radboud UMC was therefore higher than mortality predicted using the additive EuroSCORE system and above the STS level. However, it should be noted that the number of patients in this subgroup is too small to permit detailed analysis.

For the combined aortic and mitral valve repair/replacement care programme, the average risk profile was 6.4 ± 2.8 per cent. Yet again, this is indicative of a low-risk population for a university hospital. The observed mortality was 19.3 per cent, once more above the 95 per cent reliability interval. The STS data reveals a US mortality rate ranging from 10 per cent in 2000,

to 9.2 per cent in 2005. The observed mortality at St Radboud UMC was therefore higher than mortality predicted using the additive EuroSCORE system and above the STS level. As with the previous programme, the size of the group (just thirty-one patients) precludes detailed analysis.

Table 4. Average risk profile, STS mortality and observed mortality per care programme

Care programme	Average risk profile	STS mortality ⁵ (2000-2005)	Observed mortality
CABG	2.9 ± 2.6%	2.7 – 2.2%	3.2%
Aortic valve replacement			
- isolated		3.8 – 2.9%	
- with coronary vascularisation		6.0 – 5.0%	
- total	5.6 ± 2.4%		9.4%
Mitral valve			
- replacement		6.2 – 6.2%	
- repair		1.6 – 1.2%	
- replacement with coronary vascularisation		12.2 – 10.3%	
- repair with coronary vascularisation		9.0 – 7.2%	
- total	5.5 ± 2.7%		12.4%
Combined aortic-mitral valve	6.4 ± 2.8%	10.0 – 9.2%	19.3%

4.1.7 Comparison with other Dutch centres

In the NICE system, the APACHE III score is used as an indicator of the seriousness of a patient's condition in the first twenty-four hours following admission to intensive care. The NICE report distinguishes a number of bands of APACHE III scores: 0-20, 20-30, 30-40, 40-50, 50-60, 60-80, 80-150 and higher than 150. For 2004, the NICE database records the details of 433 CABG and heart-valve patients treated at St Radboud UMC. This is 121 fewer than recorded in the CORRAD database. It is not apparent whether the discrepancy may be attributed to the size of the patient population whose details are recorded in the NICE database being limited by the application of APACHE III score exclusion criteria, or to the Intensive Care Unit providing an incomplete data set to the NICE Foundation. Where patients with APACHE III scores of 60 or above are concerned, elevated mortality may be observed, both among those undergoing coronary surgery only, and those undergoing valve surgery either in isolation or in combination with coronary surgery.

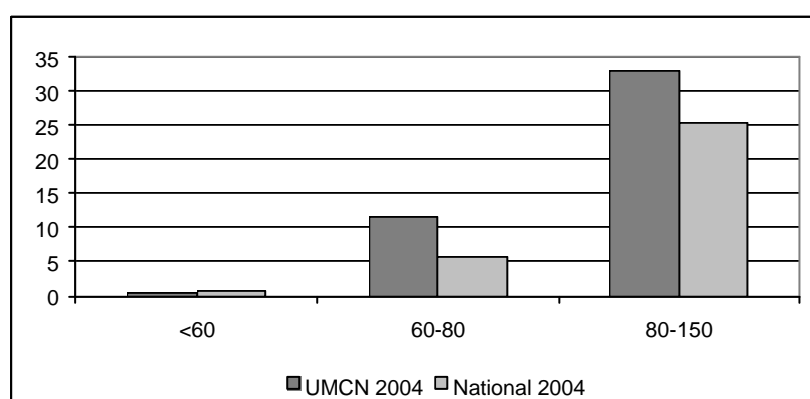


Figure 2. Mortality rates for CABG patients, grouped by APACHE III score (2004)

⁵ The reported figures are the highest and lowest annual percentages in the period 2000 to 2005. In all cases, the highest percentage recorded was for 2000 and the lowest for 2004 or 2005.

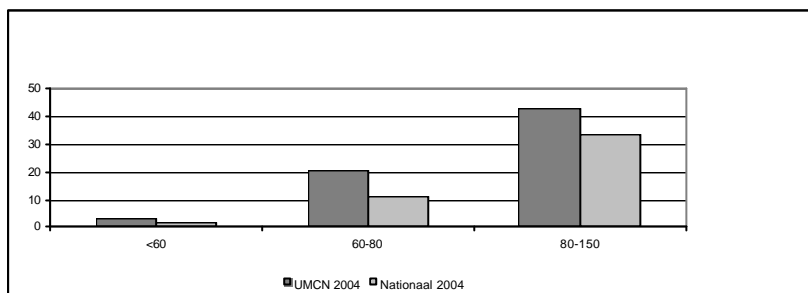


Figure 3. Mortality rates for valve surgery patients, grouped by APACHE III score (2004)

4.2 Morbidity

The morbidity data have been assessed on the basis of the following general principles:

- The incidence rates for all serious complications should be less than 10 per cent.
- The normal incidence of cases requiring re-sternotomy is 3 per cent; the best-performing centres can achieve figures as low as 1 per cent.
- The normal incidence of renal failure is 2 to 3 per cent; the better-performing centres can achieve figures as low as 1.4 per cent.

The value of extrapolating the published data to the situation at St Radboud UMC is limited by certain case-mix factors. Nevertheless, the EIC makes the following observations:

- Among patients undergoing CABG procedures, it is notable that between 2003 and 2005, the incidence of re-sternotomy cases was high (7.9 to 8.8 per cent). The incidences of post-operative gastrointestinal complications (3.6 per cent in 2004 and 4.2 per cent in 2005), pulmonary complications (7.8 to 11.5 per cent) and renal failure (5.1 per cent in 2005) were also high.
- Among patients undergoing aortic valve replacement in isolation or in combination with CABG, the incidence of re-sternotomy cases was very high (15.6 to 18.7 per cent). High incidences of renal and pulmonary failure were also observed (respectively, 6.3 to 12.6 per cent and 8.9 to 15 per cent).
- Mitral valve replacement in isolation or in combination with CABG was associated with high incidences of re-sternotomy (12 to 18 per cent), renal failure (18 per cent in 2004) and pulmonary failure (11 to 23 per cent).
- Although only a very small number of patients underwent combined aortic and mitral valve replacement at the centre during the observation period, many of them suffered complications. Between 2003 and 2005, the incidence of organ failure following other cardiac and thoracic surgery was very high. Re-sternotomy was necessary in 15 to 18 per cent of cases. Some 15 to 23 per cent of the patients exhibited renal insufficiency, and the incidences of pulmonary, gastrointestinal and neurological complications were high as well.

In summary: cardio-surgical treatment at St Radboud UMC between 2003 and 2005 was associated with high to very high incidences of re-sternotomy (generally due to haemorrhaging or tamponade) and postoperative organ failure.

4.3 Interview summaries

One important element of the EIC's investigations consisted of individual committee members familiarising themselves with the activities of the Cardio-Pulmonary Centre by means of interviews. Summaries of the interviews are presented below, grouped by medical specialism.

The EIC would emphasise that the summaries contain only the views of the interviewees. The EIC's assessment of the information gleaned through the interview process is given in section 5, 'Observations and discussion'.

4.3.1 Thoracic and cardiac surgeons

CLA problem

In 1999, all medical staff members became government employees. The changeover process was not easy. Medical staff members were guaranteed certain financial benefits over and above the remuneration provided for in the CLA. In the years following the changeover, it proved difficult to adhere to the CLA provisions where workloads were concerned. Medical staff found themselves working well in excess of the hours specified in the CLA, even without taking shift work into account. Some medical staff members were not prepared to accept the situation, mainly on the grounds that the CLA made very little allowance for the cardiac surgeons to undertake the research and training work associated with their academic role. Direct patient care took up all the hours they were expected to work under the CLA. The cardiac surgeons had to focus all their attention on direct patient care in order to prevent waiting lists from lengthening and to ensure that they performed the numbers of procedures required by their professional group. A split gradually formed between the surgeons and other professional groups, which found it easier to work to the CLA format and thus to secure an appropriate level of remuneration. In the latter part of 2003 and early 2004, intensive talks on this issue were held with the Board of Governors. The Board of Governors undertook a survey of other university hospitals in order to provide a benchmark, and concluded that medical staff members at St Radboud UMC were actually paid more than the average. Eventually the group was awarded a special allowance to secure the loyalty of its members. However, the cardiac surgeons continued to demand better pay, threatening to go over to a four-day working week if they did not get what they wanted. The Departmental Head asked the Chairman of the Board of Governors to call in an arbitrator, and this request was granted in mid-April 2004.

Management capabilities

In April 2004, the Thoracic and Cardiac Surgery Department's medical staff made it clear to the Departmental Head that they had no faith in his management capabilities. They also indicated to him that he was considered technically wanting as a surgeon. Various measures were taken in response. The make-up of the department's management team was changed. Consultation between staff members ceased, with people speaking to one another only when absolutely necessary. The Departmental Head approached the Board of Governors, which established a committee consisting of two emeritus professors (Professor J. Ruys and Professor P. van den Broek) to look into the situation. The conclusion of the professors' report to the Board of Governors was passed on to the medical staff of the Thoracic and Cardiac Surgery Department in a letter. They were told that no variation could be detected in the performance of and outcomes achieved by the various cardiac surgeons. (Although several medical staff members questioned the committee's competence for arriving at this conclusion.) The committee's recommendations were as follows:

- The rebuilding of mutual trust
- Better management of the staff's support needs
- The appointment of a Professor of Paediatric Cardiac Surgery
- The recruitment of more staff to facilitate greater compliance with the CLA provisions
- The provision of more time for reflection and research

The events of April 2004 were in fact the culmination of developments that had been in progress within the department for some time. There had been felt to be a lack of leadership for several years. Agreements made at staff meetings were not kept; staff meetings were increasingly infrequent and eventually ceased altogether.

Indeed, dissatisfaction went back quite some time. As early as 1999, the so-called Small Management Team (SMT) was disbanded, although it had been successful in improving various operational aspects of patient care and increasing production considerably.

Negotiations chaired by a human resources adviser

Prompted by the CLA problem and the issue of confidence in the Departmental Head, from September 2004 the cardiac surgeons started negotiations chaired by a human resources adviser. The central theme of these negotiations was the reconstruction of mutual trust, in pursuit of which a number of agreements were made regarding conduct and communication, a policy plan was developed, and a production and deployment plan was produced on the basis of the CLA provisions and the staff complement. The outcome of the negotiations was generally regarded as disappointing. However, a policy plan was produced, to which all medical staff members contributed. This policy plan was adopted at the meeting held to discuss the cardio-surgical care chain on 9 September 2005.

Professional competence

In addition to the dissatisfaction concerning the leadership of the department, there was increasing doubt regarding the professional competence of certain medical staff members. Doubts were also expressed by referring cardiologists. The disquiet mainly concerned the activities of two members of the medical staff. Questions were raised regarding the diagnoses and the outcomes of the two individuals' procedures, which included post-operative haemorrhaging, the need for re-intervention and the occurrence of infection. Members of the nursing staff clearly preferred not to work with certain surgeons. At case meetings (morning shift change), it was not uncommon for people to be reluctant to express themselves openly concerning complications and other problems that had arisen during surgery or at other times, if the surgeon who had performed the operation gave an account of events that differed from the junior doctor's recollections. People saw little sense in highlighting problems, because nothing happened when they did so. The demand for IC beds was sometimes nearly three times what might be expected from the number of operations performed. The medical staff were unaware just how abnormal and serious the situation was, because they did not have access to the CORRAD data. The cardio-surgical medical staff did ask to be provided with the data, but no reports were forthcoming. The data gathered for the BHN were also forwarded without the medical staff having access to them. They were given only aggregated annual data, not data concerning their own activities.

During the interviews, various people indicated that they had the impression that the hospital management was more interested in training and research than in patient care, and allocated funds accordingly. It was also said that concerns regarding the professional competence of the relevant individuals were repeatedly made known to the surgeons in question, to the cluster management team and to the Board of Governors.

Adherence to agreements

Numerous agreements reached at general meetings of the cardio-surgical staff were not kept. For example, direct patient care was repeatedly discussed, and agreements made regarding matters such as doing rounds of the department, attending IC meetings on behalf of the medical staff and taking a post-operative interest in one's own patients. When the inspection committee visited in 2004, a meeting of the entire staff was held. However, not all medical staff members adhered to the agreements that were made. Although these issues were repeatedly raised at group meetings and with the Departmental Head, there was no improvement. Another medical staff member therefore assumed responsibility for trying to get something done, and the problems were repeatedly made known to the cluster management team and to the Board of Governors. However, several medical staff members indicated that these bodies failed to take the reports sufficiently seriously.

By contrast, the situation in the Paediatric Thoracic and Cardiac Surgery Department was felt to be healthy, with good communication, structured meetings and frequent person-to-person contact.

Anaesthesiologists

The cardiac surgeons indicated that they would like to see dedicated cardio-anaesthetists working in the department. The pool of anaesthesiologists presently involved with thoracic and cardiac surgery is too large. Professional coordination between the cardiac surgeons and the anaesthesiologists has not yet been achieved at the group level. No joint protocols have been formulated. The surgeons have long campaigned for dedicated cardio-anaesthetists and protocols, but without success.

Intensivists

The cardiac surgeons were critical of the availability of the staff physician intensivists. They often have to work with trainee intensivist, and only see the staff physician intensivists if they insist on doing so. The accusation was made that the intensivists showed insufficient commitment to the particular needs of cardiac surgery patients. Much is said and written about quality, but little is put into practice.

Procedures and protocols

The cardiac surgeons as a group do not have fixed procedures for each form of surgical intervention, although they do have a standard pre-operative procedure and prescribed methods for the pharmaceutical preparation of patients. Post-operative care protocols are now in place and a clinical path for uncomplicated procedures was introduced with effect from 1 January 2006. IC nursing staff have considerable autonomy in the implementation of the protocol.

4.3.2 Cardiologists

Adherence to agreements

The experienced cardiologists specialising in cardio-surgical care complained that the cardiac surgeons did not adhere to agreements. It was claimed, for example, that the preoperative examination protocol – a list of tests to be performed to obtain information about the patient prior to surgery – was often not followed. As a result, it was common for tests to have to be performed at the very last moment. This was inefficient in terms of time and energy, because the tests had to be fitted in between appointments, and the surgery could not go ahead until the results of all the prescribed tests were available.

The experienced cardiologists specialising in cardio-surgical care were also annoyed that no meeting had ever taken place concerning the outpatient consultation system for pre-operative cardio-surgical screening and care set up by one of the cardiac surgeons. No cardiological assistance was provided at these consultations.

Both the experienced cardiologists specialising in cardio-surgical care and others were convinced that in recent years, the complexity of the surgical procedures attempted in the Cardio-Pulmonary Centre had increased considerably; they also believed that more complex procedures were attempted more often than in other cardiac surgery centres. It was suggested that this might have been because an apparent fear that referrers would be reluctant to refer cases if some were rejected.

Care chain

The cardiologists are responsible for the supervision of medium care. As part of their training, junior cardiologists provide day-to-day patient care. On the Thoracic Surgery Nursing Ward, supervision is provided by the thoracic surgeons and patient care by junior thoracic surgeons and physician assistants. The cardiologists argued that the frequent changes of personnel meant that there was insufficient continuity of care in the department. The cardiac surgeons, anaesthetists and intensivists failed to appreciate or were unconcerned that the experienced

cardiologists specialising in cardio-surgical care were the only people who remained involved with cardiac surgery patients throughout the hospitalisation period. This was particularly problematic in the context of complex cases, where the patient was admitted to the Cardiology Department before undergoing surgery, in order to facilitate thorough examination and preparation.

For their part, the anaesthetists and intensivists complained that the cardiologists did not have clear policies for responding to complications, such as impending cardiac tamponade, unexplained hypotension and the like, in connection with which the cardiologists needed to initiate echocardiography and other tests. The situation was particularly problematic in the evenings and at weekends, when the cardiologists specialising in cardio-surgical care were not present; at such times, there was felt to be insufficient expertise and decisive leadership within the department.

Professional competence

It was said that the cardiac surgeons varied not only in terms of the attention they gave their patients in the pre-operative and postoperative phases, but also in their surgical skill. When accepting patients for cardiac surgery and thereafter, insufficient account was taken of the manual dexterity, experience and technical views of the cardiac surgeon who was to perform the operation.

The technical skills of the Professor of Thoracic and Cardiac Surgery were questioned by the cardiologists.

Leadership

Care practitioners, it was said, held the cardiologists in high esteem, but the management did not. The management was felt to have little interest in patient care. The hospital's governors were felt to be preoccupied with, and therefore to devote financial and human resources disproportionately to, research and training. The cardiologists specialising in cardio-surgical care took the view that there was insufficient manpower and material support to cope with the increasingly complex care requirements. However, the management failed to respond adequately to questions and suggestions on this issue. The mediocre or weak management response to feedback regarding poor performance and poor-quality cardiac surgery may be attributed to the lack of cohesion among the thoracic and cardiac surgeons and the lack of leadership.

Leadership and cohesion in the Department of Thoracic and Cardiac Surgery were sadly lacking. For example: for various reasons, a fellow departmental head advised the head of the department several years earlier to focus more on research and training and to cut back his daily surgical load. This advice was never acted upon. Numerous interviewees indicated that structural improvement was not possible without changes in the cardio-surgical staff; personnel with technical skills and the ability to communicate and inspire were required to bring about an improvement in the standard of cardio-surgical care.

Case complexity

Both the experienced cardiologists specialising in cardio-surgical care and others were convinced that in recent years, the complexity of the surgical procedures attempted in the Cardio-Pulmonary Centre had increased considerably; they also believed that more complex procedures were attempted more often than in other cardiac surgery centres. It was suggested that this might have been because of an apparent fear that referrers would be reluctant to refer cases if some were rejected. Concerns were expressed not only regarding the preoperative condition of some patients, but also regarding the nature of the surgical procedures undertaken. In this context, the additive EuroSCORE served as the measure of case complexity.

The acceptance of more complex cases was felt to be attributable not only to the wish to secure the loyalty of the referrers, but also to a general trend in recent years towards the referral of more difficult cases for cardiac surgery, as relatively simple cases were increasingly treated by cardiologists using percutaneous techniques. Furthermore, however great the risks involved in a surgical procedure, the cardiac surgeon's compassion for the patient, often compounded by pressure from the referrer, often persuaded the surgeon to proceed.

4.3.3 Referring centres

Since a cardiac surgery centre was opened at the Twente Medical Centre in Enschede, almost all patients from Queen Beatrix District Hospital in Winterswijk requiring heart operations have been referred to the new facility (see Table 3, subsection 2.2.9).

Referral of complex cases

Some referring centres countered the view that St Radboud UMC was able to handle more complex cases. One centre performed an analysis of the complications developed by patients undergoing surgery either at St Radboud UMC or at another cardiac surgery centre in 2000. It was found that, in the first year after surgery, complications were more than twice as common in patients treated at St Radboud UMC (22 per cent) as in patients treated at the other centre (10 per cent). The cases examined involved re-fixation of the sternum, re-thoracostomies during hospitalisation, premature occlusion of LIMA and other grafts, infection of the sternum and such like. This referring centre in question reported that the patient populations were similar and that the complication rate was certainly not attributable to case complexity, since the more difficult cases were referred to the other centre. Furthermore, two of the eight centres that regularly referred patients to St Radboud UMC said that more complex cases were not sent to Nijmegen.

Professional competence

Other referrers were of the opinion that acute dissections of the aorta thoracalis were performed well; the numbers involved were small, however. These referrers were also satisfied with the quality of routine cardiac surgery performed at Nijmegen. Furthermore, the acceptance of emergency cases was perceived to be expeditious in Nijmegen, and no unusually high mortality or complication rates had been observed. All referring centres took the view that Nijmegen's cardiac surgery team was not skilled in mitral valve reconstruction, and therefore referred patients with operable mitral valve abnormalities to other centres.

Complications

In November 2005, two large referring cardiology centres took up the question of postoperative complications with the cardiac surgeons at St Radboud UMC. The referrers in question were disappointed by the response of the cardiac surgeons, which they described as indifferent and negative. Both cardiology departments wanted to perform percutaneous interventions such as PTCA, which require cardio-surgical assistance, in house. To this end, they sought the assistance of St Radboud UMC's Cardiac Surgery Department, but were put off by the response to questions about the frequency of complications.

Customer orientation and adherence to agreements

Several referrers complained about the lack of customer orientation at the Department of Thoracic and Cardiac Surgery: it is hard to reach the department by phone, and very difficult to speak directly to members of the department's medical staff. For the last five years, there has been no structured contact between the thoracic surgeons and any of the eight cardiology centres that regularly refer patients, except for one: the Canisius Wilhelmina Hospital in Nijmegen.

Since June 2004, a protocol has been in place covering the provision of essential preoperative data concerning referral patients. However, many of the referrers were unsure whether the protocol was actually applied or what happened to the data. It is not known whether all the referrers adhered (strictly) to this preoperative protocol.

Confidence

By the time of the interviews, many referrers said that the atmosphere within the Department of Thoracic and Cardiac Surgery had deteriorated to the point where it had lost the referrers' confidence. This led to a clear fall in the number of referrals to the Cardiac Surgery Centre. Because of the uncertainty and the outcry over complications and mortality figures, patients requiring cardiac surgery also now show a preference for referral to other centres.

4.3.4 Anaesthesiologists

Dedicated cardio-anaesthetists

Until 1985, some anaesthesiologists specialised exclusively in the cardio-anaesthesiology. There have for some years been calls for the re-formation of a dedicated cardio-anaesthesiology team with specialist expertise. However, the idea has never been implemented, because of opposition from some anaesthesiologists, who prefer a varied caseload. The formation of a dedicated team would also imply more shift work for anaesthesiologists.

A number of anaesthesiologists recognise that, not being specialists, they are not in the routine of cardio-anaesthesiology, and therefore prefer to work in other fields.

Some anaesthesiologists also believe that the present working practices are detrimental to quality. The appointment of the Professor of Cardiac Anaesthesiology was intended partly to facilitate the establishment of a smaller group of dedicated cardio-anaesthesiologists.

Motivation

The anaesthesiologists' reasons for working at St Radboud UMC vary considerably, but few were motivated by St Radboud UMC being a university facility. Only a small number of anaesthesiologists devote time to training or research. Most of the anaesthesiologists chose to work at the Radboud for pragmatic reasons.

Procedures and protocols

The anaesthesiologists do not adhere to uniform policies. They have no professional protocols and determine their own individual policies. Nor is there any liaison with the surgeons with regard to anaesthesiology policy. Anaesthesia personnel have a single page of notes regarding the preferences of the various anaesthesiologists. Several indicated that they did not consider the absence of protocols to be a problem. Others, however, indicated that there was as a result considerable variation in the policies pursued.

Teamwork

There is perceived to be a lack of team spirit among the cardio-anaesthesiologists. Nevertheless, the anaesthesiologists have a healthy sense of fellowship and are always willing to help one another out. The appointment of the new Professor of Cardiac Anaesthesiology proved somewhat fraught, with the result that there was initially considerable resistance to his ideas and interference. His many critical observations regarding the way things were done at the Radboud were not well received. Some of the anaesthesiologists felt undervalued by him.

Professional competence

The Anaesthesiology Department at St Radboud UMC does not use specially trained anaesthesia personnel as assistants; medical assistants account for roughly 90 per cent of anaesthesia assistants. The quality of care is best served by working to NVA standards and utilising suitably trained anaesthesia personnel. In this context it is preferable to have a group of anaesthesia personnel dedicated to the provision of cardio-anaesthesiological care.

Care chain

Several anaesthesiologists indicated that they are not normally involved in the preoperative assessment of cardiac surgery patients, whom they see for the first time the day before surgery. Nor are they involved in caring for patients following surgery. The transfer of patients from the OT to IC is, however, standardised within the Anaesthesiology Department. The staff intensivist physician should be involved in transfers, but this often does not happen in practice, particularly at night. Anaesthesiologists have the impression that no attention is paid to the transfer information, a fresh plan being drawn up in IC. Anaesthesiologists are never involved in the further progress of care in IC and intensivists rarely approach anaesthesiologists with enquiries regarding (newly) transferred patients. There are no structural arrangements for consultation between anaesthesiologists and intensivists for the purposes of evaluation.

Consultation

Anaesthesiologists in general and cardio-anaesthesiologists in particular habitually fail to attend the daily morning meetings. There are no structural arrangements for evaluation of the medical policies pursued. The anaesthesiologists cannot attend the multidisciplinary complications meetings held once a month on a Friday morning, because they take place at a time when the day's surgery is just getting underway and the anaesthesiologists consequently have to be in the OTs.

Case complexity

The newly appointed Professor of Cardiac Anaesthesiology does not believe that the department's caseload is unusually complex. In particular, the routine CABG patients do not have above-average additive EuroSCOREs, but the rate of mortality in this group is elevated in comparison with cardio-surgical departments at other Dutch centres.

4.3.5 Perfusionists

The perfusionists have no clear leadership. Traditionally, they were answerable to the anaesthesiologists. They enjoy considerable independence. Many anaesthesiologists do not know what the perfusionists do. No protocols or other arrangements have been agreed between the thoracic and cardiac surgeons, the anaesthesiologists and the perfusionists. It is not clear what criteria perfusionists apply when deciding whether transfusion is appropriate. It is not uncommon for disagreements to arise with anaesthesiologists as to whether to proceed to a transfusion. The problems of post-operative haemorrhaging have not been discussed with the perfusionists. Some perfusionists also expressed reservations regarding the technical abilities of the surgeons. In general, however, people are very circumspect on the latter subject.

It is not possible for perfusionists to attend the multidisciplinary complications meetings because they take place at times when the perfusionists have to be in the OT. The perfusionists are not involved in any other consultative forums relating to cardiac surgery. Perfusionists complain particularly of a lack of information prior to surgery: they are told only the diagnosis and the intended procedure. Better preoperative coordination with the anaesthesiologists is desirable regarding matters such as blood pressure changes. The perfusionists also highlight the variations in anaesthesiological approach, due to the number of anaesthesiologists and the lack of a uniform policy.

4.3.6 Intensivists

Organisation

Thoracic surgery patients are normally admitted to the AOV Intensive Care Unit. Each IC unit has a number of intensivists; AOV has three. In principle, the other intensivists should have to

work in AOV only when doing night duty. However, they do occasionally have to help out in AOV during the day.

There are always junior doctors in AOV. During the day, there is also a trainee intensivist, but out of hours, the duty trainee intensivist is responsible for the IC patients in all the units (up to thirty patients). At night, an intensivist is on call at home. The intensivist on call is contactable at all times and can attend at short notice.

Consultation

Each morning, the night-duty junior doctor hands over to the day-duty junior doctor. The duty intensivist and trainee intensivist should in principle be present as well, but in practice that is often not the case.

Early each morning, there is a single joint handover by the (duty) intensive care doctors and cardiac surgeons. At 11am, there is a preliminary meeting involving the cardiac surgeon, cardiologist and intensivist/trainee intensivist. At noon, the multidisciplinary IC meeting takes place. Cardiac surgery patients are among those discussed at the meeting, but neither the cardiac surgeon nor the cardiologist actually attend. New cardiac surgery patients are often admitted to AOV while the meeting is in progress. At 4.30pm, responsibility is handed over to the night-duty junior doctor, trainee intensivist and intensivist.

Care chain

The intensivists are not involved in either the pre-operative phase or the peroperative phase. The intensivists assume ultimate medical responsibility for a patient when he or she is transferred to IC. The surgeon is not generally present at the time of transfer. Details of the procedure that the patient has undergone have to be obtained from the anaesthetist or from the patient's records. The transfer arrangements are perceived to be unsatisfactory.

The perfusionist provides only written transfer information. Intensivists have the impression that the perfusionists are not properly managed. This is perceived to be a factor in the variable and often suboptimal condition that patients are in when they arrive in IC (cold, under-provided and haemorrhaging).

Anaesthesia practices are not regulated by protocols, making it harder to respond appropriately to complications if they occur. Peroperative echocardiography is not used as a matter-of-course and the monitoring of cardiac output is at the discretion of the anaesthesiologist.

Following transfer, it is up to the intensivists to contact the other professionals for information if problems arise. The most common problems are persistent blood loss and tamponade.

Delays in decision-making with regard to the indication of re-thoracostomy are not uncommon in cases of persistent or accelerating blood loss.

In cases involving cardiac tamponade, it is always possible to arrange echocardiography. Often, however, particularly in the evenings or at the weekend, the scans are performed by junior doctors (who may or may not be experienced). Sometimes, arranging for a transoesophageal echocardiogram has a very high threshold.

The hospital has recently introduced a protocol for the postoperative treatment of cardiac surgery patients, plus a so-called 'clinical path' for implementation of the protocol. Deviations from the normal path have to be reported to the junior doctor by the nursing staff. The junior doctor is supervised by the trainee intensivist, who in turn is under the supervision of the intensivist. The nursing staff are not perceived to have a very responsive attitude to the implementation of instructions; they do what they are asked to do in the end, but not always as quickly as the intensivists would like. The nursing staff are regarded as taking a somewhat autonomous line.

Duty personnel normally work from the desk, relying on the monitoring equipment; relatively little time is spent at patients' bedsides. However, it is not possible to observe all patients from the desk. There has been some improvement in this attitude in recent years, but nothing

substantial. The bedside activities of the nursing and medical team are supported by IC-web, a preliminary electronic status data system, which allows personnel to consult medication records, laboratory test data and other information. The system was developed in house, and has the limitations and problems inevitable with non-proprietary software. Generally speaking, however, people are satisfied with it.

After receiving treatment in IC, patients are transferred to Medium Care.

Treatment in MC is supervised by a cardiologist. The junior cardiologists who treat patients in MC and are called in when acute problems arise have little or no specialist surgical knowledge or skill.

NICE data

NICE data are collected in IC. They indicate that mortality is above the national average, both among cardiac surgery patients and among other IC patients in the higher APACHE bands. This suggests that there is scope for improving the treatment of very poorly patients in general.

Quality policy, feedback and analysis

The quality policy with regard to cardiac surgery patients finds expression mainly through the recently introduced medical protocol and the care path. In addition, data concerning the first twenty-four hours of treatment in IC and patients' statuses on discharge have been recorded for the NICE system since 2004. Intensivists do not attend complications meetings as a matter-of-course, partly because the meetings take place at inconvenient times. Only a few cases are actually discussed at the complications meetings. There are no formal arrangements for providing feedback regarding complications and outcomes. Openness, transparency and feedback are lacking in the cardio-surgical care chain as a whole, and could be improved in IC as well.

Performance of the intensivist group

The intensivists meet on a monthly basis. Key figures are regularly absent from these meetings, which is regarded as unhelpful, mainly because it compromises decision-making and decisiveness. The group does not have any unified representation in dealings with outside parties. It is not difficult to raise issues, but solutions are not often forthcoming. The Departmental Head tends to have a top-down approach, which some intensivists do not like. It is not a popular management style. Interviewees expressed discontent with the times that duty lists are produced. Members of the group also believe that the performance of some staff members is significantly below average.

4.3.7 Nursing staff

None of the nursing staff interviewed were surprised to learn that doubts had been expressed regarding the quality and safety of the cardio-surgical care chain at St Radboud UMC.

The interviewees believed that there was a systemic problem. There is apparently insufficient coordination and cooperation within the cardio-surgical care chain. According to the interviewees, the lack of coordination and cooperation is to a large extent attributable to the cardiac surgeons, who do not communicate with one another regarding treatment policies, or with the nursing staff. This is considered particularly problematic in the OT.

In IC, responsibility for the treatment policy lies with the intensivists. Cooperation between the intensivists and the nursing staff is now regarded as good by the Head of Nursing, partly as a result of the formulation of the Clinical Path within IC.

Leadership

Nurses have little confidence that the situation will improve without more effective management of the care chain. It needs to be made clear who is responsible for treatment and who has the authority to make decisions in the context of a course of treatment. At present, for

example, a nursing manager works with one specialist (the workstation MT), with whom policy and work arrangements are made. However, the other specialists do not respect these arrangements, because there is no coordination among the specialists.

There is no integrated management, except in IC. Medical treatment and nursing care are separate activities. The surgeons show no interest in change, as evidenced by the poor collaboration and communication within their group.

Case complexity

Nursing care within the cardio-surgical care chain is increasingly complex. The patients are increasingly old, co-morbidity is more common and the surgery is becoming more complex. More and more patients now undergo several heart operations, for example.

Developments in the training of nurses

A pilot scheme has been started, in the context of which nursing ward A10 (Thoracic and Cardiac Surgery) is acting as a training ward, mainly for BOL interns, who are trained to level 4 under the supervision of qualified nurses. This may mean that in the future the ward always has a large number of trainee level-4 nurses at its disposal.

5 Observations and discussion

5.1 Introduction

In this section, the EIC presents the conclusions of its investigation and its commentary on what has been established. In accordance with the remit given to the committee, considerable effort was devoted to verification of the reported mortality and morbidity data. The EIC also went over the case record reviews performed by the departmental heads. The report begins below with a discussion of the mortality and morbidity data, in the context of which plausible explanations are sought for the recorded levels of mortality and morbidity.

Thereafter, consideration is given to the findings of the analysis of the cardio-surgical care chain performed by members of the EIC collectively and individually. The conclusions drawn from the interviews with personnel proved to be largely consistent with the findings of the case record reviews.

5.2 Assessment of risk profile and complexity of care

Mortality during and following cardiac surgery depends partly on the pre-operative risk profile of the patient population. Strikingly, most people working at St Radboud UMC assumed that the risk profile of the facility's patient population was high, and that this explained the high mortality and morbidity rates. This view was echoed by some referrers, who said that St Radboud UMC accepted more complex cases than other cardiac surgery centres. The acceptance of complex cases was suggested as a possible reason for the high levels of mortality and morbidity.

However, the hospital's data indicated that, if anything, the average risk profile for all patient groups (CABG patients and patients undergoing valve replacements or repairs, in isolation or in combination with CABG) was below average, also allowing for the fact that the Cardio-Pulmonary Centre is a teaching facility.

The EIC reviewed a sample of cases to check the risk classifications applied by the department. No mis-classifications were encountered. The EIC accordingly concludes that the data provided by St Radboud UMC concerning the additive EuroSCOREs of and mortality among patients undergoing cardiac surgery at St Radboud UMC are correct.

The perceptions that hospital personnel had with regard to the risk profile may have been out of step with the EIC's observations because people at St Radboud UMC did not have an overview of the situation. Although data were collected, their interpretation was lacking. The medical specialists and other individuals did not monitor their own performances. It may be concluded that the perceptions prevailing within the hospital were based on supposition, rather than statistics.

5.3 Mortality

The obvious way of judging the mortality rate at St Radboud UMC's Cardiac Surgery Centre is to compare it with that observed at the other cardiac surgery centres in the Netherlands. However, the scope for meaningful comparison is limited.

Although national data on the numbers of operations performed and on mortality at the Netherlands's cardiac surgery centres are collated by the Dutch Cardiac Surgery Supervision Committee (BHN), this organisation is unable to publish the data in a form that allows comparison between the centres. When asked, the Dutch Society of Thoracic Surgeons indicated that it planned start collecting 'mirror data' for the Dutch cardiac surgery centres in

2006 via the Cardiac Treatment Supervision Committee, with a view to helping the centres interpret their additive EuroSCORE data properly. This will mean that in future the cardiac surgery centres are able to establish internal quality monitoring and quality improvement systems and to submit to peer review.

The St Radboud UMC's Cardiac Surgery Centre has for some years recorded and published its results. By doing so, the Centre has made itself more transparent but also more vulnerable. The EIC considers it regrettable that proper comparison of the performances of the various cardiac surgery centres in the Netherlands is not currently possible.

The EIC does, however, have at its disposal comparable material in the form of NICE data. Analysis of St Radboud UMC's NICE data for 2004 reveals that, among patients with APACHE III scores⁶ of 60 or more, mortality rates at St Radboud UMC were elevated. Elevated mortality was observed in patients undergoing coronary surgery only, and in patients undergoing valve surgery, in isolation or in combination with coronary surgery.

For the purpose of assessing mortality associated with the cardio-surgical care chain, it was decided to recalculate the additive EuroSCORE, as a basis for determining the expected rate of mortality. Because high additive EuroSCOREs (more than 10) are considered to be unreliable predictors of mortality, the EIC confined its attention to patients with lower additive EuroSCOREs (10 or less). Hence, the conclusions drawn expressly exclude mortality levels among high-risk patients (i.e. those with additive EuroSCOREs of more than 10).

The EIC has verified the mortality figures and cause of death information presented by the St Radboud UMC's Cardiac Surgery Centre; these data have been adjudged reliable. Analysis of the mortality figures reveals that mortality among cardiac patients undergoing surgery at St Radboud UMC between 2003 and 2005 was 0.8 percentage points (18 per cent in relative terms) higher than one might have expected (see subsection 4.1)

A CUSUM analysis shows that the performance of St Radboud UMC was consistent with the norm in 2003. In 2004, however, performance was significantly below average; the number of patient deaths was 17.9 higher than might have been expected. In 2005, performance was above average; the number of patient deaths was six fewer than might have been expected. In conclusion, the committee observes that in 2004 mortality was outside the bounds of acceptability, but fell considerably in 2005. The CUSUM analyses revealed no demonstrable differences in the mortality rates associated with individual cardiac surgeons.

Analysis of the various types of cardio-surgical intervention – CABG, aortic valve replacement, mitral valve replacement and combined aortic and mitral valve repair or replacement – reveals that, where CABG procedures are concerned, observed mortality at St Radboud UMC was consistent with mortality forecast on the basis of the additive EuroSCORE, but significantly higher than the STS mortality level (the level calculated from data published by the US Society of Thoracic Surgeons). Where the other programmes are concerned, mortality rates are well above both the additive EuroSCORE levels and the STS levels.

As previously indicated, the patient population of St Radboud UMC was relatively low risk, particularly in view of the Cardiac Surgery Centre's teaching role. The elevated rate of mortality cannot be attributed to a fall in the number of low-risk patients treated at St Radboud UMC's Thoracic and Cardiac Surgery Centre in the years 2003 to 2005, or a rise in the number of high-risk patients treated.

⁶ An APACHE III score is an expression of the seriousness of a patient's condition.

The EIC concludes that high-risk cases were not over-represented in St Radboud's cardiac surgery patient population. This conclusion is in direct conflict with the conclusion previously reached by St Radboud UMC's Board of Governors, as reported in the initial analysis communicated to the inspectorate in a letter dated 5 October 2005.

5.4 Morbidity

On the basis of a comparison of morbidity data from St Radboud UMC with data published in the academic press, the EIC concludes that cardio-surgical treatment at St Radboud UMC between 2003 and 2005 was associated with high to very high incidences of re-sternotomy (due mainly to haemorrhaging or tamponade), postoperative organ failure and infections.

The statistical evidence of high morbidity was corroborated by the case record reviews. It appeared that the facility had been dogged by high morbidity levels for some years. However, it did not seem that the morbidity was associated with the activities of individual cardiac surgeons. Although many of the St Radboud personnel interviewed by EIC members suggested that certain surgeons lacked appropriate levels of technical skill, the EIC was unable to find any objective evidence to support these claims in the form of morbidity or mortality data attributable to individual surgeons.

5.5 Conclusions of the case record reviews

The findings of the case record reviews may be summed up by saying that the EIC's conclusions are consistent with those drawn by St Radboud UMC's Internal Investigation Committee. Various cases appeared to involve avoidable actions and events that could have contributed to the death of the patients concerned. In none of the cases, however, was the EIC able to conclude that the patient would not have died if it were not for the actions or events in question. Various complications and errors identified in the case record reviews were also mentioned during the personnel interviews.

In-depth analysis of the actions and events involved in sixty-six mortality cases highlighted certain issues that the EIC considers to warrant special attention, in accordance with the analysis and interpretations of the internal committee.

- The number of re-thoracostomies was unacceptably high. The overriding and immediate requirement is for an explicit (pre-) and peroperative anticoagulant policy and agreement regarding the procedures to be followed to minimise surgical haemorrhaging. This observation is backed up by feedback from the personnel interviews. The interviewees had markedly conflicting views regarding appropriate anticoagulant policy and the causes of the haemorrhaging.
- The procedures were not sufficiently clear to ensure that post-operative problems and complications are identified in good time. This often compromised the ability of carers to respond promptly and appropriately. For example, it was unclear who was best qualified to perform particular tasks (e.g. TEE assessment, assessment of patients who developed problems when in MC following open-heart surgery, etc), or how appropriate personnel were best deployed (e.g. what circumstances justified calling in an intensivist).

5.6 Causes of the elevated mortality and morbidity

Because the elevated mortality and morbidity cannot be attributed to the risk profile of the patient population, or to the suboptimal performance of any individual cardiac surgeon, or indeed to any other specific cause, the EIC has concluded that the problems are attributable to systemic shortcomings in the cardiac surgery care chain as a whole.

Analysis of the care process has revealed a complex of factors, which had a detrimental effect on the quality of the care provided, thus leading to the high rates of mortality and morbidity.

The factors identified by the EIC are:

- Process control
- Multidisciplinary collaboration
- Leadership
- Internal tensions
- Specialisation and technical/surgical skills
- Focus on quality
- Personnel motivation

5.6.1 Process control

The likelihood of surgery or other treatment having an unintended outcome (and therefore the likelihood of a patient dying or suffering avoidable harm) increases if the process in question is neither documented nor structured. If the normal course of events is not defined, the identification of and response to abnormal developments is inevitably compromised.

St Radboud UMC suffers from such a lack of process control: the care process within the Cardio-Pulmonary Centre is barely standardised at all. The Centre has neither documentation to regulate the care system as a whole, nor protocols to regulate various critical elements of it. Most of the protocols that are in place relate to nursing activities, rather than medical activities or aspects of them. The anaesthesiology discipline has no protocols relating specifically to thoracic and cardiac surgery. Such protocols as there are within the other business units concern particular features of the process, as opposed to the process as a whole. One exception in this regard is the IC protocol for the treatment of cardiac surgery patients, which forms the basis for the clinical path introduced in January 2006. Neither the nursing protocols nor certain operational nursing practices reflect modern thinking, one example being the storage of sterile materials in open cupboards.

Because there are no protocols in place, individual personnel perform their duties in the manner that seems appropriate to them at the time. Although their actions may indeed be perfectly appropriate, the absence of protocols is liable to lead to complications because, in a complex organisation, interdependency between one action and the next has a profound influence on outcomes. A clear process definition is especially important in the context of a complex process such as the performance of a cardio-surgical procedure involving extensive preparation, input from numerous highly qualified professionals and a highly technical postoperative care programme. This is certainly the case where routine procedures such as CABGs and valve replacements are concerned.

The EIC cannot understand why the perfusionists are so isolated within the care chain. Although they perform a vital role within cardiac surgery, they report directly to the Cluster Management Team and therefore have no links with the cardiac surgeons or anaesthesiologists. This makes it less likely that procedures and protocols will be properly harmonised, when in fact the provision of care to cardiac surgery patients requires a considerable degree of interaction between surgeons, anaesthesiologists and perfusionists.

The EIC considers it unacceptable that at night a single trainee intensivist has responsibility for a large group of IC patients, distributed across four locations. There is not normally a qualified staff intensivist present in the hospital during the night. Nor do IC personnel have anyone to refer to regarding certain specialist matters.

The design of case files is indicative of a focus on the numerous separate disciplines involved in the care process, rather than on the patient. If the process were patient-oriented, a joint case file

would seem natural. At St Radboud UMC, however, each discipline has a separate file for each cardiac surgery patient.

Examination of the case files revealed that the individual departments' records were often incomplete and lacked critical diagnostic information, such as TEE data and the results of electronic laboratory and radiology tests. It was common, for example, for a file to include no indication as to whether X-ray diagnosis was considered appropriate, or (if a decision to proceed with such diagnosis was recorded) to include no reference to the findings.

5.6.2 Multidisciplinary collaboration

The care given to a patient requiring cardiac surgery should be thought of as a chain, in which the numerous relevant disciplines form the links. The cardio-surgical chain at St Radboud UMC is highly fragmented: the patient comes under the responsibility of a succession of separate disciplines, none of which is answerable to the others. For example, the treatment of patients in the ICU is the responsibility of the intensivists, while the treatment of patients in Medium Care is the responsibility of the cardiologists, and the treatment of those on the nursing ward is the responsibility of the cardiac surgeons. In the OT, there is no coordination between the anaesthesiologists, cardiac surgeons and perfusionists. The intensivists are not involved with the provision of treatment in the step-down department (MC). Furthermore, the EIC has observed that information gathered in the operating theatre is not effectively communicated to Intensive Care.

From the interviews conducted by the EIC, it is apparent that there is insufficient collaboration and communication between the various groups involved in caring for cardiac surgery patients. Mutual trust and dialogue are lacking. One manifestation of this is the lack of an early-morning daily handover meeting at which cardiac surgeons, intensive care doctors and anaesthesiologists can discuss the patients and problems dealt with in the previous twenty-four hours. Cardiac surgeons and cardiologists do not attend the daily multidisciplinary IC meetings. There is no effective system for the multidisciplinary discussion of complications. There is no coordination of anaesthesiology policy between anaesthesiologists, surgeons and intensivists. Although in theory there are numerous transfer junctions and meetings (see Appendix 3), interviewees repeatedly said that meetings were not attended by the appropriate people. There are no checks on attendance and no sanctions for non-attendance. The AOV nursing team does not have a responsive and constructive attitude towards the treatment team as a whole. For their part, the cardiac surgeons are preoccupied with technical procedures and leave all preoperative and postoperative matters to the cardiologists.

Although there used to be a clear structure for consultation between referrers and thoracic surgeons, it has gradually fallen into almost total neglect over the last five years. It is important that referrers and receiving specialists have frequent practical discussions, so that referrers remain abreast of developments in the indication and practice of thoracic and cardiac surgery. Such contact is conducive to proper information of patients before and after cardiac surgery and helps to ensure that referrals are made on the basis of current thinking on the indication of such surgery. Also, the communication of postoperative data helps to hone the expertise of the cardiac surgeon. Continuous interaction not only has an influence on mortality and morbidity, but also means that patients receive the best cardio-surgical care, since under-treatment can be avoided.

To sum up, such interaction is vital, not only for the patient of the moment, but also for the patient of the future. Hence, the gradual cessation of interaction between St Radboud UMC's cardiac surgeons and the referrers is regrettable and dangerous.

5.6.3 Leadership

As indicated earlier, the various disciplines involved in the provision of care to cardiac surgery patients are grouped in organisationally distinct clusters. As a result, the care process is not only fragmented in operational terms, but also in management terms. This inadequate process has lost its equilibrium because of the absence of strong, clear leadership, particularly in relation to cardiac surgery. The EIC concludes that the care chain lacks a management structure capable of exercising effective control over operational, logistic and organisational matters.

This state of affairs is *not* mirrored in the Paediatric Thoracic and Cardiac Surgery Department. The latter department is characterised by good communication, systematic consultation and frequent contact; there is a strong team spirit, which provides a basis for a successful collective leadership.

The EIC believes that disbandment of the so-called Small Management Team (SMT) in 1999 was a mistake. In spite of the demands of training and research, the SMT successfully exercised responsibility for the provision of care to cardiac surgery patients. In the period that the SMT was operating, production increased considerably. Disbandment of the SMT deprived St Radboud of considerable expertise in the implementation of a practical multidisciplinary approach.

Responsibility for the existence of a poorly structured care process without the protocols necessary for multidisciplinary working must lie with the management of the organisation. Furthermore, the fact that specialists within the organisation have apparently lacked real motivation to contribute to process improvement and the use of protocols is indicative of inadequate leadership. It is one of the tasks of the management to bring people on side and keep encouraging them to bring about process improvements and establish protocols.

The Head of the Department of Thoracic and Cardiac Surgery does not enjoy the confidence of his fellow cardiac surgeons or other colleagues. This is evidenced not only by feedback from the people interviewed by the EIC, but also by the process set in motion in the latter part of 2004 with a view to promoting team spirit. The absence of all staff members when the hospital received the Inspection Committee sent to assess cardiopulmonary surgical training in November 2004 was, for example, indicative of an unhealthy situation. Furthermore, the cardiac surgeons themselves concluded that the psychological guidance of their group have achieved very little. These problems have been seriously detrimental to the performance of the Cardiac Surgery Department and must have had negative consequences for the quality and volume of patient care provided.

The EIC takes the view that, although the Board of Governors was unable to discern any variation in the performance of or outcomes achieved by the individual cardiac surgeons, the circumstances that preceded this investigation should have alerted the Board to the need for a thorough examination of the activities and qualities of the head and other members of the cardio-surgical staff. The information available to it regarding abnormal morbidity should have given the Board of Governors cause for concern regarding the quality of cardio-surgical care.

From the interviews, it is apparent that many personnel have good ideas and suggestions, but have found the management unreceptive to them. Ideas, proposals and comments regarding possible improvements have repeatedly been made to the management both formally and informally. In many cases, the people making suggestions had many years' experience working under different administrations and therefore had a realistic view of the performance and organisation of the Cardiac Surgery Department. The EIC interprets the disregard for opinions and ideas emanating from the 'shop floor' as a manifestation of poor leadership. The motivation of the workforce will always benefit from receptive leadership.

Even if the management is unable to agree with ideas and opinions expressed by the personnel, it is reasonable to expect the management to show professionalism in dealing with the situation, and to enter into dialogue with the personnel concerned. This is valid not only in relation to the management of the Cardiac Surgery Department, but also in relation to the cluster management and St Radboud UMC's Board of Governors.

Some personnel are offered the opportunity to take a so-called Radboud Management Training Course. The criteria applied in the selection or non-selection of personnel for participation have not been made clear to the EIC.

The EIC would have expected the Board of Governors and the Cluster Management Team to have taken a more active role. Although these managerial bodies did respond to signs that all was not well and did address the problems drawn to their attention, it is fair to say that while signs of an unsatisfactory situation were evident for several years, they behaved in a reactive rather than pro-active manner. It should have been apparent to the Board of Governors and the Cluster Management Team that the cardio-surgical care chain had become seriously fragmented and was lacking process control or appropriate protocols. Like the Departmental Head, these managerial bodies should have looked much more critically at the cardio-surgical data collected and published by the department, and at the action taken in the light of such data. The criticism of the Departmental Head was sufficiently serious to warrant more than a one-off intervention in the form of establishment of the Ruys-Van den Broek Committee, particularly when the competence of the latter committee was questioned in such a fundamental manner. Furthermore, not enough was done in response to the Ruys-Van den Broek recommendations. The measures instigated to rebuild the mutual trust of the members of the Thoracic and Cardiac Surgery Department's medical staff were not very effective.

5.6.4 Internal tensions

The tense atmosphere among the thoracic and cardiac surgeons from about 1999 has undoubtedly affected the performance of the whole cardio-surgical care chain. If personnel are unable to work well together and are dissatisfied with their terms and conditions of employment, it is inevitable that they will be reluctant to enter into dialogue over complications and working methods and will fail to contribute spontaneously to quality improvement. Quality improvement requires the existence of a culture in which people feel comfortable and share a commitment to the achievement of common goals. At St Radboud, the individuals may have been committed, but they were not collectively committed because of the internal tensions that existed. The hospital management is culpable for allowing the internal tensions and mutual mistrust among the thoracic and cardiac surgeons to persist for so long.

5.6.5 Specialisation and skills

In 1985, St Radboud stopped using specialist anaesthesiologists for cardiac surgery. The EIC regards this as a mistake, whose ramifications have been felt to this day. The pool of anaesthesiologists involved in caring for cardiac surgery patients is much too large, with the result that knowledge and experience are too thinly spread and there is a greater risk that an individual will lack the expertise necessary to assist a given surgical procedure. With a view to resolving this problem, a new Professor of Cardiac Anaesthesiology was appointed in 2005. As an experienced specialist cardio-anaesthesiologist, he was given the task of forming a group of specialist cardio-anaesthesiologists. His appointment was intended primarily to lead to a substantial improvement in the quality of cardio-anaesthesiological services at the hospital. However, for various reasons, his arrival and introduction was not universally welcome, and he therefore had difficulty implementing his ideas.

In recent years, very little attention has been given to the specialist skills of the cardiac surgeons. The organisation of refresher training and further specialisation has proved problematic. Signs that the cardiac surgeons' technical skills might be wanting have not been investigated properly, and appropriate action has not been taken to bring about improvement. Mitral valve repair procedures and off-pump bypass operations, for example, have been performed by surgeons who lack appropriate specialist expertise and without appropriate arrangements being made with other medical staff members or other disciplines. It is fair to say that the introduction of new procedures has not been handled professionally and that this may have led to unnecessary harm or even death.

The conclusions of the Ruys-Van den Broek Committee's investigations (2004) into alleged variations in the activities and performance of individual cardiac surgeons created a misleading impression. The EIC's own investigations have confirmed the basic conclusion that there are no demonstrable performance differences between the cardiac surgeons, but have also found evidence that cardiac surgery at St Radboud was generally substandard. In 2004, the Ruys-Van den Broek Committee did not consider the high morbidity figures or the level of technical skill possessed by the various cardiac surgeons. In other words, the committee's investigations ignored key aspects of the way thoracic and cardiac surgery was performed in Nijmegen. The CORRAD data, for example, could have been put to excellent use for analysis, discussion and improvement of the cardiac surgeons' collective and individual performances and results.

5.6.6 Focus on quality

From individual interviews, it is apparent that there is no perception of the risks associated with cardiac surgery. A *laissez-faire* culture prevails, rather than a culture of mutual appraisal and dialogue. The EIC failed to find the commitment to transparency, feedback and improvement that should characterise a teaching hospital; the appropriate culture was lacking within the individual disciplines, in the wider cardio-surgical care chain and in the related management structures. Process-oriented thinking is absent or underdeveloped.

One positive point is that a great deal of data registration takes place. However, the collected data are not used to improve care, nor properly brought to the attention of the relevant parties.

The Professors of Intensive Care and Anaesthesiology appointed in 2003 highlighted the poor performance of the Cardio-Pulmonary Centre and spent 2004 collecting hard data to back up their observations. Practical improvement initiatives could not yet be taken in 2004, but the improved results seen in 2005 may be attributable to these developments

5.6.7 Motivation

In the course of the interviews, the EIC was struck by the fact that personnel wanted to work in the cardio-surgical care chain of this academic hospital because of the opportunity to provide patient care without the responsibility for research or training. Few people particularly choose to work in a university setting where it is necessary to *combine* patient care, research and training. So, for example, the output of academic work of the thoracic and cardiac surgeons is low.

The EIC was unable to establish whether there is any causal relationship between this situation and the fact that several interviewees reported having the impression that the management of St Radboud UMC was more interested in training and research than in the third core activity of a teaching hospital, namely patient care.

Some medical specialists are convinced that operational and capital resources are more readily committed to training and research than to patient care. Medical specialists whose primary concern is patient care find this difficult to accept, because they perceive that the resources that should be devoted to improving the quality of care are not forthcoming, while investment in

training and research continues. Although the EIC sought information from the Board of Governors regarding the distribution and allocation of financial resources to the three core activities in the period 2000 to 2005, it was unable to either confirm or deny the medical specialists' suspicions. Cash flows and resource apportionment at St Radboud UMC are opaque, as indeed they are at all university medical centres in the Netherlands. It can nevertheless be said that in recent years the management has provided little explanation of its priorities or preferences in relation to care, training and research. On the other hand, it is reasonable to expect that medical specialists working in a university hospital are able to commit themselves to the concept of *combined* patient care, research and training.

6 Concluding remarks

The EIC was struck by the willingness to improve the performance of the cardio-surgical care chain that exists at St Radboud UMC. All disciplines and individuals at the hospital were willing to cooperate with the investigations and to facilitate the activities of the EIC. Furthermore, the EIC observed during its investigations that initiatives were already being taken and activities being started with a view to raising the standard of care.

Nevertheless, the EIC has come to the conclusion that the present situation is very serious and characterised by numerous problems. The present shortcomings represent a sufficiently serious threat to the quality and safety of patient care that immediate corrective action is required. Many far-reaching changes are necessary with regard to both the personnel and the organisational set-up. Naturally, the implemented changes should be consistent with the conclusions of the EIC.

Part of the EIC's remit was, if possible, to make recommendations with a view to improving the quality of the cardio-surgical care chain. Given the seriousness and the extent of the observed shortcomings and the importance of immediate corrective action, it is inevitable that the formulation of recommendations would entail the production of a long list specified to an arbitrary level of detail. The committee has therefore chosen to refrain from making recommendations and to leave the task of framing appropriate corrective action to the Health Care Inspectorate and St Radboud UMC's Board of Governors.

The EIC does nevertheless wish to make an unsolicited recommendation to the Dutch Society of Thoracic Surgeons. The EIC advises the latter body to act to ensure that more information is obtained and published concerning morbidity and mortality at all cardiac surgery centres in the Netherlands. This would facilitate the comparison of cardio-surgical performance throughout the country. At present, lack of insight into the standards achieved by the various centres means that poor performance of the kind seen at St Radboud UMC is liable to go unnoticed. Furthermore, mutual comparison tends to promote quality. The EIC accordingly asks the Inspectorate to consider instituting investigations into the quality of the other cardiac surgery centres in the Netherlands.

References

STS Fall 2005 report. The Society of Thoracic Surgeons, 2006.

Onmogelijk is niets. Beleidsplan Afdeling Thorax Hartchirurgie 2005-2010 (There Is No Such Thing As Impossible. A Policy Plan for the Department of Thoracic and Cardiac Surgery 2005-2010. St Radboud UMC

Hartcentrum. Jaarverslag 2004. (Cardiac Centre. Annual Report 2004.) Cardiology, Thorax and Cardiac Surgery. St Radboud UMC, October 2005

Bedrijfsplan Cluster Centrale Sterilisatie, Anesthesiologie, Intensive care, Operatiekamers (Business Plan of the Central Sterilisation, Anaesthesiology, Intensive Care and Operating Theatre Cluster), St Radboud UMC, 2003.

Appendix 1. Available mortality data and their evaluation by St Radboud UMC in response to enquiries made by the Health Care Inspectorate

We have performed a detailed analysis of our output over the last eight years. Both the aggregated figures for the eight years and the annual figures support the same conclusions. These conclusions are:

In the CABG group (a total of 3,713 patients during the period 1997 to 2004), the overall additive EuroSCORE is 2.9 ± 2.6 and the mortality rate is 3.2 per cent, against an EMR of $2.90 - 2.94$ (95 per cent reliability interval). The results for the three separate risk groups are as follows:

		OBSERVED (Cardio-Pulmonary Centre St Radboud UMC)					EXPECTED
	N	%	EuroSCORE (mean \pm SD)	Mortality	%	95% CL mortality St Radboud UMC	EuroSCORE 95%CL
Total	3713		2.98 ± 2.6 (0-18)	120	3.2	2.6 – 3.8	
EuroSCORE of deceased patients (n=120): 6.9 ± 3.3 (1-18)							
Per EuroSCORE risk group							
Low	1808	48.7	0.8 ± 0.8 (0-2)	5	0.3	0.28 – 0.3	1.27 – 1.29
Medium	1352	36.4	3.8 ± 0.8 (3-5)	45	3.3	2.3 – 4.2	2.90 – 2.94
High	553	14.9	7.6 ± 2.0 (6-18)	70	12.7	9.8 – 15.4	10.93 – 11.54

Analysis of the annual figures provides a similar picture.

For patients undergoing aortic valve surgery (in isolation or combined with CABG), the figures were as follows:

		OBSERVED					EXPECTED
	N	%	EuroSCORE (mean \pm SD)	Mortality	%	95% CL mortality St Radboud UMC	EuroSCORE 95%CL
Total	1100		5.6 ± 2.4 (2-17)	84	7.6	6.0 – 9.2	
EuroSCORE of deceased patients (n=84): 8.1 ± 2.8 (2-17)							
Per EuroSCORE risk group							
Low	123	11.2	2.0 ± 0.0 (0-2)	1	0.8	0 – 2	1.27 – 1.29
Medium	399	36.2	4.0 ± 0.8 (3-5)	12	3.0	1 – 4.6	2.90 – 2.94
High	578	52	7.5 ± 1.6 (6-17)	71	12.2	9.6 – 14.9	10.93 – 11.54

Within this subgroup, the proportion of high-risk patients has increased considerably over the years.

For patients undergoing mitral valve surgery (in isolation or combined with CABG), the figures were as follows:

	OBSERVED						EXPECTED
	N	%	EuroSCORE (mean ± SD)	Mortality	%	95% CL mortality St Radboud UMC	EuroSCORE 95%CL
Total	381		5.5 ± 2.7 (2-18)	39	10.2	7.1 – 13.6	
EuroSCORE of deceased patients (n=39): 8.8 ± 3.1 (4-18)							
Per EuroSCORE risk group							
Low	48	12.6	2.0 ± 0.0 (0-2)	0	0	0	1.27 – 1.29
Medium	159	41.7	4.0 ± 0.8 (3-5)	5	3.1	0.4 – 5.8	2.90 – 2.94
High	174	45.7	7.9 ± 2.1 (6-18)	34	19.5	13.5 – 25.4	10.93 – 11.54

In this group, too, there has been a substantial increase in high-risk patients. Detailed analysis of the risk profiles of all groups has in particular revealed that the number of surgery patients with diabetes mellitus has risen sharply in the last two years (from roughly 7 or 8 per cent to 20 per cent); the percentage of diabetics is a recognised predictor of risk.

Source: Mortality figures for cardiac surgery patients, St Radboud UMC, letter to the Health Care Inspectorate, 5 October 2005.

Appendix 2. Composition of the External Investigation Committee (EIC)

Chairman:

J. Vesseur, physician, MPH
Health Care Inspectorate

Vice-chairman:

Professor N.M. van Hemel, cardiologist, Emeritus
nominated by the IGZ and the Dutch Cardiology Society

Members:

T.S. Hoekstra, nursing scientist, Head of Cardiological/Cardio-thoracic Surgical Nursing,
Antonius Hospital in Nieuwegein

Professor J. Klein, Head of the Anaesthesiology Department, Erasmus MC Rotterdam
nominated by the Netherlands Association for Anaesthesiology

Professor P.T. Sergeant, Head of the General and Cardiac Surgery Clinic. University Hospital
Gasthuisberg Leuven
nominated by the Dutch Society of Thoracic and Cardiac Surgeons

Dr. P.H.J. van der Voort, MSc, internist-intensivist, Medical Centre Leeuwarden, from
1.4.2006 OLVG Amsterdam
nominated by the Dutch Society for Intensive Care

Adviser:

F.J.M. König, physician, Staff Director for Medical Affairs, St Radboud UMC

Secretary:

M.J. Claessens, policy officer, Medical Affairs Staff Department, St Radboud UMC

Appendix 3. Departmental consultation arrangements

Thoracic and Cardiac Surgery

The weekly schedule and the consultation arrangements relating to the internal organisation of work within the Thoracic and Cardiac Surgery Business Unit are as follows (Cardiac Centre Annual Report 2004):

General daily schedule

7:45	Coffee and morning report
8:00	Rounds of intensive care – patient ward
8:30	Start surgery and other clinical activities
16:30	Discussion of thoracic and cardiac surgery/cardiology cases

Daily activities

Monday	Paediatric Cardiology Meeting
Tuesday	Clinical lesson (2x per month) Preoperative outpatient clinic Staff meeting/MT (2x per month)
Wednesday	Cardiac Surgery Meeting Examination Clinic (2x per month) Paediatric Cardiac Surgery Meeting
Thursday	Complications Meeting (2x per month) Full rounds ULC Dekkerswald Case Meeting Postoperative Outpatient Clinic Discussion regarding patients scheduled for surgery the following week (preoperative screening)
Friday	Multidisciplinary Complications Meeting (1x per month) St Radboud UMC Cardiac Surgery Case Meeting CWZ Cardiac Surgery Case Meeting
Non-weekly activities	Dekkerswald Pulmonary Centre Referral Evening (1x per month)

Cardiology

Internal cardiology meetings (source: Cardiac Centre Annual Report 2004):

Transfers	daily
Full rounds	weekly
Junior doctor training	weekly
Referral Meeting	weekly
Imaging Meeting (angios, echoes, X-rays etc)	weekly
Case Meeting, incorporating Thoraco-cardiac Surgery	weekly
Complications Meeting and PA Meeting	
Cardiac Surgery Meeting (PTCA or surgery)	4x per week

Cardiac Surgery Meeting (OT-programme)	weekly
Cardiology Department Rhythm Meeting	2x per week
Paediatric Cardiology Department Rhythm Meeting	monthly
Staff Meeting	2x per month
MT Meeting	2x per month
Scientific Meetings	weekly
Protocol Committee	1-3x per year
Radiology Committee	1-2x per year
Radiology Meeting	weekly
Internal Specialisms Case Meeting	5-7 x per year

Regional:

PTCA Complications Meeting	3-4x per year
Joint referral evening with Thoracic and Cardiac Surgery Department	1x per year
Brabant and Gelderland Cardiologists Association meetings, including American College of Cardiology Self-Assessment Program	3-4 x per year

Intensive Care (source: CAIO Organisation Plan 2003)

A Central Case Meeting was gradually introduced to the Intensive Care Business Unit in 2005.

1x per week Management Team Meeting
1x every two weeks Medical Staff Meeting
1x every three months meeting between Departmental Head and Workstation Medical Manager
1x every two months meeting between Management Team and Cluster Management Team
1x per month IC Medical Staff Complications Meeting
1x per month Joint IC/ Pathology Medical Staff Complications/Obduction Meeting

Anaesthesiology (source: CAIO Organisation Plan 2003)

1x per day hand-over
1x per week Complications
1x per week Management team
1x every two months Full Management Team (professional coordination, expertise promotion)
1x every two months meeting between Full MT and Cluster Management Team
1x every two months O3 Meeting (preparation of policy regarding research, training and teaching)
1x per month Staff Meeting