The Report of the Independent Inquiries into Paediatric Cardiac Services at the Royal Brompton Hospital and Harefield Hospital

April 2001

To: The Rt. Hon Sir Philip Otton QC Chairman The Royal Brompton and Harefield NHS Trust

On 8 September 1999 your Trust Board announced that it had commissioned an independent Panel to consider the complaints and concerns of individual families, and those submitted on behalf of the Down's Heart Group and the Down's Syndrome Association, about paediatric cardiac services at the Royal Brompton Hospital. That was followed, on 3 November 1999, by an announcement that your Board had asked that the Panel also consider the small number of individual cases of children, operated on at Harefield Hospital, whose parents had raised their concerns in the wake of the Inquiry established to consider paediatric cardiac services at the Royal Brompton Hospital.

Although the two Inquiries were originally regarded as quite separate and distinct, the methodology and the constitution of the Panels have, with the exception of the clinical membership, been common to both. Subsequently you agreed that the work of both Inquiries should be brought together into a single report.

As members of the Panel appointed to conduct the Inquiries, we enclose the report of our investigations and conclusions. We have not named any individual parents or the individual doctors about whom complaints were made as we promised confidentiality to both parties. Nevertheless, we have sought permission from parents and doctors to quote their views on an anonymised basis. And we have given the doctors an opportunity to comment on our findings in the light of the criticisms expressed. Finally, we have made a number of recommendations that we invite the Board to consider for implementation. Some have national significance and we would be grateful if you could raise these with the Department of Health on our behalf.

Ruth Evans Nick Archer Norma Brier Fleur Fisher Barry Keeton Sarah Leigh John Wright (Chairman of the Inquiries)

2nd April 2001

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ACRONYMS

BHHCAG	Brompton and Harefield Heart Children's Action Group
BMA	British Medical Association
BMJ	British Medical Journal
BPCA	British Paediatric Cardiac Association
BRI	Bristol Royal Infirmary
CAVSD	Complete AtrioVentricular Septal Defect
CCAD	Central Cardiac Audit Database
CEPOD	Confidential Enquiry into Peri-Operative Deaths
CHD	Congenital Heart Disease
CHI	Commission for Health Improvement
CLN	Cardiac Liaison Nurse
СМО	Chief Medical Officer
DoH	Department of Health
DHG	Down's Heart Group
DSA	Down's Syndrome Association
ECHDD	European Congenital Heart Disease Database
ECR	Extra-Contractual Referral
EU	European Union
GMC	General Medical Council
GOS	Great Ormond Street
GP	General Practitioner
GUCH	Grown-Up Congenital Heart [Disease]
HDU	High Dependency Unit
HES	Hospital Episode Statistics
KCWHA	Kensington & Chelsea and Westminster Health Authority
NSCAG	National Specialist Commissioning Advisory Group
OAT	Out of Area Transfer
PICU	Paediatric Intensive Care Unit
RBH	Royal Brompton Hospital
RB&HT	Royal Brompton and Harefield NHS Trust
RSCN	Registered Sick Children's Nurse
SCTS	Society of Cardio Thoracic Surgeons
SHO	Senior House Officer
SRSAG	Supra Regional Services Advisory Group
UKCC	United Kingdom Central Council for Nursing, Midwifery and Health Visiting
UKCCAD	UK Central Cardiac Audit Database

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SECRETARIAT

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ACKNOWLEDGEMENTS

These Inquiries centre on the concerns and experiences of families. As users of the Royal Brompton and Harefield Hospitals, parents and their children are in a unique position to comment on the nature and quality of the services provided. An enormous debt of gratitude is owed to those who took the time and trouble to discuss their concerns with us. Many of the parents, all of whom had asked to be involved, will have found it harrowing to recount to us events going back over a number of years. Some raised their concerns directly with us, and others did so indirectly through the Down's Heart Group, Down's Syndrome Association and Brompton and Harefield Heart Children's Action Group. These organisations helped us in two ways. First, they brought to us a number of general concerns in connection with the care and treatment of families whose particular interests they represent. Second, they acted as advocates and advisers for some of their members who wished, either individually or in groups, to have their own concerns voiced. To all of them we record our thanks and appreciation for their courage and generosity in talking to us, so that others could benefit from their experience.

Members of the Trust Board, management and other hospital staff at all levels have co-operated fully with our investigation. We have needed access to many documents, visited the hospitals and interviewed a wide range of staff, in order to obtain as full a picture as possible about the hospitals and their services. We are conscious that our work has made heavy demands on their time, for which we record our thanks. We wish to express particular gratitude to Mark Taylor, the Trust Chief Executive, and to Rosemary Radley-Smith, Consultant Paediatric Cardiologist and Clinical Director of the service from 1998 to 2000, for their help in establishing the Inquiries and for their continuing support throughout the period of review.

Those providing clinical care at both hospitals have endured months of scrutiny of their service, first by the Hunter Review and then by us. They work in institutions committed to excellence and innovation in the delivery of care. Indeed, many have made a significant contribution to the international reputation that both hospitals enjoy in providing a world class service. External examination of existing or past practice is a challenge to any professional. It also demands time and attention that would otherwise be devoted to patients. Throughout our Inquiry, we have been conscious of the stresses and strains to which the clinicians have been subjected – a regrettable and inevitable consequence of independent investigation. We wish to pay tribute to the openness that

clinical and other staff from both hospitals have shown towards us, and to the willingness of the Trust to hear and learn from those with first-hand experience of using the hospitals' services.

Finally, we interviewed or received written submissions from many expert witnesses to broaden our perspective. We wish to record our appreciation for the time and thought that they gave to us in presenting their work.

CHAIRMAN'S FOREWORD

'This is not a vendetta on my behalf for all the bad things that happened at the end of the day the Royal Brompton saved [my child's] life you know'.

A parent

'As a profession some of us have fed the public information which is totally unrealistic – we can solve everything, we can make pigs fly. So I do not blame the public expectations have gone way beyond what we are capable of and I keep telling patients that. We are not gods, we try very hard, we still have problems to overcome.'

A surgeon

These two Inquiries address the concerns of 49 families whose children were treated for congenital heart disease at the Royal Brompton Hospital and Harefield Hospital between 1984 and 1999. Many of the children died; some suffered serious neurological injury following surgery; a few were treated successfully; and others had Down's Syndrome and congenital heart disease where access to appropriate management was questioned by the parents. Although we found a generally high standard of clinical care, all the parents found the experience of having a very sick child immensely distressing and most were unhappy with aspects of the treatment received from these hospitals.

We needed to establish whether there was cause for complaint. This involved us in three tasks. The first was to hear the trauma and loss experienced by parents and help them to understand more fully what went wrong in the care and treatment of their child and why. The second was to discuss the generalisable concerns arising from the parents' accounts with the clinicians concerned and hear their views. The third was to put these matters to the Royal Brompton & Harefield NHS Trust (RB&HT), to understand its perspective, and to consider how any shortcomings identified could be put right.

Our job was to unravel the threads of these different perspectives. This was a difficult task. Unlike most Inquiries, ours did not focus on a single incident or event, or report on outcomes. Instead, we were asked to investigate individual families' concerns, although we were not expected to act as an NHS complaints panel on each case; nor were we a substitute for the courts. We directed parents towards these avenues where appropriate. Nonetheless, we needed to understand the complex medical histories of the children whose cases we heard and to understand the course of their treatment. At the same time, in order to obtain the fullest accounts, we promised confidentiality to parents and doctors in reviewing the cases before us.

This had the consequence that we could only put the families' complaints to the doctors in general terms. This has inevitably meant that, in fairness to the doctors, we have had to be cautious about arriving at conclusions which may be thought to involve criticism of them in circumstances where, because of the promise of confidentiality, we were unable to put to them specific concerns raised by specific families about specific children. But we are in no doubt that this was a price worth paying. The promise of confidentiality has meant that both parents and clinicians have given us the fullest accounts and we have been able to discuss their concerns and the issues raised with them in an informal setting without legal representation. We believe this to have been to our benefit and to theirs. We are convinced that the promise of confidentiality and thus the willingness of both parents and doctors to speak fully and frankly have led us to a greater understanding of the issues raised by the families' concerns, which has greatly assisted us in formulating our recommendations.

We were conscious too that, as a self-selected group, parents' views did not necessarily represent the general experience of families involved with the two hospitals, past or present. We have only heard from those who felt the need to complain, as a survey of general patient experiences was not within our terms of reference. We also needed to judge concerns contemporaneously. Some of the accounts and events described cannot be substantiated for reasons set out in our introduction. We treated what the parents told us not as established truth, but as sincere and genuinely felt expressions of concern about what went wrong with their child's care and treatment. We have no reason to disbelieve the authenticity of the severe distress which parents told us they experienced. Moreover, the concerns we heard vividly portray the dilemmas and challenges that NHS Trusts face in providing high quality patient care to a group with steadily rising expectations over the period studied. Indeed, all of the doctors we interviewed confirmed that the issues raised contained few surprises.

As a result, our report departs from the norm by presenting the evidence we have heard – the experiences of families and the views of the doctors treating them – in some detail so that the RB&HT is reminded of the reality of hospital care for the families we saw and for the doctors delivering the service. We do not comment on each particular concern but offer conclusions and recommendations on the generality of our findings. We have, however, evaluated the specific

allegations of discrimination by doctors in the care and treatment given to children with Down's Syndrome separately, providing conclusions on each group of allegations made by the parents.

Our task was also difficult because, as a Panel, we found the parents' accounts of their experience at the hospitals – the bewilderment, the terror, and grief – profoundly moving. In listening to parents who have suffered, for the most part, terrible losses and have been through harrowing experiences, we provided an outlet for their grief and anxieties about whether they did the best thing for their children. We also gave them expert medical explanations and advice, delivered in the presence of our lay members who have been able to ask the questions the parents might themselves not have thought of asking at the time. Afterwards parents have been able to debrief with a trained counsellor and in a few cases of desperate grief we have been able to arrange some continuing counselling.

We were touched by the large number of parents who expressed their relief and gratitude for the way in which the hearing validated their experience and helped them to understand their child's condition and treatment more fully, many for the first time and sometimes after many years. Undoubtedly, our Inquiries have served a valuable function, in the sense of detached appraisal and a safe outlet for concerns, which is not readily available elsewhere at present.

But the costs are also high. Inquiries arouse alarm and anxiety in parents and patients who may previously have come to terms with their suffering or loss; they cause distress and demoralisation among clinical and other staff; and they can harm the reputation of the hospital reducing the confidence of its patients. They are inefficient, demanding resources which are needed only for a short space of time, and absorb large amounts of money. They are also stressful for the inquirers (many of whom will be involved in other work in the NHS). We felt that an organisation set up for the purpose, such as the Commission for Health Improvement (CHI), provided that it is adequately resourced and managed, will in the future be a better mechanism for the resolution of the type of concerns we have addressed.

In the new climate, which demands greater public accountability of doctors, the NHS is often criticised for not acting quickly enough. The RB&HT, an internationally renowned centre of excellence, is to be commended for the speed with which it responded to the allegations of an anonymous whistleblower. To set up an independent inquiry into paediatric cardiac services in the wake of a number of highly damaging scandals within the NHS risked adverse criticism and exposure. We needed to evaluate the evidence fairly in the knowledge that other comparable units

placed under the same level of scrutiny may well have produced similar findings. The concerns expressed by parents and the pressures under which the doctors work pose a universal dilemma: how to reconcile the risks and uncertainties of a highly technical life-saving specialty with public expectations of what medicine can achieve.

Nowhere are these tensions more acutely demonstrated than in surgery for congenital heart disease, a high-risk specialty, which has seen a rapid pace of development during the last 30 years. At the beginning of that period, few of the children whose cases we have heard would have survived long into adult life and many would have died in the first few years of life. Now most cardiac abnormalities can be corrected at a relatively lower risk. Such extraordinary progress has been achieved at the cost of a great deal of effort, dedication and skill by the cardiologists and cardiac surgeons involved, and the Brompton and Harefield doctors have played a significant part in this. However, it has also been achieved at great cost to children along the way who have suffered unavoidable death or injury in order that their successors should survive intact.

As diagnostic and surgical techniques have advanced, media attention and public perception has tended to focus on the success stories resulting from pioneering surgery. This has led to expectations that all outcomes will be good, and a common belief that death or major injuries must be the result of incompetence or negligence. Heart problems in newborn babies are highly emotive. When things go wrong in paediatric cardiac services the stakes are uniquely high – primarily for the children and their parents, but also in terms of the tremendous public concern and emotion triggered. The current Public Inquiry into complex paediatric cardiac surgery at the Bristol Royal Infirmary (BRI), following the General Medical Council's (GMC) finding of serious professional misconduct by three doctors over a similar period to ours is a case in point.

Any service that aspires to a holistic approach to care – and paediatric cardiac surgery is one such service – must look upon the family's involvement in their child's treatment as one of the key outcomes in measuring how successful it has been in achieving its aspirations. In the cases we heard, the Trust failed in this respect. Our report illustrates the acute gap between parents' experiences and the doctors' perspective by presenting both. The issues are highly complex – there is no simple right and wrong – the parents feel highly responsible and understandably distressed about the care their child received and the doctors too are highly conscientious and compassionate in their responses. The only way this gap can be bridged is through better communication and effective partnership between families and doctors.

Although communication problems arise in all areas of medicine and surgery, paediatric cardiac treatment has features which make good communication even more important – and arguably more difficult. First, it is impossible for parents to understand any of the conditions associated with congenital heart disease without an understanding of the normal functioning of the heart; almost every explanation has to start with that. What is more, the surgery and other treatments proposed are usually so complex and novel that we found that even parents with nursing or medical training were unfamiliar with them. Second, many children are diagnosed shortly after birth, at a point when their parents, particularly new parents, are adapting to the advent of a new member of the family. In many cases the mother is still in hospital, or at least still recovering from the birth, when she learns about her new baby's condition. In addition to these problems, some parents are told that their child has a chromosomal abnormality – Down's Syndrome – and have to adjust to this disadvantage before learning that their child had a heart defect (which is often only detectable on expert examination and investigation).

Partnership is generally regarded as a relationship of equals, but in the NHS there is an unequal balance of power. As the health secretary, Alan Milburn, told patients' organisations in a speech in January 2001: '*There is a simple principle at stake here: the health of the patient belongs to the patient, not to the health service. I want the balance of power in the NHS to shift decisively in favour of the patient, not to pitch patients against doctors but to put the relationship between patients and the health service on a more modern footing*' (1). This inequality is heightened in the delivery of paediatric cardiac services. The parents are in a state of shock and, generally, ignorant of the basic medical facts. The health professions, on the other hand, are doing their every day job to which they are thoroughly accustomed. In that situation the partnership with the clinical team. They, after all, are – or quickly become – the experts in knowing their child, and his or her needs and emotions. Sharing of information should not have to depend on the assertiveness or tenacity of parents, and nurses have a key role to play in acting as a bridge between doctors and parents – cardiac liaison nurses will be a great asset in this respect.

The RB&HT delivers world class paediatric cardiac services to children, with excellent outcomes. But the experience of the parents we met has been extremely unhappy. Our report shows how parents believe they have been failed by the Trust and identifies what can be done to overcome these failures in the future. Many changes and improvements are already underway. Some of our recommendations do have resource implications and, although the Trust's commitment to paediatric cardiac services is high, the money is not readily available. As we state in our report, this is a matter requiring early attention by Government. Other recommendations require organisational and cultural change. We hope that our report, by setting out the validity of both perspectives, will help the Trust to tackle the root problem of poor communication and encourage effective partnership between parents and doctors in the delivery of paediatric cardiac care.

Ruth Evans 2nd April 2001

THE REPORT

Part One

BACKGROUND

1. INTRODUCTION

- 1.1 On 8 September 1999 the Royal Brompton and Harefield NHS Trust (the Trust) announced that it was commissioning an Inquiry to 'consider the complaints and concerns of individual families' about paediatric cardiac services heart services for children at the Royal Brompton Hospital (RBH) (2). This had been one of the recommendations in the report of an earlier Review, chaired by Dr Stewart Hunter, into the outcome of paediatric cardiac surgery at the RBH for the period 1990-1999 (3). The Inquiry was also to consider concerns 'submitted on behalf of the Down's Heart Group (DHG) and the Down's Syndrome Association (DSA)' about alleged discriminatory treatment of children with Down's Syndrome.
- 1.2 Dr Hunter's Review recommended that the Inquiry Panel should be chaired by a lay person, with input from two paediatric cardiologists chosen by the Chairman of the Inquiry from a list of suggested names nominated by the British Paediatric Cardiac Association (BPCA). Following the Inquiry Chairman's appointment, further Panel members were sought with relevant professional and personal experience. Full details of the Panel members are given in Appendix 1.

THE HUNTER REVIEW

- 1.3 In June 1999, a columnist with *Private Eye* had received an anonymous letter from a 'concerned professional', enclosing what purported to be '*confidential audit data for babies and children with Down's Syndrome undergoing heart surgery at the Royal Brompton Hospital*'. The letter alleged that the results of surgery, particularly for children with Down's Syndrome, were worse than elsewhere, and that there were inappropriate attitudes towards children with Down's Syndrome. The letter was not published, but was forwarded to the Trust's Chief Executive.
- 1.4 Although the allegations were made anonymously, the Trust responded swiftly and decisively, believing that there was sufficient cause for concern about communication with families, and about allegations of discrimination, to warrant the establishment of an independent review.

- 1.5 The terms of reference for the Hunter Review (3) are set out in Appendix 2. In essence, its remit was to:
 - Assess outcome data, for the period 1990-1999, in respect of seven specific conditions or procedures.
 - Consider whether there was any evidence that children with Down's Syndrome had less than equitable access to those procedures, or were the subject of inappropriate attitudes.
 - Consider whether, when seeking consent, misleading information was given about potential outcomes.
 - Assess the appropriateness of current medical staffing on the paediatric intensive care unit (PICU) at the RBH.
- 1.6 The Review scrutinised the audited surgical data and interviewed the clinical and other staff concerned. The Trust encouraged the families of children at the hospital to write in and promised that their concerns and worries would be addressed. The Hunter Review Panel did not themselves meet any individual families or representatives of the DHG or DSA, although they did consider written depositions from those organisations. As we discuss in Chapter 29, the DHG criticised the fact that their evidence 'appear[ed] to have been ignored', and wondered how misleading information to parents about potential outcomes could have been considered when no families were interviewed. They observed also that the invitation to take part in our Inquiry resulted from their own initiative, rather than an approach to them by the Trust. The DSA, similarly, felt that their written submission had not been adequately addressed by the Hunter Review.
- 1.7 Surgical results: The Hunter Review found that data provided by the Clinical Audit Department had not been validated by the cardiac surgeons. The research information provided anonymously to *Private Eye* about babies and children with Down's Syndrome undergoing heart surgery was a rough draft of a retrospective review. The Hunter Review report described it as 'incomprehensible, incomplete and misleading', and felt that it might have misled the whistleblower. The Hunter Review Panel's opinion was that the RBH results were 'similar to, and in most cases better than, the results taken from the UK Register run by the Society of Cardiothoracic Surgeons of Great Britain and Ireland'. However, they stressed the importance for all units of keeping a careful account of results.

With regard to results for children with Down's Syndrome, they considered that elevated risk factors in three of the cases in the period 1.4.98 to 1.6.99 might explain the apparent higher mortality. Clusters of poor results and higher mortality were '*well recognised in all surgical departments*', and this '*blip*' was not in their view representative of the general trend of good results and continuing improvement.

- 1.8 **Management of Down's Syndrome children with heart disease**: The Hunter Review Panel found that an average of 37.4 children with Down's Syndrome and heart problems were referred each year to the RBH, which was very close to the prediction of 38 cases based on national statistics. Average mortality for correction of complete atrio ventricular septal defect (CAVSD) over the period 1990-1999 was 11%, compared with the national average of 14%. The report concluded that: *'over the period of the 1990s there is no significant difference in the mortality for correction of [CAVSD] between Down's and non-Down's operated on at the RBH'*. No evidence was found *'that Down's children suffered institutional or individual discrimination which impeded their appropriate management and treatment at the RBH'*.
- 1.9 Risk assessment and consent: The report of the Hunter Review explained that, during the 1990s, improved understanding of the frequency and nature of risk associated with cardiopulmonary bypass was accompanied by a trend towards increasing disclosure of risk information to patients and parents. Unless specifically asked, many surgeons would not have raised the possibility of brain damage. The practice by some surgeons of writing on the consent form the risk quoted to parents was to be encouraged. With regard to the whistleblower's allegation that a quoted risk of about 5% for children with Down's Syndrome was 'obviously not true', the report stated that the average mortality for repair of CAVSD between 1987 and 1998 was 13%. However, the Hunter Review Panel 'could find no evidence to suggest that the consultant medical staff or clinical teams had consistently given misleading information about potential outcomes'. They agreed with the Trust's view that: 'all clinicians should discuss any significant complication with a risk of 1% or more and serious complications, such as death, stroke or brain damage, no matter how low the risk of occurrence'.
- 1.10 Standards of staffing and care in the PICU: The Hunter Review stated that, since the middle of 1999, two consultant intensivists had been responsible for the care of patients in the PICU. A third post was to be filled in September 1999. Difficulties in providing 24-

hour junior doctor cover were occasionally experienced by every paediatric cardiac surgical unit in the UK. The Hunter Review Panel believed that: 'with regard to current practice within the UK, the current medical staffing on the [PICU] has been acceptable and advises that the specific allegations made in respect of personnel cannot be supported by the available evidence and analysis of the facts'.

- 1.11 The first recommendation of the report was that our Inquiry should be set up, as the Hunter Review Panel did not have the time or resources to interview the families. Other recommendations were that:
 - Mechanisms for data collection and analysis should be improved, and regular review, reporting and dissemination of surgical results should be emphasised.
 - Communication with families and support groups should be improved.
 - The importance of the consenting process should be emphasised to all medical staff.

The Trust Board accepted all the Hunter Review recommendations.

THE ROYAL BROMPTON HOSPITAL INQUIRY

- 1.12 The Royal Brompton Hospital (RBH) Inquiry Panel was asked to review the case histories of the families who had written in with concerns, in order to understand what had given rise to these and to consider how any shortcomings identified could be put right. Our terms of reference (attached in full at Appendix 3), agreed by the Trust, were: '*To address the concerns of individual patients or families, and the Down's Syndrome Association and Down's Heart Group, about services at the Royal Brompton Hospital since the beginning of 1991, to include attitudes towards, and communications with, such patients and their families; to find facts; and to make recommendations'.*
- 1.13 The terms of reference initially stated that only cases since 1991 should be included within our remit. Following representation from the Brompton and Harefield Heart Children's Action Group (BHHCAG), the Trust extended our terms of reference on 29 October 1999 to encompass services delivered since 1987 to be consistent with the Hunter Review, which had considered a sub-set of data in relation to Down's Syndrome patients dating back to 1987. The Panel was also asked to consider some cases of children with Down's Syndrome dating back as far as 1981 where treatment is ongoing. It was for the Trust to

decide whether a particular child's case should be included in the Inquiry. They informed us that requests from parents for inclusion would be accepted unless there had been no treatment or care since 1 January 1991. This resulted in five requests being declined.

- 1.14 Only those families who had requested that their concerns be addressed by the Hunter Review or our Inquiry were considered by the Trust for inclusion. We have been asked by some RBH doctors why we did not take into account the views of a wider range of parents who may be satisfied with the services they received. We were also asked by some parents why we had not sought out the views of more dissatisfied parents whom they knew about. The Trust did not attempt to contact other parents whose children had been treated at the RBH during the 13-year period covered by our Inquiry, to assess levels of patient satisfaction with the service or to identify complainants, as in their view advertising for further complainants was unnecessary in the light of the extensive media coverage of the issues. The concerns raised with us cannot therefore be seen as a representative crosssection of the views of users of heart services for children at the RBH, as they address particular issues not the generality of care at the RBH. Indeed, evidence from Heartline suggests high levels of patient satisfaction with RBH services. Nevertheless, we judge that the complaints and comments made reflect the dilemmas and challenges that exist in providing high quality patient care to a group with steadily rising expectations over the period studied. We do not make the assumption that the cases we have heard are the norm, but neither do we conclude that the problems about which the families complain are untypical. Even so, throughout our deliberations we have been mindful of the limitations of reaching conclusions on the basis of concerns voiced by a self-selected group of parents.
- 1.15 In a very small number of instances, allegations have been made to the Panel about the performance of individual clinicians. Natural justice, and the Panel's own set of guiding principles, require that the clinicians concerned be given full details of complaints and the opportunity to consult the medical records and respond. We are handling this small number of cases separately, and they do not form part of this report.
- 1.16 Unlike a Public Inquiry, both the RBH and Harefield Inquiries were commissioned by the Trust. Since commissioning these Inquiries the Trust has received financial support from the NHS Executive towards meeting these costs. Its decision to use resources that could otherwise have been put to direct patient care reflects, in our view, a strong and commendable commitment to addressing the expressed concerns of families and, where

unmet needs are identified, to improving the quality of service. Throughout our work we have been conscious of the need to proceed with economy and efficiency so as to minimise the loss of resources to patient care. However, the volume of work generated by the complaints from RBH families was not accurately predicted either by the Trust or by Panel members at the start of the Inquiry. We soon discovered that there was no quick or easy way to review 49 individual cases and, at the same time, do justice to the families' concerns and the responses of the staff. As a result, the RBH Inquiry took far longer than originally envisaged to complete. Although this was a source of frustration to the Trust, it did not place any constraints upon us beyond those designed to ensure that we adhered to our remit, and that we used resources prudently.

1.17 From the outset, the Trust ensured that the Inquiry was set up and run as an entirely independent body. Although the Panel kept the Trust and all other stakeholders informed about what we were doing, the responsibility for the way in which we conducted the Inquiry, and for the analysis and conclusions, is ours.

THE HAREFIELD HOSPITAL INQUIRY

- 1.18 On 3 November 1999, the Bristol Royal Infirmary released reports comparing the outcome of children's surgery at that hospital with outcomes at 11 other centres in the UK for the period 1984-1995. The Trust confirmed, in a Press Release issued that day (4), that 'centre 10' was Harefield Hospital. The results, which the Trust described as 'unvalidated' and perhaps containing 'significant errors', appeared to show that performance at Harefield was 'worse than average in the case of children aged over one year'. The Trust commented as follows: 'If the figures are correct, the higher mortality rate at Harefield during this time was almost certainly partly due to the fact that the Harefield team accepted children for treatment who were more profoundly sick, some of whom had been turned down by other hospitals. All the children undergoing these complex surgical procedures including transplants were very ill and many would have died without surgery'.
- 1.19 The Trust asked Dr Hunter, supported by a consultant paediatric cardiac surgeon and a medical statistician, to carry out an independent review of the Harefield Hospital results to verify these findings. It also requested that, in parallel with our RBH Inquiry, we conduct a similar exercise to address the concerns of the small number of Harefield families whose

cases had been excluded from RBH Inquiry. The terms of reference were as follows: 'To address the concerns of individual patients or families about paediatric cardiac services at the Harefield Hospital in the period 1984 to 31 October 1999, to include attitudes towards, and communications with, such patients and their families; to find facts; and to make recommendations'.

- 1.20 We recognise that we have only seen a very small self-selected group of parents referred by the Trust, just seven cases, representing less than 0.5% of the approximately 2,000 cases treated at the hospital during the period 1984-1999. The Trust requested that the Inquiry address the concerns raised by the Harefield families who had come forward as a result of the publicity given to the establishment of the Hunter Review Panel. It is likely that if the Trust had invited all past patients to raise their concerns with us more cases would have been identified. We did not therefore hear a representative cross-section of the views of parents – whether good or bad – about the services provided at Harefield during this period.
- 1.21 In one case, specific allegations were made to us about the performance of individual doctors. Natural justice, and the Panel's own set of guiding principles, required that these doctors be given full details of the complaint, and the opportunity to consult the medical records and respond. We have dealt with this case separately from the main body of work through meetings and correspondence with the relevant clinical staff. Our findings do not form part of this report, except in so far as they have a bearing on generalised concerns.
- 1.22 A different paediatric cardiologist was appointed to the Panel for the Harefield Inquiry to review the individual case notes. With this exception, we have been able to use the same Panel members, Secretariat and advisers and have adopted a common approach and system for both Inquiries. The Trust was understandably concerned that we should not allow considerations about one hospital to influence those about the other. We have observed that requirement during the course of our work, and also in reaching our conclusions and preparing this combined report.

2. GUIDING PRINCIPLES AND PROCEDURES

INTRODUCTION

- 2.1 We found that there was neither precedent nor guidelines to draw on to help us run the Inquiry. This is surprising given the number of non-statutory reviews commissioned within the NHS.
- 2.2 We were therefore faced with having to develop our own policies and procedures, a process that occupied much of our time in the early weeks of the Inquiry's work. This involved identifying key objectives to show the parties how we would set about our work, and publishing guiding principles on independence, equity, accessibility, openness, accountability, effectiveness and confidentiality to describe the values underpinning them. The objectives and guiding principles are reproduced in Appendix 3 as a resource for others embarking on similar inquiries.
- 2.3 We explored this problem with the Commission for Health Improvement (CHI), whose remit includes powers to carry out investigations for the NHS and to produce practical guidance for other bodies undertaking such investigations. The CHI came into existence in early 2000, so had not yet had time to address this. Many inquiries now carried out by panels such as ourselves will in future be carried out by the CHI, and we welcome this development. However, we recommend that early attention be given by CHI to the preparation of guidance for other inquiries, commissioned by government or an NHS Authority, to conduct an independent review of the delivery of a clinical service.

CONFIDENTIALITY

2.4 Our Inquiry was not an alternative to the courts or a substitute for the NHS complaints system – our approach was to identify generalised concerns on an anonymised basis. Many of the parents we saw have lived with the traumatic outcome of their child's treatment for several years, and some have already either pursued the NHS complaints system or explored the possibility of litigation. Several others have children who are still attending for treatment or follow up. All parents were reassured that they could speak to

us openly and confidentially about their concerns without their identity being disclosed either in our report or in discussion with hospital staff, unless they so directed. One of the factors that deters parents from complaining about a service provided under the NHS is a fear that the care of a child continuing to receive treatment would subsequently be compromised. Parents clearly felt this was a danger, even where the child was no longer being treated at the hospital in question, because they understood that the world of cardiac surgery was a small one. We felt that this fear was unfounded in the sense that it was extremely unlikely that children's care would be directly affected, but well founded in the sense that the knowledge that they were complainants might well affect the parents' relationships with the doctors treating the child, and this in itself was an important factor in the child's treatment.

- 2.5 As for the staff about whom the allegations were made, we gave the same undertaking of confidentiality and assurance that they would receive a fair hearing. Had we not given that assurance, it is doubtful that they would have given us the same degree of co-operation and involvement which has been so helpful to us in carrying out our task.
- The constraint of confidentiality meant that we were unable to put specific allegations to 2.6 the clinicians concerned. We also had to weigh the accuracy of evidence, from parents and clinicians, about events, many of which occurred several years earlier. Parents told us that their experiences of their child's treatment remains vivid in their memories. Consultants, on the other hand, have seen many children since then and will generally have very hazy recollections about a particular consultation. Both the NHS complaints system and the courts operate time limits (which can only be waived in exceptional circumstances) because as time passes recollections fade and supporting evidence becomes more difficult to trace and examine. The Panel has had to strike a delicate balance here. It might have been considered unreasonable to dismiss the parents' concerns simply because they could not be specifically challenged or corroborated, yet it could also have been seen as unfair if we were to criticise the hospital staff on the basis of unproven allegations. We decided to overcome this as best we could by raising the issues with clinicians in generalised terms, telling them what was said but not who had said it. In this way, we hoped to convey to the Trust the parents' concerns without recourse to the judicial process where the identity of parents and doctors would be disclosable.

2.7 Exceptionally, the Panel asked some parents if they would like us pursue their individual case. This was either to inform our consideration of a particular issue, or to obtain answers and resolution for parents about what went wrong in the care and treatment of their child, and why. Where we followed this course of action, it was on the understanding that our findings on particular cases would not feature in our report and nor would we adjudicate on the answers received. We also explained that the Inquiry could not act as a substitute for the NHS complaints procedure under which parents might be entitled to a detailed investigation by a panel which included clinicians expert in the specialities relevant to their particular case.

LEGAL REPRESENTATION

2.8 Early on in our Inquiry, a request for legal representation at hearings was raised with us by the BHHCAG, and by some clinicians. The Panel concluded that none of the parties, including the Panel itself, should be represented by lawyers as this would have made our proceedings disproportionately adversarial, time consuming and costly. We were informed that many parents would not have wanted such representation. The overwhelming priority for the majority of families was to have an opportunity to talk through their concerns, to receive a fair hearing, to receive explanations where possible, and to see changes in hospital practices made as a result of their experiences. Clinicians would not unreasonably want to be represented if they felt that parents had legal support, and that could have prevented us from getting a first-hand understanding of the issues. We concluded that a non-adversarial approach offered the best way of achieving a satisfactory resolution to the concerns that the Trust asked us to address.

EVIDENCE

2.9 Our evidence was obtained from written documentation and oral hearings. A questionnaire was completed by all parents, some with help from a legally trained advocate, and this is reproduced in Appendix 4. We obtained from the Trust copies of the medical records for all the children whose parents presented oral evidence but not for children whose parents gave evidence as a group (we describe in Chapter 24 some of the problems that we encountered with the records). From these documents, clinical and case summaries were prepared which identified the key clinical facts and key parental concerns for the Panel to address when meeting families.

- 2.10 We saw a total of 49 families. Forty-two related to children treated at the RBH and, of these, 14 were children with both heart problems and Down's Syndrome. The remaining seven cases related to Harefield Hospital. As noted in Chapter 1, the Panel was conscious that, as a self-selected group, parents' views might not be representative of the general opinion of families involved with the two hospitals. Parents' views were, however, treated as sincere expressions of concern about what went wrong with their child's care and treatment. Although what parents told us could not, for reasons of confidentiality, be submitted to challenge, this does not mean it was poor evidence. It was beyond the scope of our Inquiry to test the parents' concerns against those of a wider survey of users, but the extent of common ground from numerous and diffuse sources gave the issues sufficient credibility to warrant our relying on them to some degree.
- 2.11 Of the 42 children who attended the RBH:
 - 20 died, the parents in most of these cases being concerned that the death of their child might have been preventable. The age profile of these children was as follows:

Under 1 year	7
Aged 1 to 4	5
Aged 5 to 14	6
15 or over	2

- Six survived treatment but with neurological impairment, in most cases severe, the parents being concerned to find out what went wrong and why. One of these children (included in the category above) died some years after treatment at the RBH at the age of 20.
- Three survived with few continuing problems although, some time after treatment at the RBH, one of these had a successful transplant at the age of 13 after complete heart block. This child's parents wondered whether this might have been avoided by better follow-up and earlier diagnosis of his cardiomyopathy.
- Fourteen had Down's Syndrome, the parents asking us to assess whether there was any evidence of discrimination in the treatment given by the RBH. Two of these children died, one in the post-operative period and one unexpectedly some 18 months after surgery.
- 2.12 We saw the families of seven cases referred to us from Harefield Hospital, of which:
 - 6 children died, one of who was a transplant patient.
 - 1 child suffered severe neurological impairment.
- 2.13 The hearings themselves took place at our offices in Paddington and lasted up to three hours. Although we tried to make the meetings as informal as we could, some parents found the process both daunting and painful. We had trained counsellors on hand to support parents and family members through the process. Although we had expected that many parents would find recounting their experiences upsetting and sometimes traumatic Panel members too found many of the accounts harrowing and distressing.
- 2.14 We were struck by the large number of parents who expressed their relief and appreciation for the way in which the hearing helped them reach a better understanding of their child's condition and treatment, many for the first time. As one parent said: *'If I had not come here, I would not know what has happened I am happy that I came here, because I know the details now, which really I should have known before'*. The majority of parents told us that simply to have their concerns addressed by an independent panel was therapeutic. Although we do not know whether the benefit would endure over time, we were left in no doubt of the value to parents of an unhurried face-to-face discussion of their child's condition and treatment with information and explanations backed up by the medical records. And we were moved by the expressions of gratitude from parents, particularly for the way in which our clinicians enhanced their knowledge and understanding.
- 2.15 After the hearings we prepared follow-up letters summarising the main issues which had been discussed with conclusions on the evidence heard. This follow-up letter was an important factor in achieving satisfactory closure of cases.
- 2.16 Nevertheless, not all parents were satisfied with the Panel's findings. A few wanted us to make judgements on issues of negligence and to attribute blame to particular individuals for what had happened to their child. That was not within our remit, not least because we did not have the legal powers to act in that way, nor did we have the resources, time, legal services and evidence to do so. We went as far as we felt we reasonably could to resolve

their concerns, but in these cases we recommended that parents pursued other avenues for the remedy they sought.

- 2.17 In addition, we were asked to address group submissions of evidence from the BHHCAG and also from the DSA, the DHG and Heartline, agencies that represent many hundreds of families across the UK. The DSA and DHG were concerned about the treatment of children with Down's Syndrome and congenital heart disease, whereas the focus of the other two bodies was the general treatment of children with congenital heart disease. After preliminary discussions, each group made written submissions, which were followed up with meetings with the Panel. At one of the meetings with the DHG we heard evidence from a number of parents of children with Down's Syndrome and congenital heart disease, who did not feel able to go through the main Inquiry process, which would involve notifying the Trust of their concerns and appearing at individual hearings.
- 2.18 From the individual hearings and these meetings with the groups involved, we devised a method of distilling and analysing the points to be taken up with clinical and other staff. The issues raised about the treatment of children, specifically about what was regarded as evidence of discrimination in treatment of children with Down's Syndrome and congenital heart disease, are set out in Part Five of this report.
- 2.19 We recognised the need to evaluate the concerns raised with the Panel contemporaneously, ensuring that the best standards operating at the time in question were applied, rather than judging events with the benefit of hindsight. Nevertheless, in the course of our hearings we found that a number of improvements could be introduced to services to meet current day expectations. In some cases these improvements were already being made.
- 2.20 We realise that most of the complaints arose before procedures improved in some critical ways for example, adverse incident reporting was introduced and a medically and legally qualified risk manager was appointed in 1997, and the handling of bereavement has improved so one of our purposes in meeting with clinicians was to hear how things have changed.
- 2.21 We took evidence from the consultant medical staff involved in the care and treatment of children during the period under review, including all those against whom complaints were made. We did not include junior medical staff, anaesthetists, perfusionists, technical staff

or the majority of nurses who worked on the wards during this period. We ensured that clinicians had a note setting out the key issues and questions in advance of the hearing.

- 2.22 All the clinicians paediatric cardiologists, intensivists, surgeons and others expressed their willingness to meet us and gave us a great deal of their time. Each was interviewed separately. The cardiologists were seen twice, on one occasion to discuss general issues and on the second to discuss issues relating to the allegations of discrimination against children with Down's Syndrome. In addition to attending the oral hearing, some clinicians provided written comments on the topic areas.
- 2.23 The Trust's Chairman, non-Executive Board members, Chief Executive, and other Executive members of the Trust Board provided a great deal of helpful information about the two hospitals and their services, funding and resources. They also gave us access to the clinical and other areas of the hospitals that we considered relevant to our Inquiry. In addition to meeting the Chairman and some of his Board colleagues, we conducted formal hearings with key managerial, nursing and other staff in order to obtain their views on the issues identified.
- 2.24 In Parts Two to Four of this Report, we describe each set of issues raised by the parents, giving the clinicians' responses and, where appropriate, the Trust's responses, our conclusions and any recommendations for future action.

RECOMMENDATIONS

The Panel recommends that:

1. The Department of Health ensures that early attention be given by the Commission for Health Improvement to the preparation of guidance for those commissioned by government or an NHS Authority to conduct an independent review of the delivery of a clinical service.

3. POLICY AND SERVICE CONTEXT

INTRODUCTION

- 3.1 In all areas of public service, user empowerment has had a significant impact on service delivery over the past two decades, nowhere more evidently than in the NHS where patients and their carers have demanded fuller participation and partnership in their health care. In recognition of patients' demands for greater clinical accountability, the Government's NHS Plan (5), published in August 2000, requires Trust Boards to appoint patient representatives. However, it also proposes the abolition of Community Health Councils set up in 1974 to represent the local community and help individual users take up their concerns with NHS authorities.
- 3.2 This assertion of patients' rights has coincided with a series of high profile and extremely damaging cases within the NHS. These, together with publicity about the Inquiries set up to review what went wrong and why, have undermined public confidence in the NHS and in those regulating the professions. As we noted in Chapter 2, the Government established the CHI in 2000 in response to this. The CHI acts as a quasi health inspectorate, undertaking performance assessment on a rolling programme and incident basis.
- 3.3 In addition to formal inquiries set up by the Secretary of State for Health, there has been an increasing recourse by NHS Trusts and other NHS authorities to independent reviews commissioned and funded locally. Ours is one such review among a great number of others. The cost and disruption involved for patients and clinicians alike can in our opinion be justified only against the criterion of a commensurate benefit for future users of the service in question. Without such a cost-benefit equation, they are an expensive way of addressing alleged shortcomings in performance.

REGULATING THE HEALTH PROFESSIONS

3.4 Most of the professions involved in direct patient care may only be practised by those who are registered with a regulatory body established by Statute. For nurses this role is fulfilled by the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC). The regulatory body for doctors is the General Medical Council (GMC). The remit of the GMC has recently been extended beyond issues of professional conduct to include competence and performance.

- 3.5 We have not encountered actions or issues at the RBH or Harefield Hospital which, on the basis of our inquiries and the information we have obtained, should in our view have been reported to the GMC or to the UKCC. However, there is a long-standing need for all health professionals to be kept up to the mark with current practice, both clinical and attitudinal. Since the early 1990s, the GMC has been reforming the way in which it frames its guidance to the medical profession, basing it on the perspective of what patients should be able to expect of their doctor. The 1998 version of their booklet *Good Medical Practice* (6) differs from the original 1995 edition by emphasising the quality of doctor-patient relationships the need for good communication, and for doctors regularly to review their performance.
- 3.6 This is being carried forward through the GMC's drive to modernise its fitness to practise procedures and its commitment to ensure that doctors practise in accordance with these standards, through regular assessments of their performance linked to revalidation of registration. In a speech given in early 2001, Sir Donald Irvine, the President of the GMC, argued that the current crisis within the NHS will only be solved if the profession and managers of the profession admit deficiencies and adapt to the changing expectations of the public: '*Cultural flaws in the medical profession show as excessive paternalism, lack of respect for patients and their right to make decisions about their care, and secrecy and complacency about poor practice. These all contribute to a picture which leads the public to believe that a lot of doctors put their own interests before that of their patients' (7).*
- 3.7 The Medical Royal Colleges, Societies and Associations also make an essential contribution to improved care standards. The Royal Colleges in particular operate the higher qualifications needed for specialist practice and, as part of that, undertake the recognition or approval of particular institutions or schemes for training purposes. They are also involved in the appointment of consultants in order to ensure that candidates have the necessary skills and experience. All these bodies also give guidance to their members, and disseminate information on good practice.

ADVERSE EVENTS

- 3.8 In 2000, the Department of Health (DoH) published the report of an expert group, chaired by the Chief Medical Officer (CMO), Professor Liam Donaldson, on the importance of learning from adverse events in the NHS (8). An *'adverse health care event'* is defined in the report as *'an event or omission arising during clinical care and causing physical or psychological injury to a patient'*.
- 3.9 The report, *An Organisation with a Memory*, identified four key areas that had to be addressed:
 - Unified mechanisms for reporting and analysis when things go wrong.
 - A more open culture, in which errors or service failures can be reported and discussed.
 - Mechanisms for ensuring that, where lessons are identified, the necessary changes are put into practice.
 - A much wider appreciation of the value of the system approach in preventing, analysing and learning from errors.
- 3.10 We recognise that adverse events may not lead to adverse outcomes, and that adverse outcomes are not necessarily the result of adverse events. Although we must learn from adverse events because they may in some situations lead to adverse outcomes, many adverse outcomes are due to the disease or to unavoidable complications of it rather than to any adverse event in treatment.
- 3.11 Some of the parents whose cases we examined were convinced that there had been a treatment error resulting in death or neurological injury. It is important to stress that these children had extremely serious illnesses and that major surgery carries risks. There may be tragic outcomes without any error in judgement or performance being made by the clinicians concerned. The importance of drawing up and adhering to well-defined consent procedures is an issue that we explore in Chapters 8 and 15 dealing with consent and risk.
- 3.12 The difficulty in classifying adverse events in cardiac treatment in a meaningful way is that there are many variations, both of condition and combinations of defects. For this reason the cases which can be classified into one category with any meaningful effect in any one

centre, whatever its volume of work, are likely to be so small in number as to be of limited statistical value. This is because the relatively low incidence of the disease means that the number of procedures for each diagnostic group, without taking into account detailed anatomical variations or variations in patients' pre-existing condition or other morbidity, is relatively small. Similarly, although the complication rates are on the whole low, they vary in both manifestation and severity and change over time. For this reason it is important that data are pooled and evaluation shared on a national and international basis. The medical bodies have a vital role to play in encouraging their members to be active participants in audit arrangements. As the expert group observes: *'insufficient effort is made to target high-risk clinical procedures or to prevent the recurrence of specific catastrophic events'* (8).

3.13 We discuss this further in Chapter 25 on clinical audit, which is the process whereby clinical activity and its outcomes are recorded and analysed for the purpose of evaluation and service improvement. This approach has been described as the 'learning loop'. As with the new system set out in the expert group's report, its value and potential for benefit are dependent on participation by all the health professionals concerned. We applaud the expert group view that the NHS owes it to those who suffer adverse consequences of health care to ensure that lessons are learned wherever appropriate.

4. HISTORY AND DEVELOPMENT OF HEART SERVICES FOR CHILDREN

INTRODUCTION

- 4.1 In this Chapter we review briefly the nature, incidence, morbidity and treatment for congenital heart disease over the past 20 years and, more specifically, the provision of paediatric cardiac services over a 13-year period of rapid change, in which new diagnostic and treatment techniques have been introduced leading to significant improvements in success rates. In evaluating the effectiveness of services over this period of change, the Panel has attempted to judge performance contemporaneously against the standards that obtained at that point in time.
- 4.2 We learnt from parents that cardiac treatment for children imposes huge stresses on families and family relations. We were struck by the courage and commitment of the parents in dealing with their children's problems. We were also impressed by their degree of understanding about heart disease in general, and their child's condition in particular. Many of them had searched for information in libraries, journals and on the internet. Whereas some parents found it helpful to have a full explanation in lay terms from one of our cardiologists sometimes they claimed for the first time others wanted the opportunity to discuss issues arising from their own research. They did not always appreciate the incredible pace of change in developments in paediatric heart services. Hence a pioneering technique or diagnostic procedure now known to parents may not have been available at the time of their child's treatment, or might have existed only in a particular centre as part of a research trial.
- 4.3 The Heartline Association has produced a useful booklet *Heart Children A Practical Handbook for Parents* (9). Nowadays a copy of the booklet is issued to the parents of all children undergoing treatment at the RBH and Harefield Hospital. It gives information and advice about a wide range of medical and social issues and has a section about 'specific heart problems', many of which had been present in the children whose cases we considered. There is also a comprehensive glossary, or dictionary, of medical terminology.

We commend this booklet to anyone wishing to have a more detailed understanding of the subject.



Fig.1: Diagram of the inside of the heart

Heart disease in children

- 4.4 Paediatric cardiac disease can be either present at birth or acquired later. The former congenital heart disease (CHD) is commoner than acquired heart disease in developed countries and, in children, uses more of the specialised skills of cardiological and surgical services than acquired heart disease. This is in complete contrast to adult cardiac services. The known causes of CHD include genetic factors or environmental factors such as maternal infection or drugs. In about 15% of cases there will be other abnormalities present, including chromosomal disorders (about half of children with Down's Syndrome have a cardiac lesion), or congenital structural problems in other body systems such as intestines or kidneys.
- 4.5 CHD is found in about 6-8 individuals per 1,000 live births in the UK, of whom about half will require treatment of some kind in the first year of life. Eight common conditions

make up 80% of congenital heart lesions. The approximate incidence in live births is as follows:

	4 . 4 . 40
Atrial Septal Defect	1 in 1548
Ventriouler Centel Defect	1 : 522
Ventricular Septal Delect	1 in 552
Coarctation of the Aorta	1 in 2323
Confetation of the Atorta	1 III 2525
Patent Ductus Arteriosus	1 in 1340
Aortic Stenosis	1 in 2787
Pulmonary Stenosis	1 in 1620
I unionary Stenosis	1 III 1020
Fallot's Tetralogy	1 in 1834
6,	
Transposition of Great Arteries	1 in 3319
*	

Adapted from: Keith, Row and Vlad, *Chapter 1: Prevalence, Incidence and Epidemiology. (Table 103, pp 4 – 6).* In: *Heart Disease in Infancy and Childhood,* 3rd edition, Macmillan, 1978.

This excludes common but usually trivial conditions in the population such as bicuspid aortic valves and mitral valve prolapse. Untreated, congenital heart disease would result in death in the first month of life in about a quarter of cases and in up to 60% in the first year. Only 10-15% of those with important structural abnormalities would reach adult life without medical intervention.

4.6 The surgical correction of congenital heart defects always carries a degree of risk, but can improve both the length and quality of life. Some procedures cannot be undertaken until the child is older, and these may require an interim or holding procedure to be undertaken at a younger age, with further corrective surgery being done at a later stage (10). The RBH would have expected to treat around 400 babies a year, and Harefield Hospital would have expected to treat 150-200 babies a year during the period under review, the majority of whom required surgery.

The 'journey' of the child with congenital heart disease

4.7 The existence of a heart problem will be diagnosed – or suspected – either by foetal screening or as a result of symptoms in the baby or older child. The paediatrician or GP may be alerted to possible problems by such signs as a heart murmur, cyanosis (bluish coloration of the skin or lips), abnormal heart action, heart sounds or pulses or failure to thrive. The baby or child is then referred to a paediatric cardiologist. Depending on the degree of urgency, the child will be seen either as an emergency or at a booked

appointment. The RBH operates peripheral clinics across its catchment area, so the consultation may be at a general hospital within reasonable reach of the family's home.

- 4.8 At that consultation the child is assessed. There will probably be a range of investigations, initially of a non-invasive nature (chest x-ray, electrocardiography, echocardiography, saturation monitoring and possibly blood tests). Some children will need further investigation or assessment and possibly invasive procedures (such as cardiac catheterisation) as an inpatient before a complete diagnosis is made. The initial treatment strategy will be discussed with, and explained to, the parents. Some children will need emergency treatment, while others will require urgent treatment within a few days or weeks. Sometimes a delay may be appropriate either for further observation or because the child is too young, or not well enough, to tolerate early intervention. Some patients will have less severe abnormalities, which may not require treatment initially. The cardiologist should ensure that the parents clearly understand the reasons for and the risks and benefits of the proposed management plan.
- 4.9 Where surgical treatment needs to be considered, the child is referred to a paediatric cardiac surgeon. The parents and the child, if old enough to understand, need sensitive and careful preparation for a procedure which may be both life-saving and life-threatening. The child is admitted for surgery and, after the operation, is usually transferred initially to the PICU and then to the paediatric ward. Follow-up action takes the form either of consultations at intervals or, where the child has died, bereavement support. Responsibility for follow-up action and monitoring usually reverts to the paediatric cardiologist.
- 4.10 The specialist team treating a child will normally comprise the paediatric cardiologist, paediatric cardiac surgeon, anaesthetist, intensivist, nursing and technical staff, and other support staff such as social workers and psychologists. They need to work in close collaboration, meeting to discuss any significant changes in the child's condition or treatment.
- 4.11 If the child has died during or following heart treatment, the way in which bereavement is handled can make an enormous difference to the family's recovery from the trauma of their loss. The need for a hospital or coroner's post mortem has to be dealt with sensitively and, as has been underlined in recent publicity surrounding Bristol and Liverpool, poor

handling of the retention of organs can re-awaken acutely a family's grief. This highly emotive issue was not within our terms of reference, but we refer to it briefly in Chapter 10. There should be a mortality meeting where the clinical team reviews the clinical and other circumstances surrounding the child's death, not least to ensure that lessons are learned, where appropriate, for the benefit of future patients and shared with the child's parents and other clinicians in the same specialty. In Chapter 25 we consider the wider question of clinical audit which, together with clinical governance, provides the mechanism and opportunity for sharing information on a common basis for improving standards.

Issues and practice in clinical management

- 4.12 Parts Two to Four of our report show that issues of concern can arise at each stage of the child's 'journey' through referral, assessment, diagnosis, treatment, peri-operative care and follow up. Not only are there issues of adequacy of care, but there are also issues about the approach to care. Management of heart disease must, like other life-limiting conditions, follow a holistic approach. This means involving not just the child and his or her parents, but any siblings or other close family members. It calls for clinical and communication skills of a high order. The time needed for developing trust and confidence with the family makes heavy demands on the time of the cardiologist in a specialty where skilled and experienced staff are in short supply.
- 4.13 So far as the family is concerned, communication skills are particularly important in respect of consent to treatment, which are examined in Chapters 8 and 15. There may be more than one treatment option, the risks and benefits of each of which need to be considered by the clinical team and with the family. The paternalistic approach that 'the doctor knows best' should no longer have a place in the relationship between doctor and patient or parents. Enough time at the consultation, and follow-up support, need to be given to ensure that the parents have a full understanding and are informed partners in the decision on how to proceed.

Developments in diagnosis and management

4.14 The field of paediatric surgery has developed rapidly over the past 20 years and children who would have inevitably died at the beginning of this period are now able to benefit from innovative surgery or catheter intervention. Operations involve detailed procedures and, in many cases, for ease of reference they tend to be called after the surgeon who pioneered it, as a shorthand label (for example, the 'Senning'). Operations may be essentially corrective as in closure of a hole or in 'switching' the great arteries in transposition, or they may be palliative in that they do not return the anatomy to normal but counteract either fully or partly the adverse blood flow pattern. Even in the so called 'corrective' procedures later complications of the disease or of the surgical procedure may occur.

- 4.15 The first surgery for congenital heart disease for ligation of patent ductus arteriosus (PDA) was undertaken in 1938. Open heart surgery using the heart-lung bypass machine to pump blood around the body began in the early 1950s, with the first atrial septal defect (ASD) repair, with bypass, in 1953. Throughout the period covered by our Inquiry the development and refinement of diagnostic, surgical and non-invasive techniques has been remarkable, and it is still continuing. Success rates have also been improving. For example, the survival rate for surgery in infancy for CAVSD, where a child has almost no septum dividing the two sides of the heart, was 53% in 1985 and can now be as high as 95%.
- 4.16 The age at which operations are undertaken has fallen for many conditions. А consequence of this is that intensive care facilities and expertise for young infants have had to be developed separately from those for adults. That is because the surgery, equipment, skills and clinical context are quite different. The surgical approach to some conditions has also changed completely since the mid 1980s. For example, the approach to transposition of the great arteries has changed markedly. Children born with transposition of the great arteries have an aorta which connects to the right ventricle (normal connection is to the left ventricle) and the pulmonary artery connects to the left ventricle (normal connection is to the right ventricle). As a result blue blood circulates round the body and very little of the blue blood would get to the lungs to be re-oxygenated. In the 1980s, the standard technique was to perform an operation on the atria, either a Senning or Mustard operation, to redirect the pink and blue blood and thus counteract the adverse effects of the abnormality. Today it is corrected by the arterial switch operation in which the abnormally placed great arteries (the aorta and the pulmonary artery) are cut and repositioned so that they now connect to the correct pumping chambers of the heart (the ventricles).

- 4.17 Surgeons and others caring for these children have not only to keep their existing skills well practised but also to learn, and in many cases pioneer, new skills and techniques. For example, over the last ten years treatment for hypoplastic left heart syndrome has been revolutionised, moving from no treatment or medical supportive measures to the use of the Norwood surgical procedure, involving a series of palliative measures which offers, albeit with a high risk of death in the early stages, the prospect of survival through childhood for successful cases. Progress has been such that there is virtually no condition for which there is not a surgical option, although some approaches are palliative rather than curative and death rates following surgery for some abnormalities remain high.
- 4.18 Cardiac catheterisation is a diagnostic procedure allowing a fine, flexible, hollow tube to be inserted into a vein and/or artery and passed through the vein or artery into the heart. It enables cardiologists to obtain detailed information on cardiac anatomy and function as well as to study blood flow patterns. Over recent years it has become a much more exact diagnostic tool than it was in the early 1980s. Since 1985 there have also been many improvements in less invasive diagnostic technologies, including echocardiography, colour flow Doppler, MRI and Helical CT, so diagnostic catheterisation is used much less often now.
- 4.19 More recently, cardiac catheterisation has also become a means for treatment in an increasing number of conditions, such as atrial septal defect, patent ductus arteriosus, aortic valve stenosis and pulmonary valve stenosis. Interventional catheter procedures have been accompanied by improved technology of catheters, sheaths, balloons, stents and other devices. They often allow much shorter stays in hospital, with little or no need for post-operative intensive care. The immediate results and longer-term outcomes of new techniques must be carefully monitored. The BPCA has published guidelines for interventional cardiology with the objective of ensuring high standards of practice (11).

Organisation of paediatric cardiac care

4.20 The provision of care for infants and children with congenital heart disease is complex and multidisciplinary, extending from before birth through adolescence and adulthood. Some of the children also have associated or unrelated abnormalities or complications, and others may need access to other specialities, such as obstetric and neonatal services, vascular or neurological surgery, and other paediatric sub-specialities – particularly renal and

neurology - during the course of their treatment. Links with adult cardiology are particularly important not only for the ongoing management of grown-up congenital heart disease patients but also for exchange of scientific knowledge, and sharing of improvements in management, notably but by no means exclusively in areas such as electrophysiology, pacing and drug treatment. Genetic, foetal medicine, radiology and other imaging disciplines are also worthy of special mention. Many other professional groups also play a crucial role, including specialist nurses (paediatric, paediatric cardiac and general intensive care, liaison nursing) and perfusionists (10) (who deal with cardiopulmonary bypass machines). Children with heart abnormalities and severe illness also need the expertise and training of staff in the professions allied to medicine. The full range of paediatric disciplines needs to be within easy and immediate access, not only for diagnosis but also for multi-disciplinary consultation. This is particularly important where heart transplants are undertaken. Support and expertise in helping families through what is invariably a highly stressful time, particularly if the child dies, need to be viewed as an integral part of a total service. A centre providing care for infants and children with cardiac problems is therefore involved in a highly complex and rapidly evolving area of medicine and needs to provide ready access to specialist skills from a wide range of disciplines.

NATIONAL CONTEXT

- 4.21 The RBH was one of the 'supra regional' centres designated in 1984 (under a system introduced in 1983) for surgery of congenital heart defects for neonates and children under one year of age. A joint working party, established between civil servants at the DoH and representatives of the medical profession, devised the system and funding protection followed in 1985-1986. A Supra Regional Services Advisory Group (SRSAG), comprising representatives from the Department of Health, the medical profession and the NHS, was responsible for overseeing the designation and operation of this and other very specialised clinical services that had previously been unable to secure adequate recognition and funding. The Group worked closely with the relevant Medical Royal Colleges, Societies and Associations. When it came to considering which centres should be designated, the advice of the relevant Medical Royal College was sought.
- 4.22 In England and Wales, nine centres were initially considered appropriate for approval and designation under the supra regional system. In the 1990s the following cities in the UK

provided the service: Belfast, Birmingham, Bristol, Cardiff, Edinburgh, Glasgow, Leeds, Leicester, Liverpool, London (Great Ormond Street, Guy's Hospital, the RBH and Harefield), Manchester, Newcastle, Oxford, and Southampton.

- 4.23 With the introduction of the NHS internal market in the early 1990s, central funding of the services came to an end. As most patients would come from outside the immediate area covered by the local health authority, treatment for these patients had to be funded, as an extra-contractual referral (ECR), or under a contract arrangement by the purchaser health authority for the area where the patient lived. In March 1999 that system came to an end, and centres are once again responsible for financing the services from core funding and what they can secure from service agreements. Further rationalisation has resulted in the two Scottish centres being combined for surgical provision. Proposals have recently been agreed for the RBH and Harefield to combine. Cardiff has recently stopped offering surgery and Manchester does not perform paediatric cardiac surgery. Most centres now operate a retrieval service for sick newborn babies whereby the baby is collected from the referring hospital by members of the cardiac or paediatric intensive care team rather than brought to the tertiary centre by staff from the local hospital.
- 4.24 As we discuss further in Chapter 12, the history of recognition and funding for Harefield Hospital differed from that at the RBH. Hillingdon Health Authority, which managed the Hospital, applied for recognition and funding for neonatal and infant cardiac surgery in 1986. The SRSAG (which has been succeeded by the National Specialist Commissioning Advisory Group) was unwilling to designate a fourth centre in London (the others were the RBH, Great Ormond Street and Guy's Hospital), but agreed to encourage a joint programme between the RBH and Harefield. Additional funding for the latter was therefore included in the RBH allocation for 1987-1988. Subsequently, both centres came to be recognised in their own right. Harefield Hospital had been separately designated and funded centrally as a heart transplant centre in 1986-1987 although, from 1997-1998, heart transplant services have been funded by health authorities from a separately identified allocation.
- 4.25 As a specialist service, the Trust has, in collaboration with the Imperial College School of Medicine, an extensive research programme in congenital heart disease, closely integrated with clinical practice. In 1977 the UK and Ireland Society of Cardiothoracic Surgeons introduced a system of annual reporting in order to promote learning, performance and best

practice in and between the various centres, but there has been some criticism of the register in that outcomes are reported retrospectively and are not validated. It is expected to be improved this year with the establishment of a register for all interventions of congenital heart disease, whether surgical or by interventional catheter (see Chapter 25 on clinical audit). So far these central registers of outcome have been concerned only with early mortality (occurring in the admission during which the surgery took place, or within 30 days of the intervention). Later mortality, and other adverse outcomes such as neurological impairment, which we consider in Chapter 21, are not reported.

4.26 The Panel noted that the BPCA, in written evidence to the BRI Inquiry (12), has expressed concern that there is at present '*a vacuum in relation to the enforcement of standards*' across the disciplines involved in paediatric cardiac care. While the BPCA and other professional bodies play an important role in promoting good practice and professional development, we share their view that NHS management has a responsibility for encouraging and ensuring the highest possible standards of care.

CONCLUSIONS

4.27 We have briefly described the nature and organisation of services for treating children with congenital heart disease, and the staff and other resources needed to support these services. As more of these children with congenital heart disease are able to survive, greater demands are placed on services by the increasing numbers requiring re-operations and long-term specialised care following early successful surgery or catheter interventions. This need for specialist care continues into the adult age group. Increased public and professional expectations of success also place extra demands on staff. If these expectations are not recognised and managed, the confidence of staff and families will suffer.

Part Two

ISSUES AT THE ROYAL BROMPTON HOSPITAL

5. SERVICES AT THE ROYAL BROMPTON HOSPITAL

INTRODUCTION

- 5.1 Until it became an NHS Trust in 1994, the RBH was a Special Health Authority. This meant that it obtained all of its funding direct from the DoH and, unlike other health authorities, was not subject to direction or oversight by the Regional Health Authority. Then, in 1998, the RBH and Harefield Hospital were brought under common management with the formation of the Royal Brompton and Harefield NHS Trust (see Appendix 5).
- 5.2 Together the two hospitals form one of the largest centres in the UK for specialist heart and lung services for adults and children. There are some 27,000 inpatient and day cases and almost 80,000 outpatient attendances at the RBH each year. In 1999, the number of paediatric cardiac procedures was as follows:

•	Inpatient surgery including operations to the heart and chest	350 operations
•	Day case and inpatient investigations to the heart	1,354 admissions
•	Outpatient heart services	5,116 attendances

- 5.3 Clinical directorates were introduced at the RBH in 1990. Until last year paediatric services were managed jointly with another directorate. Since mid 2000 an associate director has been appointed, and paediatrics now has its own directorate manager.
- 5.4 Children are cared for and treated at both RBH and Harefield Hospital for broadly the same range of heart and lung conditions. The only major differences are that transplant services are carried out at Harefield, and the treatment of respiratory diseases particularly cystic fibrosis is a specialist service offered at the RBH.

DEVELOPMENT OF PAEDIATRIC CARDIAC SERVICES

5.5 The contribution of the RBH to the development of clinical services for children with congenital heart disease is internationally recognised as outstanding. We document the key service developments over the last 30 years in Appendix 6.

- 5.6 The growth in the number of specialist paediatric staff has, with the exception of short periods for consolidation, been a continuous process. The Trust attributes this growth to changes in clinical practice, changing patient and family expectations of the service, and developments in professional standards. Alongside this, a conscious decision was made by clinical and managerial staff to invest in, and nurture, the paediatric service over the past six years. Consequently the service now operates with a lot more doctors' time available for patient care than was the case at the beginning of the period under review, when two cardiologists covered all the paediatric cardiology work of the service, working unacceptably long hours.
- 5.7 The RBH has pioneered the development of non-surgical treatments for children's heart problems, and one of the most significant clinical service advances has been in the use of closure devices, inserted by catheter, as an alternative to surgery. This development was pioneered in the early 1990s. Although not suitable for all congenital lesions, it has shown enormous benefits. Not only has it achieved successful outcomes, but it has also reduced the length of hospital stays and has avoided the need for children to undergo surgery and intensive care.
- 5.8 The RBH also plays a leading role nationally in post-graduate training and research. Its academic contribution has, for example, included risk stratification work on identifying patients at risk of arrhythmia or sudden death. This work has been adopted internationally, as has right ventricular function assessment through non-invasive imaging.
- 5.9 Another key feature of the clinical service is the development of peripheral clinics, which were pioneered by the RBH in the late 1970s. The cardiologists run clinics jointly with consultants at local District General Hospitals (DGH), bringing specialist knowledge and expertise much closer to where patients live. They operate at 43 hospitals, with a total of 434 clinics per annum and account for over half the outpatient workload by the RBH consultants.
- 5.10 Other specialist centres have since emulated the model so that a peripheral clinic system is an integral part of the service at most major centres. Indeed, some of the DGHs have clinics serviced by more than one centre. Recently the service has been expanded to cover foetal cardiology and adult congenital heart disease. We comment further on peripheral clinics in Chapter 7.

FUTURE LOCATION OF SERVICES

- 5.11 In September 1999, the Kensington & Chelsea and Westminster Health Authority (KCWHA) issued a Public Consultation Document on the future of children's heart and lung services at the RBH and Harefield Hospital (13). It stated that the current service at the Trust needed to change to ensure that it served its patients well in the future. According to the Consultation Document, research shows that hospitals with a larger PICU and specially trained staff give children a better chance of survival. Such units should have at least eight staffed beds, and treat a minimum of 250 patients a year. Larger specialist units also ensure more effective out-of-hours cover, with no gaps between consultant level and junior doctors.
- 5.12 Although the establishment of the Grown-Up Congenital Heart (GUCH) clinic at the RBH had improved services for older children, the Trust believes that for children who need care beyond the age of 15, an advantage of providing services for adults and children on the same site is that the hospital and its staff would be familiar to them. The Consultation Document proposed that, of six possible options for the future provision of services, the option which involved transferring all such services from Harefield Hospital and concentrating them at the RBH was the best. Among the criteria considered as essential were sufficient size to attract and maintain specialist staff with the required skill and competence; an adequate caseload for intensive care; ready access to other relevant services; and a research and teaching environment. The need for adequate physical facilities, affording dignity and privacy for children and their families, and overnight accommodation for relatives along with accessibility by public transport, and car parking on site, were also highlighted.
- 5.13 Although the consultation period officially ended in January 2000, the KCWHA made it clear that no final decisions would be taken until the outcome of our Inquiries was known. At that stage they expected this report much earlier than proved possible. In particular, they wished to consider our assessment of the concerns expressed by individual families. In an interim report, we provided a list of the key issues that we expected to feature in our published report (see Appendix 7). We stressed our hope that re-location would not compromise existing staffing levels and service standards, especially in respect of services provided at Harefield. We were pleased to note that the KCWHA took into account our interim report in planning future service development and preparing an implementation

plan. In the event, the proposed move was the subject of a formal referral by Hillingdon Community Health Council to the Secretary of State, which was refused in November 2000. Detailed planning for the move proceeded in the meantime. Our recommendations in respect of the proposed merger are included in Chapter 11.

5.14 In July 2000 the KCWHA, acting on behalf of the four health authorities in West London, issued a further consultation document about options and proposals for *Modernising Specialist Acute Hospital Services in West London* (14). It referred to advice from the relevant professional bodies that: 'specialist [children's] services should be located with general inpatient children's services, on a site also providing both adult and accident and emergency services'. St Mary's Hospital was identified as the 'optimal location' for a specialist children's centre. The document also concluded that heart and lung services for both adults and children would be best served by co-locating them in a new heart and lung hospital in the Paddington Basin, closely linked to the specialist centre in St Mary's. Undertakings given in respect of the merger of the RBH and Harefield Hospital, regarding help with car parking and family accommodation, would be honoured in the further changes now proposed. Completion of the new hospital is expected in 2006.

6. THE ISSUES

INTRODUCTION

- 6.1 We outlined in Chapter 2 the procedures that we followed in order to learn about the experiences and concerns of the families covered by our terms of reference. From the hearings with the families, and the evidence of the questionnaires which they completed for us beforehand, we identified a number of generalisable issues to put to the clinical and other staff concerned. We should emphasise that the number of RBH cases considered by the Panel was less than 1% of the total number of children treated at the hospital over the period 1987-1999. It is also important to note that most of the children attending in the 1990s were treated in the new hospital in Sydney Street. Fourteen of the RBH cases considered by us involved children with heart problems who also had Down's Syndrome. We discuss these separately in Chapter 29 as the parents' concerns were primarily about whether or not there had been discrimination in the treatment provided. The other 28 RBH cases seen by the Panel cannot be regarded as representative since, as we described in paragraph 2.11, most of them related to children who had poor outcomes from surgery. Six suffered neurological impairment, and 20 of the children died.
- 6.2 As far as we are aware, parents of children who were successfully operated on at the RBH did not choose to contact the hospital following publicity about the establishment of the Hunter Review either because they were unaware of the existence of the Review or because they were satisfied with the treatment their child received. We did receive, however, one letter early on from parents whose child had Down's Syndrome praising the treatment and care their child had received at the RBH. We also heard oral evidence of generally high levels of parent satisfaction from the Chairman of the Down's Heart Group and the Chairman of Heartline.
- 6.3 Nonetheless the cases have provided informative and useful insights into the provision of paediatric cardiac services at the RBH. The majority of issues complained of by parents were consistent with each other and therefore generalisable. By setting up our Inquiry, the Trust itself recognised that the hospital had experienced problems in communicating with some families and in meeting parental expectations and that this warranted further scrutiny.

CHANGES IN PARENTAL EXPECTATIONS

- 6.4 It is clear from the evidence heard by the Panel that there has been a major shift in the expectations and entitlements of patients and parents over the last decade in their requirement for fuller information and involvement in decision making. What may have been regarded as acceptable in the early days of paediatric cardiac surgery in the 1970s is no longer so regarded. Parents want more information, better communication and more time with consultant surgeons when making difficult decisions, for example when consenting to major open heart surgery. As the BRI Inquiry has pointed out (15) ... 'the model of public involvement which has predominated in recent years is that of people as customers or consumers whose role is defined in terms of their economic relationship to the service i.e. they are receivers rather than producers of care. The language of consumerism has pervaded the health service since the late 1980s and has been seen as an advance in replacing more patronising assumptions about the passivity and dependence of *patients*'. Yet both the imbalance of power between patients and doctors, and patients' need to believe in the competence of their doctor in such technically complex areas as children's heart surgery, make it exceptionally difficult for patients to communicate on equal terms with clinicians.
- 6.5 If we add to this the fact that parents are making decisions for their children in what for many is one of the most harrowing experiences of their life, it is not surprising that problems arise. The social consequences of treatment in hospital can be profound; published research demonstrates that the discovery of a heart disorder in a child is more emotionally destructive for the parents than the diagnosis of any other disability and is associated with a high rate of marital breakdown. Researchers have found that: 'Women whose children have congenital heart disease, cerebral palsy, are blind or had a low birth weight appear to have higher risks of marital disruption than mothers of healthy children' (16) and that: '.... in comparison with parents of infants with cystic fibrosis, and parents of healthy infants, parents with infants with congenital heart disease generally reported the highest levels of stress' (17).
- 6.6 Most of clinicians interviewed by the Panel were sympathetic to the needs of the families and indicated that they would have been happy to spend more time with parents giving more information and responding to their concerns. However, they cited the difficulties of

fitting yet more commitments in to an already pressurised timetable, especially when children were admitted as an emergency needing urgent life-saving treatment.

- 6.7 We recognise that parents' need for more information is making ever-greater demands on consultants' workloads and that a judgement needs to be made in balancing the expectations of parents against the resources available. However, we regard the investment of sufficient consultant time with parents, supported when appropriate by other members of the clinical team, as an essential component of any service where parents are expected to make life or death decisions for their children, often in situations where they are having to absorb rapidly unfamiliar and technically complex information. We return to this issue in respect of parents' ability to assess risk in Chapter 8.
- 6.8 The majority of clinicians we interviewed acknowledged that the issues we raised reflected parents' concerns and resulted from rising patient expectations, coupled with rapid advances in technology and surgical experience that lead to improved but not guaranteed results. As one doctor noted: 'If you had fallen asleep as a paediatric cardiologist ten years ago, you would not believe the difference in practice now in terms of what we do; the new procedures; very short hospital stays; many, many day case procedures; people having major heart surgery and being discharged on the 5th-6th day.... treatments have improved; anaesthetics have improved mortality has got lower, morbidity is lower for surgical procedures and so in a way it has been a success story'. Similarly, a parent commented that: 'We live in a time when you almost take it that.....people aren't going to make mistakes, and it is going to be all right because people do fantastic marvellous surgery....and it's no guarantee that the simple things are going to be faultless'.
- 6.9 However, for those parents whose child died or was adversely affected by surgery, it was no consolation to know that the vast majority of children having surgery would have a good outcome without ongoing complications. As one clinician pointed out: *One is always aware that families whose child has died or has suffered major complications will always have great difficulty coming to terms with the death or with the complication'.*

CHANGES IN PAEDIATRIC SERVICES

6.10 In the early days of paediatric cardiac services, the emphasis was naturally geared to care and outcome for the child. By the 1980s, the profession had become increasingly aware of

the importance of partnership and the involvement of families. Medical students were taught at this time that 80% of paediatrics was about dealing with families and not just the child. Paediatricians have led the way in recognising the need to communicate with parents but, if done well, this is very time consuming and requires skills that not all members of the clinical team may possess.

- 6.11 The majority of paediatric cardiac centres, including the RBH, have struggled to keep up with the increase in demand over the period reviewed by the Panel. Famously the difficulties experienced by the Birmingham Children's Hospital in 1987, where children died whilst waiting for admission to hospital, is widely seen as the genesis for Mrs Thatcher's NHS Reorganisation in 1988.
- 6.12 Although the introduction of supra regional funding for neonatal and infant cardiac surgery in 1986 eased some of the pressure, evidence given to the BRI Inquiry has showed that most centres experienced difficulty in accessing funds to appoint consultant grade and other support staff in the numbers required to offer a comprehensive service to families. In addition, difficulties occurred throughout the period under review in recruiting and retaining sufficient trained staff, especially intensive care trained nurses, which led to the frequent cancellation of operations, distressing parents and demoralising staff. As we explain in Chapter 11 on resources, factors such as these consistently undermined efforts to create more family-orientated services at all paediatric cardiac centres.
- 6.13 A number of clinicians pointed out that if any of the paediatric cardiac centres were held under the microscope and scrutinised in the same level of detail as the RBH over the last 13 years, it is highly likely that the same generalisable concerns would have surfaced, as they reflect the dilemma of providing child-centred services within the context of operating a high-risk, technically demanding service with the many uncertainties involved. As one doctor said: '*Many of the things that you have covered are common to many units around the country, or have at least been common to many units in the country*'. Doctors felt they were caught in the trap of trying to respond to parents' expectations whilst at the same time having to respond to managerial exhortations to be more efficient in their use of resources. One doctor told us: '*of necessity all doctors tend to sail a bit close to the wind because in order to keep waiting lists to a reasonable level you have to practise in what is deemed to be a very efficient way to be efficient and to reduce costs and do more has been the*

message which has come from the managers to all doctors continuously for the last ten or 15 years'. This imperative does not sit well with responding to the needs of parents.

- 6.14 Nevertheless it appears that the RBH may have been slower to recognise and respond to needs and implement change than other centres. This view was expressed by one surgeon who said that: *'there was not enough time to focus on paediatric practice.... I had this feeling that other units were appointing staff and we were not, cardiologists and intensivists in particular. The ratio of staff to patients was increased elsewhere and I didn't see that happening in our unit'.*
- 6.15 As we have outlined in Chapter 11, the RBH paediatric cardiac centre was required to cope with only one full-time surgeon and cardiologist right up until 1987, when an additional surgeon and cardiologist were appointed to double the input of clinical resources at senior level. A third cardiologist was recruited in 1991 to coincide with the move to the new hospital but the unit had to wait until 1997 before it was able to recruit its first intensivist, against an assessment that three posts at this level were required to provide an acceptable level of service and reduce the on-call commitments of existing clinical staff. A second intensivist was appointed in 1999. In 1991 improvements were also made in the range and type of facilities made available to parents and provision was made for children's educational needs, but this still was not regarded as sufficient and further improvements are planned in 2001 as set out in Chapters 5 and 11.

THE SINGULARITY OF THE RBH

- 6.16 In comparing practice at the RBH to that of other paediatric cardiac centres, three issues stand out. The first is that the RBH is a specialist hospital concentrating only on heart and lung diseases and does not have instant access to advice from other paediatric specialities when required.
- 6.17 The second issue, to which we shall return later in this report, is whether the right balance was struck in terms of the allocation of resources between the needs of adult and paediatric services and cardiac and thoracic services. RBH is not a children's hospital. As one doctor said: '*The Brompton has always been labelled with being a children's unit in an adult hospital There was always the debate as to which was the best model and the benefits of that model*'. A similar comment was made by a nurse: '*The Brompton is not and*

never has been a children's hospital. The Brompton has continued to improve its paediatric service in the mid 80s it was a very good cardiac centre but it was not a centre of excellence for paediatric nursing. Many of the services we had were tailored from adult services and were not suited or geared to children, and that is the key root of the problem'.

6.18 The third issue is that, as a postgraduate research centre, the RBH has a strong academic research base, which may occasionally exert too strong a bias. A number of clinicians expressed the view that the RBH was slower than many other paediatric cardiac centres to introduce family support services, and that this was strongly bound up with the fact that a very high premium was placed on research and academic excellence.

7. DIAGNOSIS

INTRODUCTION

- 7.1 Diagnosis is the stage at which parents first come into contact with the hospital. In many cases, diagnosis of congenital heart disease is made within a day or two of birth. Sometimes the baby needs urgent treatment, for example, to have a shunt inserted as a palliative measure within hours of diagnosis by echocardiography. This means that while the mother is still recovering from the experience of giving birth, the parents are faced with having to come to terms with the knowledge that their baby has a major life-threatening heart defect and will require complex surgery. They have to contemplate the possibility that they may lose their precious new baby in the first weeks or months of life precisely at the moment when they are trying to bond as a family. It is therefore not surprising that many find it extremely difficult to take in and understand the diagnosis.
- 7.2 Acceptance of the reality and implications of a diagnosis of congenital heart disease is no less difficult or traumatic if it is made when the child is older. By then the family unit will have become well established, with the child progressing through education and perhaps leading an active life. Often the child will have experienced increasing breathlessness or discomfort, which the parents may attribute to tiredness. A visit is perhaps made to the GP, who tells them that a referral to a cardiologist is advisable. Within a relatively short period a child who was leading a normal and apparently healthy life is faced with a diagnosis of a life-threatening condition. That is devastating not just for the parents but for the child, who has probably reached the age of understanding and is very frightened.

CONCERNS EXPRESSED BY PARENTS

7.3 Some parents described to us the anxiety and stress they experienced in having a very sick child who remained undiagnosed for weeks or months before a heart murmur was detected by their GP and/or local paediatrician, requiring further investigation at a heart centre. One young mother endured weeks of *'hell'* as she struggled to feed her baby, with the health professionals refusing to take her concerns seriously although it was clear that her baby was failing to thrive: *'I just feel that it has been a battle all the way. I was only 17 my*

husband was 19 at the time and we were just judged because of our age. We have had to fight, fight, fight'. After eight weeks the child was referred to the RBH and diagnosed as having total anomalous pulmonary venous drainage and surgery was performed. The child did not make a full recovery and after six further months of investigations at the RBH the parents were advised in 1986 that: 'nothing was wrong. I was heartbroken....He said "the only problem that [your child] has is her parents. Take her home, get on with your lives. There is nothing wrong with your child". I was absolutely furious to be quite honest with you. I was so angry. I thought, how dare you. I will never, ever forget as long as I live what that man said to me, the way he said it, as if we were some sort of neurotic parents that enjoyed going to hospitals'. Five years later when diagnostic equipment had improved, their child was diagnosed as having a mixed form of total anomalous venous drainage, a comparatively rare condition, which required major surgery

- 7.4 Parents find it equally difficult to understand and come to terms with the complex nature of congenital heart disease in an older child. A family with an apparently healthy 12 year old who regularly played football and cricket were deeply shocked to be told at a regular follow-up check that their son needed surgery as his condition was life threatening saying: 'You don't think at the time really, everything is being bombarded at you. Nothing in my life prepared me that [my child] would have to go and have surgery'.
- 7.5 One parent was unhappy at the way in which she had been given information on her teenage daughter's diagnosis and treatment options. Very little information was given to her or her daughter at the initial diagnostic appointment although she subsequently learnt that her daughter was seriously ill and needed a heart and lung transplant. The parent accepted that doctors may have found it difficult to speak freely in front of her 15-year-old daughter, but she felt very unsupported in terms of how to manage the immediate situation saying: '*I felt it was obfuscation at every stage*'. Many weeks later, at a meeting held with the consultant to discuss the unexpected death of her daughter, she was surprised when one of the two doctors present said: '*I didn't realise you wanted to know the minutiae of your daughter's case*'.
- 7.6 A large number of parents told the Panel that the nature of their child's diagnosis and proposed course of treatment had not been explained adequately or in terms that they could readily understand. In one case the parents said they had been told to buy a book to read about their child's condition. One parent said: '*We had been told a few hours before*

"Your child has a heart defect" It is like somebody saying, "You have cancer" So we pulled up outside the hospital. The doctors were waiting for us. There were people waiting for us as we have gone in – test, test, test. We just did not have a clue. Somebody should have come and said to us: "Look, this is going to be your son's surgeon" or "To the best of our knowledge or ability, this is going to be what is going to happen". It did not happen like that every time we tried to ask somebody, the only people that were any good to us were the nursing staff, and they were absolutely superb. At the end of the day, these people have a job to do and I appreciate that. But why did [the surgeon] not come and see us?'. Another parent said: 'He had an echocardiogram carried out by Doctor X, with several students present, all of us crammed in to a small, hot and stuffy room, just off a corridor lined with families and children, all looking worried – After Dr X had explained to students (and indirectly to us) what he was seeing and the interpretation of his observations, we were told: "Your son has a heart condition known as Tetralogy of Fallot and he will die before he is two unless he has surgery". This was totally unsatisfactory and distressing. We had to ask a student what Tetralogy of Fallot was – he stood with us in the main corridor – no room with privacy, no seats, no support given or offered'.

- 7.7 Although we recognise that parents can be extremely traumatised by news of their child's diagnosis and may be unable to take in all that is being said, we were surprised that more than half of the parents whose child's cases were reviewed by the Panel felt that they had been given insufficient information about the nature of the risk associated with treatment as one parent said, with little reference to the possibility of brain damage or other organ failure. This made it all the more difficult for those six RBH families whose children suffered neurological damage, as we discuss in more detail in Chapter 21.
- 7.8 A number of parents indicated that they would have liked access to a hospital library or to be given internet references to pursue, as they wished to have access to more information on their child's condition, including details of innovative treatments being developed in the rest of the world. As one parent said: *'There were problems with pacemakers that we were never told about, I mean pacemakers generally. I have been looking this up, I have spent days on the net'.*
- 7.9 We have already stated that the self-selecting group of parents is not representative of those whose children have attended the RBH. Almost 71% of families seen by the Panel had experienced the death of their child at the RBH. Very few claimed to have really

understood that a 90% or 95% success rate quoted for a particular operation still meant that 1 in 10 or 1 in 20 children would not survive the procedure (a fuller discussion on risk is included in Chapter 8).

- 7.10 At several of our hearings with parents the question arose about whether they could have asked for a second opinion. Not all parents knew that they could have requested one and even those parents who were aware of this facility did not necessarily know how to proceed without resorting to paying for private treatment. As one parent commented: 'I think his words [the GP's] were that we could have a second opinion if we wanted to, but there wouldn't be much point because we are going to the world's leading heart hospital anyway. So they are only going to reiterate what has already been said to us...you are made to feel you are making a fuss'.
- 7.11 A newborn baby requiring urgent treatment will in many cases have to be transferred to the paediatric cardiac centre such as the RBH without the mother. That will invariably be the situation if she is still recovering from a caesarean section or difficult birth and is in need of specialist obstetric care. Unlike the RBH, some paediatric cardiac centres are sited within a large teaching hospital with a maternity unit. For mothers who were delivered in such a unit, the trauma of separation is not so acute. For many RBH mothers, however, mother and child may be apart for several days. As one parent, whose child died a few days later in the PICU, said to us: '[The hospital] took [my child] to the Brompton and I stayed there When you have just given birth and it's supposed to be a happy event, I really wasn't with it and don't remember a lot of it they used all these long words you don't know what they mean. It all goes above your head. You are just worrying about this tiny baby, if it is going to live or die'. Even in cases where the child is older, distance can be a significant problem. Many families travelled up to 100 miles to the RBH.
- 7.12 In an attempt to overcome problems of access, the RBH pioneered the establishment of peripheral clinics, as discussed in Chapter 5. Many of the parents whose child's case was reviewed by the Panel first attended a peripheral clinic. Whilst this model undoubtedly has many advantages in making services more accessible to patients, particularly at the vital diagnosis stage, it is difficult to staff adequately owing to its wide geographical spread.
- 7.13 Some of these peripheral clinics only took place once every two months but others were much more frequent. It appeared to us that the pattern of referral to paediatric cardiac

centres was fairly unplanned. This is not helped, indeed it is probably explained, by the random, and sometimes overlapping, distribution of peripheral clinics run by the various paediatric cardiac centres in the South East. Although parents welcomed the availability of peripheral clinics, when children need inpatient surgery parents are faced with having to travel long distances to the RBH to be with their child.

7.14 This, in turn, creates problems. We heard that some parents experienced difficulty in obtaining accommodation at the RBH which, in the old hospital, was in very short supply, and even in the current building accommodation is limited. Accommodation is discussed further in Chapter 11.

THE CLINICIANS' RESPONSE

- 7.15 Not surprisingly, the doctors viewed the situation very differently from the parents. They pointed out that the Panel was mainly looking at the casualties of the system over a period in which practice had continually evolved. The situation today with the exception of emergencies where there was no time to discuss treatment options and consequences at length was that parents were now positively encouraged to ask questions. However, as one doctor commented: 'If you are told your child has got congenital heart disease, that is probably one of the most awful moments of your life, it is a time when (parents) feel powerless, however powerful or intact they are as people, when it's their child and there are these decisions, it's a tough time, it's a horrible ordeal for families. There is something about the first outpatient appointment that, however much time is spent, however considerate, however many or few people there are in the interview, it's unsatisfactory'.
- 7.16 We asked the cardiologists what arrangements should be put in place to make the first consultation and diagnostic interview less traumatic and more informative for parents and to meet their need for timely and accurate information. All of them said that they did drawings for parents to explain the diagnosis and gave them copies of information sheets produced by the hospital. In some instances they supplied parents with a copy of *Heart Children A Practical Handbook for Parents* (9) produced by Heartline, a parents' organisation. We have seen examples from other centres of the range of material that can be given to parents. These include *Children with Heart Conditions A Guide for Parents* (18) published by the British Heart Foundation, and at Bristol, for example, a series of

leaflets about various aspects of paediatric cardiac care. Some cardiologists also showed parents the ultrasound scan to explain their baby's hole in the heart, as an effective way of reinforcing the diagnosis. One clinician said: 'If you are performing an ultrasound scan I will freeze the picture and say, "if you look here you can actually see this gap here, this hole in the wall, and that is a large hole, and that is what is causing your baby to be breathless and not feed very well, and she needs an operation to close that", and often that can be very dramatic, and you can show it quite clearly, and sometimes for some people that is satisfactory, but otherwise for more complicated things one might need to draw in a diagram'.

- 7.17 One of the doctors told the Panel that, as a result of his research interest in improving parents' understanding of their child's condition, he had instituted a research project in collaboration with a sociologist whereby, after the initial diagnosis, a pre-admission interview was held for parents to ask all the questions they wanted to in respect of the diagnosis, operation and what would happen in hospital. These sessions were normally held at the weekend when the hospital was not as busy and when more time and space was available than during a busy outpatient clinic. The pre-admission interviews were judged a great success but they came to an end when the funding for the research project was exhausted.
- 7.18 The doctors drew attention to their enormous workload, especially in the earlier part of the period under review before the appointment of a third cardiologist. One clinician pointed out: 'I normally do four or five outpatient clinics per week, and the average outpatients would have 20 or 25 patients, so particularly if I do an outreach clinic there would normally be about 25 patients. The time I spend tends to relate to what I perceive as the severity of the problem to start with within the constraints of a busy clinic'.
- 7.19 All the cardiologists interviewed by the Panel indicated that they were willing to meet families a second time to discuss the diagnosis and options for treatment. One cardiologist said: 'I do have one clinic at the Brompton which I run every week at which I just have six or seven patients who have got major heart problems and I can spend more time with, if I thought they need more time, and six or seven per week may sometimes not be enough, but I do try and sort of have a quiet clinic at which I deal with those sorts of problems'. However, he pointed out that this did have resource implications as it meant more cases
were having to be seen in his other weekly clinics in order to achieve Patient's Charter Standards on waiting times for outpatient appointments.

- 7.20 The doctors were proud of the fact that the RBH had led in the introduction of peripheral clinics. As one clinician said to us: 'It's much better if you can go out to the District General Hospital, work with paediatricians. It improves care in any case When we started, early diagnosis was crucial, because there weren't all the facilities, there weren't the drugs that we have now What you needed to do was to ensure that the possibility of congenital heart disease was recognised as early as possible by the paediatricians and then have the children referred in before they deteriorated It was essential for good clinical care'. However, the volume of work generated by peripheral clinics has placed additional workload pressure on the paediatric cardiologists. For example, in 1999, consultant cardiologists at the RBH attended peripheral clinics at 43 different district hospitals in an area ranging from Cambridge to Colchester and from Worthing to Milton Keynes. One doctor attended 63 peripheral clinics a year taking up at least one day a week of his contracted sessions, whilst others attended only one peripheral clinic every two weeks.
- 7.21 Doctors recognised that the cardiologists' policy of being open to new referrals added enormously to their workload, with one doctor saying: *Sometimes it's just the pressure if* you are seeing 24 children in the morning, you have to get a bit of a move on I have always adopted a policy that any family who want their child seen, that child is seen that week. So there is never an embargo in adding children to outpatients. You can't have it both ways. Either you see every child and there can't be the concern [about waiting times]. On the other hand, you have a Patient's Charter saying that nobody should wait longer than 20 minutes or half an hour there is a conflict between the two and I would rather the child was seen and the parents had to wait'.
- 7.22 The doctors also pointed out that the RBH had established what they described as one of the first 'walk-in' echocardiogram clinics. Children could come to the echo clinic at very short notice so no family had to wait more than a day or so for an appointment, and they would be seen by a consultant. The Panel felt that maintaining this was a considerable achievement.

- 7.23 One clinician said to us: 'It was probably the best referral diagnostic service anywhere. You would never wait more than 24 hours for an echocardiogram, for all parents, so they are not sitting at home waiting for the referral letter to get to the Brompton, the Brompton to send the appointment, three or four weeks by the time you get up there, sitting at home with quite often nothing wrong with their child's heart, but agonising and hand-wringing for the vast majority How do you square that with the casualties? I do not know. I think all you can do is try and avoid the casualties, and that was addressed three or four years ago'.
- 7.24 Doctors accepted that the space available for taking echocardiograms in the old hospital was very crowded. The situation was made worse because postgraduate students were often present making it very difficult for doctors to communicate with parents sensitively. As one clinician said: 'You would find somebody with a horrendous heart problem it was a very dynamic clinic, lots of things happening, and our visiting professors, visiting fellows, visiting students were all standing there, and it was like a gallery watching the echos, but then you would find yourself standing there saying, "I am terribly sorry, but Johnny has got this, this, and this", and you would have the assembled crowd behind you. There were not good facilities for going into another room, and there was such pressure on time, there was not much motivation, frankly, for going off to another part of the hospital, and so that felt awkward, sometimes it was not ideal. For some parents it just did not matter, but you could feel it for some parents having their grief sort of thrown out in front of sometimes ten people in the room'.
- 7.25 In 1991 when the move to the new hospital took place, doctors had the use of a much better echo suite where there was a small ante-room where parents could be given the bad news that their child had a serious heart condition. The Panel was told that in the mid 1990s: 'A nurse was appointed specifically for the echo clinic, which was very helpful, because she could take the parents away, sit them down, discuss the implications of what was being said. If there was a problem she would come back and say, "Mr and Mrs Jones did not understand a word of what you said, and they were so worried and upset", and if there was a question about admission or surgery she would quite often then take them around the ward or up to PICU'.
- 7.26 As for the right of parents to obtain a second opinion, the Panel was told by doctors that they regularly made such referrals, and were also used to seeing new patients referred from

elsewhere who were seeking second opinions. Doctors did not see this as a problem, although one or two acknowledged that it had been more difficult in the 1990s when the NHS 'internal market' was at its height.

CONCLUSIONS

- 7.27 The Panel heard from many parents that, despite the best efforts of staff, they were unhappy with the amount of information given to them about the diagnosis and treatment options for their child's heart condition. In part this reflects the fact that attitudes concerning the involvement of patients and their families in discussions on diagnosis and treatment have changed over the last decade. There is now much greater acceptance of the right of patients to participate fully in decision making, with an increasing number of parents using the internet to obtain the most up-to-date information on treatment options for their child's condition. It also reflects the growing desire of parents to try to maintain some form of control by searching out sources of information so that they could become more knowledgeable about their child's condition.
- 7.28 We have considered what back-up services could be put in place to give parents an opportunity, after the consultation ended, to raise further questions or obtain additional information on their child's diagnosis and the proposed course of treatment. The Panel acknowledged that access to the internet would not have been appropriate for the earlier part of the period under review when it was still in its infancy but agreed that this would be useful for families in future. Access to the hospital library and details of relevant websites would also be helpful. A number of doctors felt that it would be useful for the initial diagnostic interview to be taped so that parents could replay this at home. We are aware that similar approaches have been implemented in other areas of medicine with great success. The Panel notes the success of the pre-admission clinics and regrets that these had ceased with the end of research funding. We would urge the Trust to explore alternative sources of funding to reinstate this provision, which was highly valued by families as it provided an additional resource by which they could gain a fuller understanding of the treatment proposed, what is involved, and any associated risks. We commend the cardiologists for their current practice of inviting parents back for a second consultation, even though this puts added pressure on their clinics.

- 7.29 Some of the most distressing evidence came from parents who told us that they were advised that surgery would be inappropriate for their child. Some parents suffered considerable doubt and anxiety about whether the decision they made on the RBH clinician's advice was the right one, for example, when they have a child who is now dying from inoperable pulmonary vascular disease. Most involved children with Down's Syndrome whose parents asked the Panel to investigate whether there was any evidence of discrimination in the treatment given to their child at RBH. The issues related to children with Down's Syndrome and congenital heart disease are discussed further in Part Five of this report.
- 7.30 The Panel considered what course of action is open to parents whose children are not offered surgery or who are concerned about whether they made the right decision about a proposed course of treatment. NHS patients do have the right under the Patient's Charter to be referred for a second opinion to another clinician either at the RBH or at another paediatric cardiac centre. We have been told that the doctors regularly make such referrals, but this does not appear to have been the case at the RBH during the period covered by our Inquiry or parents were not aware of this facility in respect of those we heard from. This may be, at least in part, because for most of this period the operation of the NHS 'internal market' made it much more difficult for patients to obtain second opinions. Any such referrals made outside the contractual arrangements agreed for that particular locality are likely to have been particularly problematic. Funding of health care has now changed, but entitlement to a second opinion means little if those to whom it applies have no knowledge of it. It should be made explicit to parents that they have the right to a second opinion if they have concerns about what they are being told.
- 7.31 Regarding peripheral clinics pioneered by the RBH, we noted that this model undoubtedly has many advantages in making services more accessible to patients. For many parents, this has brought the initial consultation much closer to home, although it is also clear that in most cases parents were prepared to travel long distances to access specialist care and were delighted to be referred to such a renowned specialist heart centre. However, the fact that the concept has been adopted, in an apparently haphazard fashion, by a number of centres across the whole of the South East of England added considerably to the workload of the cardiologists.

- 7.32 We find it surprising that the three paediatric cardiac centres in London have not met to rationalise the network and staffing of peripheral clinics. It is clear that there is scope for reorganising the peripheral clinics to produce greater efficiency and value for money without compromising on quality. If each of the London centres took responsibility for a defined geographical area, that would reduce travel time and enhance co-operation and effective working with local paediatricians and GPs. There should also be discussions between the Trust and local NHS Trusts to ensure that equipment is provided to a uniformly high standard for all those referred to the specialist paediatric cardiac service.
- 7.33 We were pleased to note that the situation in the echo clinic had improved in the mid 1990s when a nurse was appointed specifically to support parents and discuss the implications of what they had heard. If there is a problem, the nurse is able to ask the consultant to return to respond to parents' questions. Quite often the echo clinic nurse will take parents up to see the ward and the PICU to give them a better idea of what is likely to be involved in agreeing to proceed with surgery. However, we also noted that the space problems had not been entirely resolved, with a constant tension between the needs of parents and the need to meet the RBH's requirements for teaching the next generation of consultants. One suggestion for resolving this dilemma was to establish a video link between the echo room and a separate teaching room to minimise the number of junior doctors and research fellows attending consultations. The Panel agreed that a video link could prove useful although it would not remove the need for supervising junior doctors and research fellows performing an echo, but this could be done on a one to one basis once a video link is in operation.
- 7.34 In line with the recommendations of the Hunter Review (3), the Trust is recruiting two paediatric cardiac liaison nurses whose role is to work alongside parents and doctors to provide additional diagnostic information to complement that given by the consultant. Experience elsewhere demonstrates that cardiac liaison nurses have significantly improved parents' understanding of their child's diagnosis by being available on the telephone and in the community to reinforce and explain the information given by the cardiologists. We explore their role further in Chapter 22.
- 7.35 Finally, we understand that accommodation on the RBH site is expected to change markedly when the Harefield paediatric cardiac service transfers there later this year. We look to the Trust to take this opportunity to maximise the space available for consultations

to achieve greater privacy for parents and children, and to provide sufficient staffing to enable parents to be given the time they need to understand and access the implications of a diagnosis of congenital heart disease.

RECOMMENDATIONS

The Panel recommends that:

- 2. The Department of Health ensures there is no organisational or financial impediment within the NHS to parents exercising their right to a second opinion.
- 3. The Trust considers doctors providing tape-recordings of key consultations about diagnosis and treatment options, with a detailed follow-up letter being sent out within 20 days confirming what was said.
- 4. The Trust ensures that letters to GPs are copied to parents so that they can see any changes in the diagnosis or planned treatment.
- 5. The Trust devises ways of giving parents, guided by cardiac liaison nurses, access to appropriate sources of information including the hospital library, details of relevant websites, books, journal articles, reviews, nursing articles and teaching videos providing information on the diagnosis and treatment of congenital heart disease and details of relevant support organisations.
- 6. The Trust explores how restoration of pre-admission clinics might be funded, as an important contribution to parents' understanding of proposed treatment for their child.
- 7. The Trust makes it clear to parents or patients, through its information booklets and at consultations, that they have a right to ask for a second opinion.
- 8. The Trust approaches other paediatric cardiac centres in London with a view to rationalising the staffing of, and responsibility for, peripheral clinics, ensuring that medical, nursing and technical staffing levels are sufficient to allow adequate

consultation time, appropriate investigation facilities and support for parents and patients.

- 9. The Trust discusses with local NHS Trusts the provision and funding of equipment at peripheral clinics so as to secure a uniform and high standard of service delivery.
- 10. The Trust ensures that accommodation and staffing levels are improved for outpatient consultations in paediatric cardiac services with the merger of the RBH and Harefield services in 2001.

8. CONSENT

INTRODUCTION

- 8.1 It is well established that patients have the right to receive information about the nature and risks of any proposed medical treatment and of any alternatives, and to give or withhold consent to that treatment. This subject has been discussed in more publications about clinical and ethical practice than would be realistic or necessary to review. The circumstances in which children should be consensual have also been widely examined in the literature. As Dr Priscilla Alderson (who was invited by Dr Shinebourne to undertake research into consent at the RBH) notes in her book *Choosing for Children: Parents' Consent to Surgery* (19): 'Consent is more than being passively informed. It is also about becoming actively aware, learning through thinking and feeling. Informed proxy consent involves exchanging and evaluating information in order to make the best or least harmful decision for the child and, wherever possible, with the child. The way in which details are explained can be almost as important as the actual details'.
- 8.2 Paediatric consent is particularly complex as it involves the doctor, the patient and his or her parents rather than a simple doctor-patient relationship. Obtaining consent is part of a process that must begin with an understanding of the condition and the treatment options. It should proceed eventually to signing a form, but the actual signing should be a formality. This Chapter concentrates on the concerns voiced by parents and what the clinicians said in response to those concerns. In reaching our conclusions we have taken into account the published material, expert evidence, and the Trust's own procedures.

CONCERNS EXPRESSED BY PARENTS

8.3 Many parents expressed grave concerns about the consent process. In many of the cases we heard, the child died or suffered serious impairment as a result of surgery. That led the parents to question the way in which their consent was sought and obtained, and the extent to which they were given, or able to understand, information about the risks associated with the surgery or procedure involved. One said: '*I was told he would lead a normal life after the operation, but this was not true as my son died four weeks after surgery*'.

- 8.4 Many parents wanted to meet the consultant who would be performing surgery on their child for him to explain the proposed surgery. However, some complained that they had not seen the surgeon at all before the operation took place. Indeed, seven families said the doctor obtaining their consent was unfamiliar to them and lacked detailed knowledge about their child's particular case. Two parents told us in graphic detail how they were taken into what they described as a 'storeroom' to sign the consent form, where they had nowhere to sit except on cardboard boxes. Both of these cases occurred in the mid 1990s. Another parent, whose child had a cardiac catheterisation, was asked for consent by a junior doctor and we discovered from the child's medical records that the section of the form dealing with risk had been crossed out.
- 8.5 We also heard how the consent discussion was sometimes rushed, with insufficient time to raise questions. As one parent said to us: 'I felt he didn't have time for us, that he was in a hurry and so just fitted us in. You don't seem to take everything in. It just all goes above your head'. Another parent said: 'We believe that a formal meeting should take place with parents and doctors before any consent to surgery ever takes place. This would allow parents to eliminate any questions or doubts that they may have about the surgery'.
- 8.6 Parents complained about the timing of the consent procedure. In one case the consent discussion took place on the way to the operating theatre. The father said: '*I signed it when, you know, they were taking him to the operating theatre*'. Another was signed in the late evening by which time one of the parents had gone home and was unable to participate in the process. When asked, parents could not always remember whether the doctor had signed the consent form in their presence or whether this had already been filled in.
- 8.7 Many parents complained about the lack of clarity around risks when consenting to their child's surgery. We heard cases where:
 - Parents did not understand the figures given to them.
 - The degree of severity of risk had not been explained or given accurately.
 - The nature of the risk had not been covered, or had been explained inadequately.
 - It had not been clear whether the quoted degree of risk related to experience just at the RBH or was a reflection of outcomes across the UK.
 - When the risk of death had been mentioned, other morbidities such as the possibility of neurological impairment had not been discussed.

- 8.8 One parent giving consent to a Tetralogy of Fallot repair remembered: 'We were told that this was a simple plumbing job'. Most felt that they had not been given enough information about the degree of risk involved with the proposed treatment '[There was] a very strong emphasis on the positive view and it is very difficult, especially if you don't know what questions to ask'. In several cases the parents felt that the nature of the procedure itself had not been adequately explained to them: 'I suppose to him he deals with it all the time, so it's probably routine to him, but to us it wasn't'.
- 8.9 We were also concerned to hear that information about alternative treatment options had not been forthcoming. Most parents had been pleased and relieved that their child had been referred to the RBH because, it was, as some put it '*the best*'. Because of that, they were not disposed to challenge or question the advice they received from specialists known to be pre-eminent in their field.
- 8.10 In two cases, parents were dissatisfied with the way in which they had been asked to give consent to their child participating in a clinical research trial. 'I do not think they should have asked consent for the trial the night before surgery, when I was so wound up after the surgery had been cancelled the day before. It gave me no chance to think about it or discuss it with my husband'. This put intolerable pressure on the mother who was herself a doctor elsewhere: 'Basically you will consent to anything, because you want to be helpful, and you want to be seen to be doing everything you can to help them do the best for your child'. Tragically, this child subsequently died. The family felt that the inappropriate way in which consent was obtained, without the father being able to participate, made the process of coming to terms with losing their child much more difficult to bear.
- 8.11 When children are involved in the consent process, experience and even expectations varied widely. For example, in one case the parents were concerned that the consultant had discussed the proposed plan of treatment in front of their child. In contrast, in another, the parents wished their child had been present for a discussion about care. We heard about a 15 year old who asked to have catheterisation under a local, rather than a general, anaesthetic. Despite this being agreed and written up in the notes, the consent form, which the parents were asked to sign on the day of the procedure, referred to general anaesthetic. The mother told us that her daughter said: ' "Oh Mum just sign it Let's just get it over with", and it was on that basis that [she] had a general anaesthetic'.

THE CLINICIANS' RESPONSE

- 8.12 Doctors emphasised that the doctor obtaining consent, whether for surgery or for other interventions, such as cardiac catheterisation, should be capable of carrying out the procedure and know the attendant risks. That need not necessarily be the consultant although this is the most desirable option. Senior house officers (SHO), and other medical staff not previously involved in the care of the patient, were unlikely to be appropriate. We heard that usually the surgeon or cardiologist (in the case of cardiac catheterisation) will have seen the child and family before the admission for treatment and discussed what was proposed and when it was likely to happen.
- 8.13 Several clinicians suggested that consent for elective surgery should be obtained at a preadmission outpatient consultation with the surgeon, thus reducing parental stress in the preoperative period. We are aware that this may cost more, but we believe that improving the pre-admission experience for parents warrants this. This would reflect the fact that informed consent is a dynamic interaction rather than an event. As the Clinical Director put it: 'Obtaining of consent is a process. Timing varies according to the situation of the patient. If patient/parents have seen the surgeon in outpatients then they should have been well informed prior to hospital admission. I personally offer all patients the option of an outpatient appointment when possible. If this is not possible, then parents are seen by at least two members of the surgical team including the consultant surgeon with an interval between the two visits. In an emergency situation consent is obtained through a joint cardiology/surgical approach'.
- 8.14 All the doctors agreed that the risks of cardiac surgery should be represented to parents in a realistic way, over-emphasising neither the risks nor the benefits of treatment. The Clinical Director described it in the following terms: 'Location needs to be improved the current facilities are not adequate. Brain damage should be discussed in each case. Risk assessment the manner of discussion varies according to the nature of the heart condition, unit experience etc. Parents need to understand that all heart surgery carries potential risks and that their child could conceivably and regrettably suffer an adverse event'.
- 8.15 We raised with doctors the concerns expressed by parents about how the nature and extent of risks was explained to them. In some instances the failure to give adequate information

on the risks attached to surgery might have been a misguided attempt to avoid worrying parents, but this made it all the more difficult for parents to accept the outcome when things did go wrong. Several doctors commented on the difficulties involved in communicating information on risks accurately to parents and, as one said to us: 'I remember one child, who I will never forget, who died and the family were very, very upset and they said "Nobody ever told us our child could die" which shocked me... we had several meetings with them and I said "But didn't anybody say there was a risk, or anything like that?". They said, "We were told that there was a 90 per cent chance that he would survive". I said "Well you know, the doctor who said that was probably trying to suggest there is a 10 per cent chance that your child will not survive". You tend to say there is a 90 per cent chance that it is going to be all right, but you may not say that there is a 10 per cent chance that he or she may die. We are in the situation in medicine where I think – and it is not paternalistic – where you sometimes protect parents. if somebody told me that my child was going to die, I do not think I could cope with that. When things go wrong then people can be very angry'.

- 8.16 Another doctor said that he would never discuss cardiac surgery without mentioning that the child might die. However, other consequences such as severe brain damage, although catastrophic when they occurred, were uncommon and therefore not routinely discussed with parents in the earlier part of the period under review. What was crucial was the emphasis placed upon the risks and the way in which information was given. '*It is always* my approach to talk to families myself in a sense I am not too worried about the consent form. The issue is whether you can demonstrate somehow and record that you have actually spent some time, and on perhaps more than one occasion, discussing things, what you have discussed, what figures have you put to them, on what basis have you put those figures.'
- 8.17 Another doctor said that any risk of death or serious impairment in excess of 0.5% would be spelt out, although, for a simple procedure, or minor complication a risk of under 1% would not be mentioned. The risk of death had to be handled in a way that did not alarm the parents unduly. They would be advised if the procedure was likely to be difficult, or moderately so. For fairly rare conditions such as hypoplastic left heart syndrome, the degree of risk nationally would be quoted, even if the RBH had managed to reduce that risk. One doctor told us: '*Risk is so complex. I think families often do understand the figures given to them, but when things go wrong, overwhelming guilt is often transferred to*

events which in themselves are not of prime importance. The death of a child is so awful that displacing some of the anger and misery onto some other event is understandable'.

- 8.18 With regard to the involvement of the child in the consent process, one doctor said that: *with children over ten years I would attempt to involve them in decision making, if I assumed the child was capable of understanding the issues. Below that age I think it is for the doctors in collaboration with the parents to make the decision to operate or not to operate'.* Others adopted a more flexible approach, in partnership with parents.
- 8.19 We recognise that it is ultimately the doctor's responsibility to make the decision on what treatment is needed in the best interest of the child. If parents challenge this advice, in extreme cases the doctor may need to ask the courts to adjudicate on whether treatment should proceed where parents are unwilling to give consent.

EVIDENCE FROM OTHER SOURCES

- 8.20 The GMC, in its guidance to doctors, Seeking Patients' Consent: The Ethical Considerations (20) states that: 'the amount of information you give each patient will vary, according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the patient's own wishes'. Assumptions should not be made about patients' views, and they should be asked whether they have understood the information given to them. That information 'may include for each option, explanations of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks'. Informed consent involves a 'continuing dialogue' and, to ensure voluntary decision making, a 'balanced view of the options' should be given, explaining the probabilities of success or the risk of failure or harm 'using accurate data'.
- 8.21 A signed consent form does not necessarily mean this has happened. The doctor should, close to the time of treatment, review any consent previously given especially if there have been material changes in, for example, the patient's condition or information about the risks of treatment. For young people under the age of 16, the doctor should assess whether the child understands enough to consent to the proposed procedure.

- 8.22 With regard to consent to research, the GMC emphasises the need to take '*particular care* to be sure that anyone you ask to consider taking part in research is given the fullest possible information You should ensure that the participants have the opportunity to read and consider the research information leaflet [and are allowed] sufficient time to reflect on the implications'.
- 8.23 The British Medical Association, in *Medical Ethics Today* (21), points out that the doctor's role is not just to 'provide a list of alternatives from which patients select options'. They should also, as part of their duty of acting in the patient's best interest, '[attempt] to recognise what the patient wants Whilst information and uncertainties should not be forced upon patients at a time when they are particularly vulnerable and clearly unready, most people do deal with very difficult choices despite their anxieties Most doctors appreciate this and automatically take their cue from the patient as to the amount of information required'. The BMA publication goes on to say that: 'ideally, the doctor should inform the patient about any risks inherent in the treatment which might be particularly important to that patient as well as explaining the risks and benefits of alternatives and of non-treatment'.
- 8.24 In *Choosing for Children: Parents' Consent to Surgery* (19), Dr Alderson discusses why it can be hard to estimate risk factors in heart surgery for children. There are only a small number of cases for any new procedure, with varying success rates between hospitals and individual clinicians and over time, and a lack of information about long term effects. There may be uncertainty about how to classify in the statistics a child who survived the operation but died a few weeks later. Indeed, one of the parents raised this very point with us.
- 8.25 When she met with us, Dr Alderson commented that discussion about risk was often restricted to numerical terms, or percentages, and did not address the crucial issue of severity of outcome. A serious and adverse potential outcome, even if rare, did not seem to feature in the debate about risk. She described how some parents did not want to raise concerns or questions in case that was interpreted as a lack of faith in the doctor's judgement, or parents wanted the doctor to decide as they could not cope with such a difficult decision. She was clear that parents had a duty to their child to make the decision, where the child was not competent to do so.

- 8.26 Dr Alderson's observations of consent interviews at the RBH and Great Ormond Street allowed her to understand the extent to which what gets explained depends on what parents *want* explained. She describes how parents left some interviews without a clear idea of the danger and frightening possibilities involved in surgery; she noticed how some doctors described problems by suggesting rather than actually stating risk, and how parents either engaged in or, more often, distanced themselves from such discussions.
- 8.27 On the child's role in the consent process, Dr Alderson describes how inadequate parental understanding of the risks and benefits of a proposed treatment can make the child's suffering worse. Similarly, children adjust better to pain and discomfort when they are old enough to understand it, if they realise that it is for their benefit, otherwise they readily interpret pain and discomfort as being punishment. Alderson quotes research that shows that children do better clinically if there is informed consent. She points out that children quickly pick up parents' attitudes, subconsciously perhaps, and if parents are angry, upset, doubtful or worried even a young child will understand this and find it correspondingly hard to adjust. If they do not adjust, Alderson suggests, they do worse.
- 8.28 Gill Brook, a Clinical Nurse Specialist, Liver Unit, Birmingham Children's Hospital said it was 'very difficult to define, assess or measure' whether a child under the age of 16 was competent to assess information about treatment options and to make a reasoned decision. It was crucial to give children the right to consent to their own treatment so that they were better informed and had a deeper understanding of what was going to happen to them. In an article in *Paediatric Nursing* (22) she wrote that: 'the "lived" experience and knowledge [of children with chronic illness or disability] has a powerful influence on their ability to contribute to decisions on treatment [and] must be given serious consideration'.
- 8.29 At her hearing with us, Ms Brook described the key principles that should underpin the multi-disciplinary team's relationship to children and their parents:
 - Work in partnership with the child and family, who should make informed choices about their treatment.
 - Talk with, not to, children.
 - Competence is more than a skill, it is a way of relating.

- Give children and parents support and opportunity to make choices together on treatment.
- Privacy and time should be given to information sharing.
- Adopt an open, honest and sensitive manner.
- Use tools (such as visual aids) to help children understand.
- Always check on the child's and parents' understanding.
- 8.30 We were told that the whole process worked best where there were liaison nurses or nurse specialists. We asked a group of nurses from the RBH about where and when to obtain consent. They told us that it should be done '*in a quiet area where people can concentrate*'. They said that nurses had a definite role in helping the parents to interpret the information that they were being given by the doctor, and it was also important that the nurse knew what the parents had been told about the proposed procedure.

THE TRUST'S PROCEDURES

- 8.31 In February 1999, the Trust issued a revised version of its comprehensive procedural guidance on *The Obtaining of Consent*. The stated objective was: 'to encourage the active participation of individual patients in decisions relating to their treatment'. Information to patients 'should contain an estimate of the relative risks and benefits of proposed treatments, and should be sufficiently detailed to enable patients to arrive at a balanced judgement'. Details of significant risks explained to patients should be clearly recorded. With regard to young people under 16, staff should ensure that they have 'a sufficiently broad understanding of the hazards involved in any proposed treatment, and of any available alternatives'.
- 8.32 The Trust states in its guidance that it is 'committed to the provision of appropriate written information concerning risks and benefits of proposed treatments before consent is sought'. The assumption must be that most patients wish to be well informed. Only in exceptional cases may disclosure of information rightly be withheld. The member of staff obtaining consent 'must have sufficient knowledge of the proposed treatment and be capable of performing the procedure'. Where a health care professional is acting on behalf of the physician or surgeon, that person must be 'properly trained' and have 'good communication skills'. Ideally, consent should be obtained when the patient joins the

waiting list, at the time when the treatment is proposed and explained. At admission, the doctor must ensure that no significant changes have occurred in the meantime.

8.33 Where the clinician wishes the patient to be included in a randomised clinical trial, 'special care must be taken to ensure that sufficiently detailed information is provided to enable patients to give informed consent. No undue pressure may be exerted to encourage participation'.

CONCLUSIONS

- 8.34 Consent is a process that begins with the first consultation. Parents should fully understand the nature of the condition and the proposed operation to the extent that it is settled in advance before the child comes into hospital and both should be explained by the responsible surgeon or paediatric cardiologist and should be confirmed in writing. At this point the risks and probable outcomes should be thoroughly discussed. It should be explained, for example, that some children appear neurologically unwell after the operation but recover without injury, that the operation is not the only hurdle and that the post-operative period can be extremely risky. Again these should be recorded in writing so that the other clinicians and nursing staff treating the child know exactly what parents are expecting. At some point either before or after admission the parents should see the surgeon so that he can confirm and explain the procedure further.
- 8.35 The Panel welcomes the excellent guidance by the Trust in February 1999 and regrets that similar guidance was not available during the earlier part of the period under review. Practice regarding how much information should be given across the NHS has changed over the period covered by our Inquiry. Since the early 1990s, more patients have both expected and demanded to be treated as equal partners in care and decision making, and to be given the information needed to exercise that right. Doctors have also become more open about the choices, risks and benefits, both in recognition of the change in public attitudes and because of the fear of litigation.
- 8.36 It remains for the doctor to exercise clinical judgement in deciding how much information about risks and options to impart to the patient. It would be unrealistic, and unreasonable, to expect the doctor to provide information about every conceivable treatment option,

however remote or unrealistic in the particular case, and every potential outcome, however rare. In our view, however, doctors are not entitled to deny the patient – or parent – the legitimate right to decide by failing to discuss real alternatives or to disclose significant risks. Even if there is no real alternative, the risks must be openly discussed. We believe that there were occasions when RBH clinicians failed to ensure that parents had sufficient information and understanding about the risks and benefits of planned procedures. Although clinicians need to be sensitive to the parents' anxieties, it is not their role to deny patients and parents the chance to consider dilemmas and difficulties. There can be no 'hard and fast' rules, but we consider that parents should at least be informed about any measurable risks of death or neurological injury. It should also be made clear whether any quoted risks relate to performance at the RBH or to experience across the UK or elsewhere.

- 8.37 Turning to the child's right to participate in decision making, we can understand both the wish of some parents to protect their child from the realities of their condition, and the importance attached by others to respecting the child's individuality and right to share in decisions. This is a matter not just of age but of competence. One of the RBH clinicians told us that any child aged ten or over would be involved in discussions about care. While that may be a reasonable position to take in many cases, the clinician should first have a discussion with the parents about their child's level of understanding. In that way it should be possible to avoid causing distress to a young child, although the Panel noted that children may get very upset if separated from their parents in a strange environment. Our clinicians believe that children need to know in simple and reassuring terms and to be prepared for what is going to happen to them. Even a child under ten, who has a chronic condition and previous experience of operations, should be able to discuss plans for treatment and have the opportunity to express feelings or preferences. In our view the surgeon and the parents should assess whether the child is old enough to understand the nature and risks of the operation for these to be explained. If not, children should be told what the surgeon and the parents together agree he or she can deal with.
- 8.38 Except in emergency situations, consent is a continuous process and the signing of the consent form should be a formality; it should not introduce information about options and risks that have not been covered in previous discussions. No child should come into hospital without the parents having reached an understanding about the nature of the condition and the proposed operation. Signing the form provides an important opportunity for checking the parents' understanding. It should be done at a pre-arranged time, with

enough time to give parents undivided attention and in a location affording reasonable privacy and comfort.

- 8.39 We are concerned about how often consent was sought by a junior doctor, sometimes unknown to the parents or unfamiliar with their child's case. The Panel noted that for diagnostic catheterisation, which is the most common procedure undertaken by cardiologists at the RBH, registrars usually obtained consent rather than the consultants. Except in an emergency, the person who presents the form should not be a stranger to the parents and no child should be operated on by a surgeon who has not seen the child before and who has not explained the operation to the parents. We were very concerned to discover from examining the medical records that in one case the junior doctor deleted the reference to risk altogether. As the Trust's own guidance states, consent should be obtained either by the consultant or a senior doctor who is competent to undertake the procedure or has sufficient understanding of it and has the training and experience to answer questions. Unless there are extenuating circumstances, signing the form should not be done in a rush or late at night, and certainly not on the way to the operating theatre or in a storeroom.
- 8.40 Where consent is sought for participation in a clinical research trial, the parents should be given written information in advance about the nature of the trial and the reason for their child being included. Such consent should normally be obtained in writing before the child comes into hospital. One consultant indicated that this is in fact the RBH policy, saying that: 'Consent to clinical trials should be obtained in advance of any particular procedure. Parents have to sign a consent form before a research procedure can be carried out. The policy is that this form should be given to the family sometime before they have to sign it, witnessed by somebody independent who should help ensure the family understand what is involved'. This did not, however, tally with the evidence given by two sets of parents. We believe that the Trust should review its guidance on clinical research trials to ensure that this policy is still appropriate and check that clinical staff are trained to implement the policy correctly.

RECOMMENDATIONS

The Panel recommends that:

- 11. The Trust, specifically the Medical Director, determines with consultant staff how to secure and monitor compliance with the Trust's policy guidance on consent, with the objective of sharing information with parents about treatment options and risks in an open and sensitive manner and of achieving partnership in decision making.
- 12. The Trust should, in addition to the existing comprehensive consent procedure, prepare succinct and explicit guidelines making clear to all medical staff that:
 - Consent must be real and informed.
 - Consent must be obtained by the consultant or a senior doctor familiar with the child's case, who is competent to undertake the preferred treatment option.
 - Consent should be sought, except in an emergency, at a pre-arranged time and in a place where reasonable privacy and quiet can be provided.
- 13. The Trust commissions a formal audit of consent procedures in paediatric cardiology and cardiac surgery, and for research on children with congenital heart disease, from the RBH Audit Department, and repeats this on an annual basis.
- 14. The Trust implements a programme of training in obtaining consent for treatment and for involvement in a clinical research trial, with the Clinical Director and Research Director being accountable to the Trust Board for ensuring that relevant existing and new staff have been adequately trained.
- 15. The Trust ensures that, when giving parents information on risks, clinicians give details of both the national and hospital figures for the surgical procedure proposed in addition to their own outcome figures and the doctor's own assessment of risk in the light of this information.
- 16. The Trust builds on its reputation for pioneering treatments and research by having more detailed and readily available information on the quality of the service it provides in all areas. This includes not only surgical and interventional catheter

short-term outcomes but also wider issues such as the provision of facilities for families, effectiveness of communication with referring hospitals and access to professional help with problems other than cardiac ones.

- 17. The Trust ensures that clinicians take whatever steps are necessary to be satisfied that a decision has been reached, with the parents, about how far their child should be included in discussions about his or her condition and future treatment, and that such a decision should have regard to the child's level of understanding.
- 18. The Trust ensures that consent for participation in a clinical research trial be sought in good time and with supporting information in writing for the parents to study before giving their consent.

9. THE CHILD'S STAY IN HOSPITAL

INTRODUCTION

- 9.1 The admission of a child for an operation is a time of considerable stress and disruption for the family. While parents hope that it will transform their child's prognosis and quality of life, they are anxious also about what might go wrong. For the child who is old enough to understand, the prospect of surgery generates a mixture of fear and hope. If the surgery is delayed, or the parents are not kept informed about what is happening, it can create extreme anxiety. Occasionally, despite the skill and experience of the surgical team, the child does not survive the operation or suffers brain damage. However sensitively and thoroughly the risks have been explained beforehand, it will come as an unimaginable shock to the parents. Sometimes they will experience an unwarranted sense of guilt for having consented to surgery. It is an event that will live with them for the rest of their lives. Their ability to come to terms with it can be helped or hindered by how quickly and sensitively the clinical team talked things through with them at the time.
- 9.2 After the operation, the child is normally transferred from the recovery room to the PICU. The parents' attention is focused on their sick child, watching for every nuance of change in his or her condition or state of awareness. Despite the best efforts of staff to make the environment as accessible as possible, the intensive care equipment, high staffing ratios and need for constant monitoring make the PICU an inherently intimidating environment for parents. It is easy to understand why they often feel like helpless observers, excluded from sharing in their child's care and progress. Their emotions are heightened even further if they are treated brusquely or see staff disagreeing with each other about treatment. It is vital that parents feel reassured about the treatment their child is receiving. Yet the primary focus of the staff is on the children under their care, all of whom are very sick, and time to communicate effectively with parents is probably more difficult to find in the PICU than in any other part of the hospital.
- 9.3 Good communication and a real sense of involvement in care are central to making the parents' experience of their child's stay in hospital a positive one. It is not surprising that many of the concerns expressed to us about the RBH and Harefield stemmed from what

parents perceived as inadequacies in this respect. Most complaints about hospital treatment have their origins in a failure in communication. Such lapses can include not sharing information, using technical – or, at the other end of the scale, patronising – language, failure to tell parents about untoward events, poor record keeping or poor coordination between different team members or disciplines. It is also about failure to treat parents as partners in health care. There has been a major shift in the expectations and rights of patients and parents over the last decade in terms of the need for information and full involvement in decision making. What may have been regarded as acceptable in the 1980s is no longer the case. Parents now expect to be better informed and involved, and to be given more time with the consultant when making difficult decisions. We recognise that this makes ever greater demands on the workload of consultants, who are under great pressure to provide more and better services from the limited resources available.

CONCERNS EXPRESSED BY PARENTS

Day of operation

- 9.4 Seven of the parents told us that their child's operation was repeatedly postponed to another date, in one case five times. As one parent said: '.... you are so psyched up for surgery, and she was. She had been starved, and so I had gone down to the ward at 7 o' clock in the morning.... she being first on the list, due to go for surgery at 8 o'clock. 9 o'clock nothing happened, 10 o'clock nothing happened, but you were waiting all morning.... It was awful, because you are desperate to comfort her'. The reason generally given was a shortage of beds or nurses in the PICU, although one family received no explanation. This caused considerable distress, particularly for parents who were worried that a delay might affect their child's prognosis. The parent of a child who had already had a distressing blood test when he was sent home again said: 'You can't do all that, send him home, and put him through it again when he comes back in. It's not fair'. This particular family had travelled over 50 miles to the hospital on a crowded commuter train.
- 9.5 In two cases the child's operation was moved to later in the operating list, which meant that pre-medication had to be repeated. Another involved a baby who became extremely distressed because of being '*starved*' for much longer than would otherwise have been necessary. 'I do understand surgery gets cancelled but they did take an inordinate

amount of time to decide it was not going ahead because it was about six hours of waiting to be told, pacing up and down the ward with a hungry baby.'

- 9.6 Another parent was forced to watch her child steadily deteriorate while waiting for a date for admission for semi-urgent surgery. The child was eventually admitted as an emergency nine weeks later and died shortly after returning to the PICU. Understandably her parents questioned whether earlier admission to hospital before she began to deteriorate would have resulted in a different outcome, especially when they discovered during their meeting with the Panel that it had been planned to admit their daughter within 6-8 weeks: '*There appears to be no procedure to ensure operations are carried out within the timescale proposed*'.
- 9.7 Even if the child's operation goes ahead as planned, complications can result in it taking much longer than predicted. The parents of one such child became worried because the operation 'took hours longer than we had been led to believe that it would take. No explanation was given to us either during our wait.... or at any time subsequently'.
- 9.8 It is understandable that during the operation and in the immediate peri-operative period, the clinical team's attention is focused on the child, not the family. What is less well recognised is that parents who have entrusted their child to the team have their own needs on the day of operation. In one case the parents told us that their child was taken down to the operating theatre in the late evening without anyone telling her mother, who was in the hospital. She said: 'I went in to see her and she had gone.... I had to run down the corridor and down the lift to find her'. In another case, the parents were very disappointed at the level of support offered to them by the hospital chaplain, who they had asked to come and see them on the ward, saying: 'It was a very unhelpful experience' as 'he seemed more shocked than we were about PICU'. The suggestion was made that this particular hospital chaplain needed training in being able to respond to the needs of parents in the hospital.
- 9.9 In six cases the parents complained to us that they had been given no support or facilities to help them through the anxious period of waiting while the operation was in progress. Most of these occurred in the period up to the early 1990s, when there was nowhere for the parents to wait in the hospital, nor were they told how or when to contact a member of staff to enquire about progress. Pagers were not available until much more recently. In 1997,

the parents of a 12-year-old boy were offered the use of a waiting room near the PICU where there were letters and some photographs of 'other children who have had operations there and it mentioned quite a few of them have died after the operation as well which isn't a very nice thing to be reading'. In this case the boy, whose heart condition had only been diagnosed as serious a short time earlier, died not long after the operation.

- 9.10 Normally it is the paediatric cardiologist with whom the family will have had most contact from the time of referral to the RBH up to the admission for surgery. Again, we heard from several parents that they had not seen the surgeon before surgery so they were unable to establish trust and confidence in the person who would be operating on their child. In one case we were told that they were not sure whether it was the consultant or a member of his team who had operated. The importance to parents of being able to meet the surgeon before and after the operation should not be under-estimated. One parent, herself a consultant in another specialty, said it was only persistence that had won her a three minute consultation with the surgeon at 8.00 a.m. before he began the day's list. She told us: 'I wanted him to have seen her and part of the reason that I insisted on seeing him is I did feel that it was very odd that the surgeon did not meet the child beforehand and that she was not a person to him You do not want to just be number two on the list.... You want to have had some sort of interaction with [the surgeon]'.
- 9.11 A few families complained that only one parent was allowed to accompany their child down to the operating theatre and into the anaesthetic room. This was particularly distressing for the parent who had to remain behind. When the operation was successful this was less of an issue. However, in those cases where something went dreadfully wrong for example, when the child died without regaining consciousness parents bitterly regretted being denied the opportunity to say goodbye to their child. In one case, where the child suffered severe neurological impairment during surgery, the parents commented: 'only one of us was allowed to go with him [to the theatre] Why not both parents at such a moment of anguish......'.
- 9.12 Some of the most significant concerns raised by parents relate to untoward events occurring either during surgery or as a direct consequence of the operation or procedure. Some have said that they found out about the event only after their child had died. The parents in three cases described to us how they had not been informed about what was happening, and had had to rely on nursing staff for scraps of information. In one of them,

the child had suffered a tachycardia and needed electrical stimulation to restart normal rhythm. The parents said: 'We only found out by chance We had been told everything had been fine, there had been no problems. I am sure they said that to stop us worrying I would rather have known'. In another, it was the post-mortem report that alerted the parents to the fact that their child had suffered a cardiac arrest a few hours after being transferred from the operating theatre to the PICU. In the third case the drains inserted at operation were found to be blocked allowing a small quantity of blood to cause tamponade, which led to severe neurological injury. As the parent of this child said: 'Things do go wrong I have spoken to parents where they have gone wrong, and that is one of the things they have all said: "Nobody told us. Nobody said anything". Doctors are not God They do their best, I think, or most doctors do their best by their patients. So I just think things like that need to be brought up'.

Post-operative care

- 9.13 Nearly half of the 28 cases of the children who did not have Down's Syndrome concerned an alleged lack of honesty or openness. 'We were desperate on that Monday to find a doctor to talk to, for someone to do something, because I could see him deteriorating in front of my eyes. No one was around. No one wanted to talk to us. No one prepared us for the fact they knew for two days before he was dying, and we did not.... But we never had a conversation "This child is near death; this child is about to die. We cannot do anything else for your child." That never happened. We were just reading between the lines and grappling at whatever we could get from whoever came along.'
- 9.14 While parents understood that their child's treatment might not be particularly unusual for the staff, there seemed to be little acknowledgement that for the families it was a unique and devastating experience. One parent, whose child suffered a catastrophic brain injury as a result of surgery said: 'We had a sense that doctors at the hospital saw cases like ours all the time, that there was nothing exceptional in what we were being told'. In another case, it was only when they met us that the parents appreciated that their child had been 'more poorly than we ever understood'. In another case, the parents had not understood, when they were told about problems with fluid balance, that their child was in renal failure, and said: 'We were never told his kidneys had failed'.

- 9.15 Eight families felt that their own observations about the progress of their child in PICU had been given insufficient weight by the staff, and some even said that their concerns and opinions had been dismissed. One parent told us: 'It just seemed like we were moaning and going on and on.... having to bully all the time to get ourselves heard. It was dreadful'. Another parent, whose child was transferred from the PICU to the High Dependency Unit (HDU), which had only been brought into use that day, made a similar criticism about an inexperienced bank nurse. In another case a junior doctor observed the baby sucking, but the mother knew that it was not really taking in nourishment 'but he wouldn't listen to me'. More poignantly, another parent described how he had to battle to get anyone to respond as his child turned blue: 'I said, "Can you get a doctor to come and have a look. He is not looking right again?". She (the nurse) said that he was fine. About three times I asked her to go and get a doctor, but she didn't'. Shortly afterwards this child suffered a cardiac arrest and died leaving the family with the question of whether the outcome would have been different if a doctor had been called when first requested by the father.
- 9.16 Four families complained about being asked to leave the PICU during the consultant's ward round. They felt anxious and suspicious, and excluded from crucial discussions about their child's care and progress. One told us: 'We did not like the way we were instructed to leave the room when consultants were on their ward rounds. We feel if there is any information to be discussed about our [child] we should have the opportunity to listen.... On [one] occasion I refused to leave as I wanted to hear what they had to say'. Another said: 'We didn't like the fact that we were kicked out at ward rounds.... If they can't deal with the parents and the people, why are they in the job? I thought that was quite insulting to parents'. In another case, the parents asked the nurses if they could stay in the PICU: 'They said "Fine. But if [a named surgeon] comes in, just leave because he doesn't like parents around" '. However, in another case involving the same surgeon, a parent said: 'He actually made some comment: "Good Lord, these parents run away from me", but it was only because we had been told to (obviously at his request)'.
- 9.17 In the same way that parents were asked to leave during ward rounds, the counsellor accompanying the parents at one of our hearings said that: 'they were left alone in intensive care when the hospital staff were attempting to resuscitate [their child]. This was for a period of one hour, where they were very frightened and desperately wanted somebody to tell them what was happening'. In complete contrast to that sense of exclusion, six

families told us that they had witnessed heated arguments between staff in front of them about the future management of their child's care, which had undermined their confidence and increased their sense of anxiety. One said: 'It was very unpleasant actually, because about half a dozen people were sort of arguing over the doses. That doesn't make a parent feel easy. You are sitting there, they are right in front of you and they are doing that If they are going to have discussions, they shouldn't have done it in front of us. Not like that anyway'. In six cases the presence of junior doctors and/or research fellows, or several other staff, in the room troubled the parents. That can happen both during the stay in hospital or in outpatients. In one such case the parents told us: 'Whatever else he may or may not have said after that was lost, because it was an awful lot to take in. The room was full of people, I just wanted to get out'.

- 9.18 In five cases parents were concerned that there had been a transfer of responsibility of care from one consultant to another between one cardiologist and another, or between cardiologist or surgeon and intensivist and as a result they had not known which doctor was in charge. They pointed out that although they realised that doctors could not be on duty 24 hours a day, it should have been possible to make proper hand-over arrangements and for parents to have been told which doctor was in charge of their child's care.
- 9.19 A significant proportion of the parents complained to us about consultants showing insensitivity in their attitude, appearing to be brusque or patronising in their manner or what they said. In some cases they described the surgeons as intimidatory and unapproachable. One parent said: '*They had their ward round, whatever at 9 o'clock in the morning, when parents are off the ward They were all walking off And no doctor spoke to us And it was almost like on the rounds that morning they decided "We are not going to intervene or treat him any more" but no one said anything other than "The medical challenge has gone" and my child was not a medical challenge. And to add insult to injury, the next day [after he had died] they were all over us like a rash. There were social workers, health workers, counsellors and a doctor saying we want to do a post mortem'.*

Follow-up care

- 9.20 Several parents commented to the Panel that, after their child's discharge from the RBH, they felt that they were left without support or advice. We deal with this further in Chapter 21 about children with neurological impairment. In one case the parents said: 'We were left to fend for ourselves.... We were left really to go to the local hospital'. This left them with the impression that the staff had taken over from them while the child was under the care of the RBH, and that the child was then handed back for them to cope as best they could. As one parent said: 'They gave us leaflets....There should have been one person who would.... talk to you about what has happened and encourage you.... because just to go off by yourself is quite hard. We were on our own'. Another commented: 'We brought him home and it was just a complete nightmare.... We had no help at all.... so we just sort of coped for ages.... He just wouldn't stop crying'. In one tragic case, after the immediate post-operative follow up, there was no further follow up until five years later when the child was referred back to the RBH by the school medical officer. A few years after that she had a cardiac catheterisation and one of her parents said: 'No information was given to [her] and I about her condition and there was no follow up'.
- 9.21 In three of the cases there had appeared to be a lack of communication between the RBH and the GP or the referring hospital. In one case, the parents told the Panel that: *'The GP said: "I hadn't received that report, they didn't even send me that"*. *When you ask the GP, he has no idea what's going on'*. When the parents in another case saw the paediatrician who had referred their son to the RBH, one of them told us: *'I asked him if he had received any letters and he said "No"'*. The Panel noted that this may be the result of lack of organisation by the GP or referring hospital and not the result of any failure on the part of the particular consultant at the RBH.
- 9.22 The most prevalent complaint involving poor communication was that staff did not keep parents adequately informed about progress, or were not always honest or open in their approach. The parents of one girl took their daughter for an echocardiograph five years after her previous consultation. They told us that the cardiologist said: '*Right, I am very sorry to tell you that we still have the [hemi anomalous pulmonary venous defect] My husband said, "I can assure you that we did not know anything. We have been told for five years that our child is fit and healthy; her heart is fine".... [The cardiologist] was very embarrassed'.*

THE CLINICIANS' RESPONSE

Day of operation

- 9.23 One surgeon told us his views on cancelled surgery: 'It is extremely frustrating, particularly with more difficult surgical procedures. You do mentally prepare yourself. It is debilitating if you have to cancel the start of an operation and start later in the day. In some ways that is actually even more stressful. Starting a case that is going to take you six hours at 4 o'clock in the afternoon when it could have been 9 o'clock in the morning'.
- 9.24 The doctors acknowledged that cancellation and postponement of planned operations occurred frequently and, as one of them commented, was 'totally unacceptable'. The cause was usually a shortage of beds in the PICU attributable, in the main, to a lack of nurses with the appropriate skills. A change in the sequence of cases on the operating list could also be caused by an emergency case, or by an earlier case taking much longer than expected. This, and the fact that many children on the waiting list were in urgent need of surgery, led to surgeons perhaps being over-optimistic about how many cases they could place on an operating list. As one doctor said: 'the road to hell is paved with good intentions'. If there were more beds and nurses, it would be easier to manage the fluctuations in demand.
- 9.25 Another doctor said: 'When an operation is postponed or cancelled at the last minute it is awful for everyone. The only way to minimise this is to have more nursed intensive care beds, which involves more resources and also the ability to recruit nurses. Usually the most senior nurse or doctor on the ward is the person who informs the parents, but that depends on who is available.... I would say, however, that people do try and explain to families and apologise for cancellations, even though it is usually not the fault of the person who is apologising. When the reasons for lack of nurses are financial constraints, perhaps it should be the business managers who go and apologise to the parent'.
- 9.26 Although it was accepted that the responsibility for telling parents about any change in the timing of an operation lay with the surgeon or his registrar, they might be unable to leave the theatre so had to leave it to the nurses to explain what was happening and why. As one of them said to us: *'If you do change your list round, you have a duty to go and explain to parents why.... If I am available and the patient's operation is cancelled because there is*

no bed, I will go and explain to the parents why. I have had to do it with individual patients five and six times sometimes.... I often give them the choice...."Now you can either stay here and I will schedule your case tomorrow, the same thing might happen, or you can go home and I will bring you in when the situation looks easier".

- 9.27 The doctors seemed unaware of any policy that only allowed one parent to accompany their child down to the operating theatre. As one said: 'To my knowledge this is simply untrue. In my experience parents have never been denied the opportunity to accompany their child down to the theatre, anaesthetic room or catheter lab. Talking to the anaesthetist they sometimes find it easier to have one rather than two parents with the child while the child is being put to sleep. If both parents request being present then to my knowledge this is never refused'.
- 9.28 Few doctors were prepared to agree to parents attending emergency procedures such as resuscitation or being allowed to watch the operation on their child in theatre or even on a video screen. Nevertheless not all doctors ruled this out. One surgeon observed: 'I have only personally come across two situations in my career where a parent was present at an ultimate resuscitation that was unsuccessful. But both of them expressed a sense of gratitude that they were permitted to be in the vicinity and they were actually close by. They were behind a curtain this close to the action, as it were. They could hear what was going on. Truthfully I do not think that we know what is right. In a sense I think this becomes more the domain of the psychologist than the surgeon....what I would not personally do is to take an entrenched attitude about what one should or should not do and if professional advice comes out that, actually, for these reasons, maybe that should change, then again I think we should change it. What I am prepared to consider is videoing the operation. That is again not an unusual thing in the United States and, in fact it is something we should consider'.
- 9.29 Regarding arrangements for parents while their child is having surgery, one doctor was clear that the RBH did not provide enough support. He said: 'Parent accommodation needs to be improved. All parents should be issued with pagers so that they are easily contactable at any time. A quiet room (no TV or smoking) might be a helpful facility where parents could have a drink or a rest. Facilities for ethnic minorities including literature in other languages, availability of interpreters and religious support needs to be secure. The psychology team at RBH is an excellent facility for parent support'.

9.30 Although parents did not always meet the surgeon before and after the operation, one of the doctors remarked to us: '*[that criticism] may not be unique to the Brompton*'. As for telling the parents about any problems that occurred during the operation, the surgeons told us that, wherever possible, they would speak to parents personally even, as one added, if that was at the end of the day. 'When I see the parents before the operation, I say to them that I will, if possible, come up and see them between cases and explain to them how the operation went. If it's not possible to do it between cases, then I will do it at the end of the day. As far as possible I try and do that'. A cardiologist commented that if he knew the child and family well, he also would go to see them and try to give some explanation. Another doctor stated that: 'a consultant should speak to all parents post-operatively if there are any untoward events....[and] should be straightforward, honest and open'. However, the Panel heard that: 'often it's the senior nurse on the ward who is landed, to some extent, with imparting the information to families, which can be very harrowing for them. But the trouble is there isn't an easy way of doing it....I am sure it can be done better but I'm not quite sure how'.

Post-operative care

- 9.31 We discussed with the doctors parents' concerns that they weren't heard. All of them insisted that they did listen and take account of parents' observations about their child in the post-operative period. Nevertheless, one intensivist acknowledged: '*I can think of no greater torture for parents, I really cannot, than to have their child in an intensive care unit*'. One added that, even so, doctors tended to be rather dismissive of relatives' statements but that his trainees were instructed to listen to what the mother said as she '*knows best*', and that he was always interested in what the relatives thought was happening. Another commented that staff needed to understand the validity of parents' observations, but should not be '*overburdened by the need to act on apparently irrelevant information*'.
- 9.32 One doctor felt that communication with parents was generally good: 'There may have been cases where people felt that communications were poor but on the whole I think they are very good. What I do know is that it is very difficult to continue to communicate well with people if their child is on the intensive care unit and you feel that the outlook is poor....It is quite difficult to keep going back every day, or twice a day, talking to people

and supporting them when you feel very pessimistic about the likely outcome'. One doctor recounted to us how a relative, to whom he remembered having spoken possibly several times a day, had accused him of not speaking to her enough. In retrospect, when things went wrong, the doctor wished he had noted down how many times he had spoken to the family. Other clinicians said that discussions with parents should be recorded in an appropriate form.

- 9.33 With regard to recording key discussions, the nurses to whom we spoke said that they did not make a detailed entry about conversations with parents. They noted when parents visited, but there was not sufficient time for them to make a fuller record of what was discussed. One of them added: *'it is the parents' perception of situations, and we might not realise that that is a dramatic situation for the parents'.* Another nurse said: *'I think that we have to be honest with parents, and if as a nurse we know that there are concerns, and the parents say to you "These are my concerns", you have to be honest and say "Yes, they are our concerns too" As a bedside nurse, you are probably with a patient 12 hours a day which a doctor is not, and therefore you get a different relationship with them, and maybe you are able to say things and start the discussion'.*
- 9.34 The nurses told us, with regard to taking heed of parents' observations, that the RBH was not open to the influences that were present in a specialised children's hospital. Services for children at the RBH had been 'tailored' from adult services, and that, in the nurses' view, had contributed in the 1980s to the fact that the RBH was 'not suited or geared to children'. As one nurse said: 'Because a lot of the doctors at the Brompton are not open to the influences that are always in a children's hospital, they have developed a style of management that does not recognise the very obvious and special input that parents have with the families'. Another commented: 'We have as a paediatric team been battering our head against a brick wall when things are in the hands of our adult colleagues, because of the special needs of children in hospital it has improved a lotover the years, but we are looking at ten or 15 years ago here, and the needs of children in the Brompton hospital were not recognised at that period of time.' They believed, however, that things had changed radically since the 1980s and that many of the concerns raised with the Panel by parents would no longer arise. The Director of Nursing said: 'if you are in a paediatric hospital everybody is geared to and understands the needs of children. That is what the whole organisation runs for, from the porter on the front desk onwards, and in an adult hospital, by virtue of the mixed populations of patients that you have, that is not the case

and, therefore, it is behoven, perhaps the paediatric people feel on them, to make sure that the food is right for children, and that the type of furniture is – all sorts of very practical things'.

- 9.35 The RBH nurses talked to the Panel about arrangements for parents to visit the PICU before their child's admission, in order to help them come to terms with what was a very intensive clinical environment. They told us that the uptake of a pre-admission clinic had not been very high, so parents often came to familiarise themselves with the PICU only on the evening before the day of operation, after the child had been settled down. Not only were the nurses very rushed at this time of day, but that was '*the wrong time*' for parents to visit. We refer in Chapter 22 to the pre-admission clinics run by a cardiac liaison nurse and a play therapist at another centre as a means of preparing the parents and child for the admission. The nurses acknowledged that once the child was in the PICU, they were able to form a different and more transparent relationship with the parents. It was emphasised to us that the training and development of nurses needed to equip them with a wide range of psychological skills, so that they could provide the support that parents needed.
- 9.36 There were facilities for relatives on the PICU at Harefield, but there was no such provision at the RBH, although the nurses understood that plans for the combined unit after the merger include more accommodation for parents.
- 9.37 The doctors all had strong, but widely differing, views about whether parents should be present during ward rounds. One doctor was very clear that they should be excluded, saying: 'An intensive care unit is not a nursery school It is a highly charged high-tech environment both for nurses, and doctors, and parents I would favour excluding relatives from both adult and paediatric intensive care units for most of the working day. To have to always watch what you are saying because of parents listening not necessarily the parent of the child that you are discussing, but the neighbouring patient's. Parents can be very limiting for decision making, and I think it is preposterous to suggest that relatives should stay during the ward rounds'. Another was clear that parents should be included, saying in his experience this had worked well in other centres: 'ward rounds' should not, in my opinion, exclude parentsIn the event of a significant and basic disagreement on patient care [between doctors] I would always recommend that the parents be offered a second opinion from without the hospital'.

- 9.38 A third doctor told the Panel that, after the nurses had persuaded him to have parents present during ward rounds, one mother had left in distress as she had misunderstood what was said. It was pointed out that the presence of parents could constrain discussions, and that patient confidentiality could be compromised with parents overhearing what was being said about an adjacent patient. '*Patients' relatives in my experience catch on to one word, or one statement spoken by a doctor, and forget the rest, or do not hear the rest of the statement. This word or statement taken out of context can be very disturbing, Therefore although I do understand why they want to be with their child all the time, it is impracticable in an intensive care environment.'*
- 9.39 One solution suggested to the Panel was for parents to be present during the ward round, and for the clinicians then to hold a separate meeting, if necessary, off the main ward where they could discuss sensitive issues which they might not wish to raise with the family present, and resolve any disagreements in private without causing the parents avoidable distress. However, not all doctors agreed with that, one of them saying: '*I am quite happy to have parents there myself. It does not bother me very much I find it easier to [discuss something] when it just comes into your head; to say it rather than to bottle it up and then at the end of the ward round have a word with somebody'.*
- 9.40 Some of the doctors accepted the parents' criticisms of disagreements between clinicians about treatment options. One remarked that, in the past, the RBH tended to attract consultants who were 'naturally aggressive' and 'egomaniacs'. That was one of its major attractions, as 'tough people got things done', and the Monday morning clinical meetings were 'fantastically vibrant and productive That is how we developed new research strategies, pushed things, produced more'. He added that: 'occasionally there would be stand up arguments or disagreements in front of parents and you cannot defend it'. He also accepted that other paediatric cardiac centres adopted a less challenging style with more emphasis on a collegiate and consensual approach to teamwork.
- 9.41 As for alleged brusqueness, one of the doctors said candidly: 'I might have been brusque. As far as is humanly possible, not in front of parents, no. Who can say they have never been brusque in that situation?'. Another raised with us the dilemma faced by doctors who were expected to be both sensitive and direct 'because otherwise if you beat around the bush then the message does not get through'. The doctors refuted suggestions that they
were inattentive or insensitive in their dealings with parents, one of them saying that: 'the care of a child is a partnership'.

- 9.42 With regard to the presence of junior doctors and others at discussions with the family, we recognise that the RBH has an added pressure as a centre for postgraduate training, research and academic excellence. This can give rise to problems not only in the ward and PICU but also in outpatient clinics. One of the doctors said: 'We have to balance sometimes this role of teaching, educating people, as well as dealing with concerns of families. Sometimes we do not get it quite right because we may have too many doctors around that does happen sometimes. I think one of the ways we are trying to get round that actually is to have a camera in our consulting rooms so that people can watch the consultation and look at the ultrasound scans from an off-site location, which might be one of the ways that we could have less people to observe the interaction between the doctor and the parents this is usually in the echo clinic actually. This is where we get a lot of people'.
- 9.43 In contrast to some of the doctors, the nurses believed it was right for the parents to be present at ward rounds. In their view there should be nothing that the team discussed which the parents should not hear. Any disagreement should be conducted professionally, and at the end of the round the person running the ward round should tell the parents what the plan of action was, so that they had a firm idea of what was to happen.
- 9.44 We raised the vexed question of parental attendance at ward rounds with non-Executive members of the Trust Board. In general, Board members did not regard it as appropriate to comment on clinical practice unless specific matters requiring a decision were brought to their attention by the Medical Director. They were unaware that parents were excluded from ward rounds and suggested that they would be happy to review the policy and seek advice both from the clinicians and the Medical Director on whether it was necessary to continue this practice, given parents' strong desire to be present.
- 9.45 We were informed that there should not be any confusion about a change of approach when the doctor in charge was off duty as most of the work of the unit was conducted with a team approach. As one doctor noted: 'Intensive care children change from hour to hour and from day to day we often do change our treatment according to what has happened over the previous hour, and that is not necessarily changing all the orders that a previous

consultant had given'. However, one doctor said that they were still learning about teamwork: 'We had a view that you have surgeons, anaesthetists, and paediatric cardiologists, all of whom have some common but also different skills. And the hope would be that the service that the child needed most would be applied in that child's best interests. Depending on the personalities of the people that can work and work quite well most of the time, but there would be stresses. That's probably not sufficient now. I think there needs to be a head of intensive care unit who is responsible for the overall management who is an intensivist who is there on the site, with obviously interaction with the surgeons and the cardiologists. The surgeons have to trust the intensivist to look after their patients, and the cardiologists and the intensivists have to trust the surgeons to do a good operation without damaging the child. I think that is, in our unit, still evolving, because we have only just had intensivists'. As for consultant cover, in the absence of the child's named consultant it was the duty consultant who adopted responsibility for decisions taken. The patient's 'named nurse' had, we were told, a key role to play in ensuring that parents were kept informed and understood what was intended.

9.46 The nurses told us that although the intensivist was generally the consultant responsible for patients' clinical management in the PICU, one of the major issues in post-operative care was: 'having the same person speaking to families on a daily basis and that does not happen'. As happened 'everywhere', surgeons occasionally came into the PICU and expected therapy to be adapted to meet their particular requirements, which could be confusing for parents. The nurses tried to channel such changes in management through the ward round. One of the nurses said: 'It does become confusing for parents but that is part of the skill of the intensive care nurses that they can present that in a positive fashion to the parents In the main on the intensive care unit the bedside nurse is an effective communicator and pulling together the events'. The Director of Nursing commented: 'Nurses work under enormous scrutiny from parents; they are there at the bedside all the time talking, watching, seeing what is being done. It cannot but be a two-way thing'.

Follow-up care

9.47 We raised with the doctors whether it was realistic or reasonable for parents to be offered more time at outpatient consultations or at follow-up appointments after the child had died or been discharged from hospital. We noted that pressure of time in a busy clinic could make it difficult to establish a sense of partnership. We were told that, particularly in cardiology clinics, consultant staffing was such that this would not be easy to achieve. During the early part of the period covered by our Inquiry, when there were only two cardiologists compared to the present complement of four, they were '*busy and....at times over-stretched*'.

EVIDENCE FROM OTHER SOURCES

- 9.48 In approaching these issues we have considered many articles, books and other published work relevant to the Inquiry investigation. Some of these relate to partnership and communications between patients or parents and NHS staff. The September 1999 edition of the British Medical Journal (BMJ) was devoted to the topic 'Embracing patient partnership'. One of the papers (23) stated that '*partners work together to achieve common goals*', but that there were several hurdles to be overcome to eradicate paternalism and achieve successful partnership. One of these was that '*some patients may not want to have an active role thrust upon them perhaps because it allows them to avoid responsibility for the consequences of "wrong" decisions*'. Doctors needed to determine whether a patient wanted an active or a more passive role. There needed to be '*more and better training in communication skills*'.
- 9.49 In another paper in the same edition of the BMJ (24), it was proposed that 'a demonstrated capacity to engage in informed shared decision making is characterised by a set of necessary and sufficient competencies'. Those for the doctor included establishing or reviewing the patient's preferences for information and role in decision making, and presenting evidence taking these into account. Competencies for patients included articulating 'health problems, feelings, beliefs and expectations in an objective and systematic manner' and communicating 'with the physician in order to understand and share relevant informationclearly and at the appropriate time in the medical interview'. Challenges to achieving partnership included a perception that it would 'take too much time', that doctors 'already do that', and that some patients 'do not want to be involved'.
- 9.50 A paper, *Struggling with Public and User Involvement and Participation in the NHS* (25), was presented to a seminar organised by the BRI Inquiry. The author suspected that in the NHS as a whole *'wishful thinking and idealistic myth rather than widespread, useful performance continue to characterise this area'*. Much of the paper was concerned with participation and representation at the policy level where lay people might be

'overwhelmed by the complexity of a professionally-oriented, large organisation replete with jargon and esoteric vocabularies'. It assumed that, at the individual level, 'most users would expect to have some say in their own individual treatment'. There was 'only one thing worse than not being asked one's opinion, which is to be asked – and then ignored'. So far as health care professionals were concerned, there was 'still vast ignorance, indifference, and even fear of users as active participants or partners in health care'.

- 9.51 The Government's NHS Plan (5), presented to Parliament in July 2000, put patient partnership at the heart of its reforms. It remarked that: 'too many patients feel talked at, rather than listened to'. To bring about change: 'patients must have more say in their own treatment and more influence over the way the NHS works'. Although patients already have the right to see their medical records, much of the communication between professionals is not available to them, and the Plan states that: 'letters between clinicians about an individual patient's care will be copied to the patient as of right'. While this is to be welcomed, doctors convey information to each other in technical and often very complex terms, which are likely to mean very little to most patients or parents unless written in plain language. An organisational framework is to be put in place to underpin patient empowerment. This will incorporate a Patient Advocacy and Liaison Service to 'act as independent facilitator to handle patient and family concerns' in every NHS Trust. A Patients' Forum is to be established in each Trust 'to provide direct input from patients into how local NHS services are run'. A review of the process of informed consent is to be undertaken, which will address the 'need to change the culture to recognise the central importance of the rights of each patient'.
- 9.52 In Chapter 8 we considered the role of the child in decision making. We interviewed an external expert a nurse specialist working in a different field of paediatric nursing who had been involved in a multidisciplinary research project developing a framework of practice to give children choices in care. The aim was to empower children with their parents, conveying information in a way that enabled the child to gain in knowledge, understanding and confidence in order to make their own choices as they lived with their illness. The framework addresses: 'the specialness of each child; the child's views of themselves, their family and friends; the knowledge of their body and organ function; their disease; their experience of hospital, and their hopes and fears and expectations....we provide the child with the opportunity to increase their knowledge, to make some sense,

of what is happening to them and to help them develop confidence in contributing to decisions on treatment'. It was also important to provide parents with ideas on how to give explanations to their child, especially as some children could be as young as two. 'Giving parents and children choices more [often], which meant that they could say no a two year old will have something to say about the way they are treated in hospital.'

9.53 The external expert told us: 'Whenever we are talking and training and helping other people to do it we talk about the honesty and consistency; the care in using a sensitive age appropriate language; care in not using analogies and acknowledging uncertainties, because that is part of the honesty and the absolute trust. We do not make rash promises that cannot be fulfilled just to get an immediate effect of compliance; consistent information; in other words, we need to have good teamwork, communication, and the documentation of our work with the children is crucial if we are to continue this choice in everyday care and avoiding glib phrases like "We will tell you later" or "When you are a bit older you will understand that"'.

CONCLUSIONS

- 9.54 Communication problems arise in all areas of medicine and surgery, but it is important to recognise that paediatric cardiac treatment has features which make good communication even more important, and arguably more difficult. First, it is impossible to understand any of the conditions associated with congenital heart disease without an understanding of the normal functioning of the heart. What is more, the surgery and other treatments proposed are usually so complex and novel that even those parents with nursing or medical training are generally unfamiliar with them. Second, many children are diagnosed shortly after birth, at a point in their parents' life where they are under great strain, new parents in particular, adapting to the arrival of a new member of the family. In many cases the mother is still in hospital or still recovering from the birth, when she learns about her new baby's condition.
- 9.55 In addition to these problems, some parents are told that their child has a chromosomal abnormality for example, Down's Syndrome which they are conditioned to believe is a disaster for the family. Many were screened for chromosomal abnormalities and told they were low risk; some will have been prepared to abort the foetus rather than have a child with such a condition. Down's Syndrome is easily diagnosed when a child is born so, in

every case of Down's Syndrome heard by the Panel, the parents had had to adjust to this before they learnt that their child had a heart defect.

- 9.56 Poor communication underlies many complaints about NHS care. From the evidence we have heard, there is a clear gap between the perceptions of parents and those of the doctors. The latter acknowledge the pressures upon them but believe they are communicating effectively, whereas parents often feel they are not treated as equal partners in the care of their child. We believe that the accounts from the parents provide telling insights into how information was shared with or imparted to them. The early years covered by our Inquiry were characterised by much more paternalistic attitudes in the NHS than are generally found today. We are encouraged that, in general, present day clinicians at the RBH are striving to achieve tangible partnership, but they appear to have failed to convey this to many of the parents that came to see us.
- 9.57 Partnership is generally regarded as a relationship of equals, but in the NHS there is an unequal balance of power. This inequality is heightened in the delivery of paediatric cardiac services. The parents are in a state of shock and, generally, ignorant of the basic medical facts; the health professions, on the other hand, are doing their every day job to which they are thoroughly accustomed. The parents need to be able to feel that they have a unique and essential contribution to make in the partnership with the clinical team. Sharing information should not have to depend on the assertiveness or tenacity of parents. We believe that the nurses have a key role to play in acting as a bridge for the parents, and checking after a consultation that they feel comfortable with their part in the child's care. Cardiac liaison nurses, discussed in Chapter 22, will be a great asset in this respect. The language and manner of communication is another important factor; complicated information needs to be given in a way that can be readily understood and does not come across as patronising. The solution does not lie in trying to protect the parents from unwelcome information. Though well intended, that will usually generate suspicion and anxiety in parents who have the insight and awareness to know that all is not well with their child.
- 9.58 Any service that aspires to a holistic approach to care and paediatric cardiology and cardiac surgery is one such service must look upon the family's involvement in their child's treatment as one of the key outcomes in measuring how successful it has been in achieving its aspirations.

Day of operation

- 9.59 Many of the problems discussed with parents and clinicians have their origins in the difficulties of recruiting sufficient nurses in the PICU. The Panel has not examined PICU occupancy and staffing levels over the period covered by our Inquiry. Even so, we consider it reasonable to accept that pressures in the PICU are likely to have been the cause of most if not all the cancellations about which parents told us. The solution is not simply a question of providing more PICU cots, as the national shortage of nurses trained in intensive care would still restrict the extent to which those cots could be used. The doctors have voiced their own concerns about the consequences of pressures in the PICU, which cause distress for parents and children and make it more difficult to organise surgical throughput efficiently in a specialty where demand is heavy and, in many cases, urgent.
- 9.60 We would expect that whenever a child's operation has to be postponed, the surgeon would review its urgency in the light of other cases on the waiting list and discuss the matter with the cardiologist concerned. It is crucial that the parents are not left wondering and worrying about their child's condition; they should be contacted by one of the consultants within two days at most to explain what happened and when the re-scheduled operation will take place. A letter should also be sent to the GP, who will then be in a position to advise the family. No child's operation should be postponed more than once, unless there are clinical or other overwhelming reasons for doing so for example, if the child is not considered well enough for the operation to go ahead. However, the Panel noted that cancellation of surgery due to a lack of paediatric intensive care beds was a problem for most paediatric cardiac centres. The Panel believes that there is an urgent need to address this issue at a more strategic level, with the DoH specifying in a National Service Framework what level of paediatric intensive care beds should be designated and funded for paediatric cardiac services.
- 9.61 We are pleased to note the undertaking given in the NHS Plan to offer another binding date for an operation that has been cancelled for non-clinical reasons within a maximum 28 days or to fund the treatment at the time and hospital of the parents choice if this encourages the prompt re-scheduling of operations at the originating hospital. Otherwise the removal of a child to another hospital will compromise the consent process and continuity of care.

- 9.62 We accept also that a child's position on the theatre list can be affected by unexpected factors such as emergencies and complications during surgery on a child earlier in the list. Undue optimism or lack of foresight on the part of the surgeon can result in a child having to be pre-medicated twice and starved for much longer than would otherwise have been the case. There needs to be a realistic appraisal of what is likely to be achieved. The ward nursing staff must be kept in the picture so that they can keep the family informed and provide support. While understanding fully the concerns expressed to us by the parents, we make no criticism of the clinical team who have to try to balance the differing needs and urgency of their patients.
- 9.63 Lack of sensitivity to the parents' concerns before the operation can have long-term adverse consequences, particularly if the child dies or is neurologically impaired during surgery. Where possible, if parents are in the hospital, their child should not be pre-medicated and taken to the theatre without their knowledge.
- The Trust, which was unaware of the practice reported to us by some families of only 9.64 allowing one parent to accompany their child to the operating theatre, has agreed that both parents will routinely be able to accompany their child down to theatre, even where space in the anaesthetic room is limited. Lack of space in the anaesthetic room should be addressed when designing any new theatre facilities at the RBH or in the Paddington Basin development. The same applies to waiting facilities for parents on the day of operation. Most, but not all, of the criticisms relate to the period before the move to the new Sydney Street building in 1991. However, we are not satisfied that even today there is adequate accommodation for parents who may have to endure many hours of waiting while their child is in theatre. There should be a room, near to either the operating theatre suite or the ward or the PICU, which offers privacy but where parents can be offered support and kept A member of the nursing staff should have specific informed about progress. responsibility for ensuring that they are not overlooked and pagers should be offered to the parents if they wish to leave the hospital. We refer further to facilities in Chapter 11.
- 9.65 One clinician observed that the RBH was not unique in the fact that consultant surgeons did not routinely see the parents and child before surgery, although they tried to do so. We believe that this is unacceptable: the service standard should explicitly state that the surgeon sees the parents of all children awaiting surgery in order to explain what is intended, particularly if there was no outpatient consultation with the surgeon before

admission. We endorse the view expressed to us by the clinicians that the surgeon who conducted the operation should see the parents as soon as possible after the operation unless there are extenuating circumstances. This is all the more vital if there has been an untoward occurrence during surgery. We were astonished to hear that some parents report that they were not given such information. It is imperative that doctors remember that parents have a right to know about anything affecting their child's care and welfare. Failure to see the parents before and after surgery undermines trust between doctors and parents.

Post-operative care

- 9.66 The nurses we saw made it clear that an adult hospital like the RBH lacks the ethos and spirit of a specialist children's hospital, where parents are welcomed as partners in their child's care. We find this lack of a child-centred focus disappointing, since many of the doctors at the RBH are involved exclusively in the care of children and should know how to communicate with them and their parents. The need to ensure that paediatric services at the RBH are focused on the needs of children and their families should be a priority of the Trust. While the clinical staff emphasised the value of parents' observations, many of the parents felt that their views were dismissed. We cannot at this distance, without contemporaneous record, determine to what extent the parents' concerns were well founded, but we were disturbed by the frequency and consistency of these parents' experience of feeling marginalised. If what we have heard from parents is a consequence of the ethos of the adult services permeating those for children, the Trust has a major problem to address, especially as it is feared by patients and clinicians alike that the warm friendly spirit of Harefield is in danger of being compromised by the merger (see Part Three). There is however an alternative view that the empathy generated by Harefield will infuse the new unit very much to its advantage.
- 9.67 The key to successful partnership lies in the training of medical, nursing and other staff in communication and listening skills. This can be difficult, but is probably even more necessary, in respect of agency, bank or locum staff. The key to effective partnership lies not just in experience and competencies, but in having the time to develop a relationship with the family. We recognise that resources are scarce in relation to total demand and that priorities have to be determined, and we acknowledge the workload pressures in the PICU but we wish to underline the importance of entering in the medical or nursing records all

concerns expressed by parents, so that these can be followed up in any future discussion about their child's care. Partnership will not be achieved unless it is accepted by managers and doctors that resources and time must be provided for a holistic approach to the child and family and that good clinical care necessarily requires excellent communication skills. Communication is not an optional 'add on'. Doctors – and nurses and other members of the clinical team – need to establish with parents how much they wish to be active participants in the care and treatment of their child.

- 9.68 Some families complained about what they felt were rudeness or intimidatory remarks by some of the doctors. We took this up with the individuals concerned who denied the allegations. Many of the events occurred some years ago and the Panel is unable to ascertain whether or to what extent the complaints are justified. Nevertheless, the force with which the parents recounted their experiences suggests a regrettable breakdown in communication and trust between doctors and these parents, which has resulted in immense distress and hurt. The type of rudeness described by these parents, if it occurred, is unacceptable. Some doctors have acknowledged that they may well have appeared rude or brusque under the intense pressure of their daily work, dealing with many patients who are desperately ill. We accept that, as in any walk of life, it can be difficult to remain calm and professional when things are not going well, but frank and open discussion should never spill over into intemperate behaviour. An apology freely given and accepted at the time could put an end to the matter.
- 9.69 We also recognise that many doctors can experience problems in conveying 'bad news' at the end of a very busy or stressful operating list or clinic. They may suffer their own distress and disappointment at the outcome of treatment and be unable to communicate as effectively with parents as they would wish. Nevertheless, all clinicians should strive to set and maintain high standards in respect of their communication and interaction with parents.
- 9.70 Regarding transfer of care, we can well appreciate that the necessary involvement of so many clinicians surgeon, cardiologist, intensivist and often many others can cause parents considerable confusion and anxiety about who is in charge. The essence of paediatric cardiac management is that it is founded on teamwork. Primary responsibility may change as the patient moves from diagnosis, through surgery to intensive care and, ultimately, to discharge. The parents should be told who, at each stage, is in overall charge

of their child's care. It also needs to be explained why an apparent change in the treatment regime is being made, as parents might otherwise interpret it as reversal of a decision rather than a reflection of changes in the child's clinical condition and needs. The new cardiac liaison nurses will complement the role of PICU nurses in explaining the child's treatment to the parents.

- 9.71 Parents felt strongly that they should not be excluded from ward rounds, a view shared by the nurses. Some doctors were content in principle for parents to attend ward rounds whilst others foresaw some practical problems with this, such as maintaining confidentiality and the use of the ward round for teaching purposes. We can see no justifiable grounds for excluding parents who have asked to remain; where debates on progress and treatment options are required which must have freedom of expression, these should take place separately after the ward round as in the case of adult patients. The Panel was alarmed to hear that disagreements between consultants occasionally flared up in front of parents. There are bound to be occasional differences of opinion, and debate can be unavoidable where the child's condition indicates no clear way forward. In no circumstances, however, should rows take place in front of parents, whose anxiety can only be heightened by such behaviour. The doctors involved should draw back and continue their discussion in private.
- 9.72 We consider that the RBH, and the NHS more generally, should encourage parents who are present to attend ward rounds, for several reasons. First and foremost, care is a partnership between parents and the clinical team and that relationship should be founded on openness and honesty. Second, the parents have an invaluable contribution to make from their own knowledge and observations of their child, and they need to feel that this is taken into consideration. Third, their presence will enhance their subsequent understanding of future treatment options and reduce the potential for anxiety which exclusion from discussion brings. It is also relevant that in an adult ward the patient is present when the round takes place at the bedside and even in intensive care; parents should be treated no differently.
- 9.73 To the extent that the clinicians' reservations have validity, there are ways in which they can be overcome. We see no reason why any criticism of clinical management, or matters that are rightly confidential, should not be discussed in the ward office or elsewhere at the end of the ward round. Ideally a suitably equipped seminar area should be incorporated into design plans for PICUs for this purpose. Disagreements about future management can

and should be conducted in a professional manner such that no distress is caused. As for ensuring that the parents understand fully what has been said and agreed, the child's named nurse – or, if that nurse is not present, the senior nurse attending the round – has a role to perform in talking things through with them. The consultant or another senior member of the clinical team should also explain the outcome to them afterwards. We should add that, while it should be open to the parents to remain during the ward round, it must also be their choice not to do so. Time has to be allocated in order to ensure that parents understand all they can; the needs of postgraduate teaching must not interfere with this process. We believe that the RBH must find ways of reconciling the needs of a teaching establishment with parents' concerns that they are being overlooked by the demands of postgraduate students.

Follow-up care

- 9.74 Doctors need to remember that once the child has left the hospital after a consultation or treatment, the parents have the continuing responsibility of looking after the child, answering questions and responding to anxieties. If they do not have or understand the relevant information and advice it can seriously undermine trust and make the child more, rather than less, anxious. It is important also that the GP, to whom the parents may turn for advice, is kept fully and promptly up to date. Not all GPs are familiar with how to manage congenital heart disease at primary care level, so this is a subject that needs to be covered in their continuing professional development.
- 9.75 As we have said, we are not persuaded that simply to copy to parents any letter between clinicians is going to be helpful. Professionals in any sphere need to communicate with each other in precise and often highly technical terms. The price of real partnership is that the doctor must provide parents or patients with an accompanying explanation in terms that they too can understand. The Panel noted that this would have resource implications in terms of increasing the need for medical secretaries and adding to the demands on the consultants' already impossible schedule.

RECOMMENDATIONS

The Panel recommends that:

- 19. The Department of Health conducts further national discussions about the right, under the NHS Plan, of patients to receive copies of letters between clinicians, with the aim of ensuring that information is conveyed to patients in a meaningful way without impeding effective communication between professionals.
- 20. The Department of Health addresses urgently the recruitment and retention of nurses trained in paediatric intensive care.
- 21. The Trust ensures that, except in a clinical emergency, the surgeon always see the parents of any child before the operation takes place and report post-operatively on surgery.
- 22. The Trust ensures that, where a child's operation is postponed, the parents and the GP are contacted within two days to explain the postponement and the proposed arrangements and timing for a new admission date.
- 23. The Trust ensures that the parents be informed without delay, personally by the surgeon wherever possible, of the reasons for any change to the operating list affecting their child, and of any untoward occurrence during the operation.
- 24. The Trust ensures that its plans for the transfer of services from Harefield Hospital to the RBH builds on Harefield Hospital's family-friendly facilities and atmosphere; specifically that there is provision for a waiting room for parents while their child is undergoing surgery, and for a room in or adjacent to the PICU for parents who wish to remain near their child.
- 25. The Trust reviews how paediatric services can best be focused on the needs of children and their families, and can record key concerns and discussions with parents about the clinical management of their child.

- 26. The Trust ensures the named nurse informs parents of any change in overall clinical responsibility for the child's medical management.
- 27. The Trust reviews its policy of excluding parents from ward rounds and ensures that, as a matter of general policy, parents who are present in the hospital when a ward round takes place are welcome to attend.
- 28. The Trust ensures that, before a child is discharged from hospital, the ward or PICU, the designated member of nursing staff on duty that day tells the parents what followup arrangements they can expect and checks that the parents have a sufficient understanding of their child's care needs.
- 29. The Trust asks patients and parents whether they experienced real partnership in care and what obstacles to effective communication they encountered, in future satisfaction surveys and audits of service quality.
- **30.** The Trust's staffing arrangements and booking systems make due allowance for time to develop trust and understanding with patients and parents.
- 31. The Trust ensures that, at the start of any consultation, patients and/or parents be asked whether they agree to the presence of postgraduate students, and that all those present wear name badges, are introduced to the patient and/or parents and have their roles explained.
- **32.** The Trust's plans for the redevelopment of facilities for children's services give consideration to including video linking for teaching purposes.
- **33.** The Trust includes communication skills in the training and development of clinical staff at all levels and in all disciplines.

10. WHEN A CHILD DIES

INTRODUCTION

10.1 Children with congenital heart disease have a condition which, without treatment, is inherently life threatening. As we discuss in Chapter 8 dealing with pre-operative consent, it is both natural and understandable that parents will hope – even expect – that heart treatment at the RBH will remove that uncertainty about the future. When the child does not survive the operation, or dies during the post-operative period, the sense of loss is made all the more unbearable by the expectation beforehand of a successful outcome. Realistic discussions with the family before the operation, and openness and sensitivity after a child has died, are critical to the process of helping parents come to terms with such a terrible loss. Failure to deal with the situation adequately can result in unresolved grief over many years.

CONCERNS EXPRESSED BY PARENTS

The moment of death

10.2 The majority of children whose cases were reviewed by the Panel died after suffering a cardiac arrest in the PICU. In most cases the parents were asked to leave the PICU while staff attempted to resuscitate their child. They were not invited back into the unit until after their child had died and staff had removed the child from life support equipment. In a few other cases parents were able to stay but could not cradle their dying baby, because the baby was still connected to equipment or the chest was splinted open. As the following comment shows, parents found this an extremely harrowing experience: *'Everyone is just standing and staring, watching the numbers drop, drop, drop. A nurse gave him heart massage and they were injecting stuff into him and [the doctor] said "Do you want to hold him. Holding him meant stopping heart massage, and the massage went on and on His heart rate was down to 10 or 20 and he said to me again "Do you want to hold him?" and eventually I said "Yes I do, I want to hold him?" and they stopped massaging and I couldn't even hold him. All I could do was put my body over his because I couldn't pick him up, because of all the wires, and he died about a minute later'.*

The death of a child is one of the supreme 'adverse outcomes' and it may in some cases result from an avoidable event in treatment. We felt that in some cases not enough appeared to have been done to identify what had caused the death and to learn from it where appropriate, as the Chief Medical Officer's report (8), referred to in Chapter 3, suggests should be done. We appreciate that a death is a very distressing event for doctors and other staff, and that sometimes emotion can overcome good management, but although staff said to us that they had talked about the death repeatedly in an attempt to work out what had happened, this was not always conveyed as such to parents.

10.3 The moment of a child's death will stay with parents for the rest of their lives. The trauma of the event may lead parents to view the staff's response to death as cruel and uncaring when this is the opposite of what was intended. One mother remembered the clinicians' handling of her son's death in an entirely negative light and though we cannot substantiate such memories they demonstrate the force of feeling that parents sometimes bear: '*They all just stood there and one by one they just walked away. The first thing they say was "Do you want some hand prints?" and I thought don't talk to me about hand prints' and they were so insensitive Eventually I held him. My husband held him. All my family were there and eventually they called the surgeon to close his chest'.*

Communicating bad news

- 10.4 A significant proportion of the parents felt that they had been given inadequate information or explanations about why their child had died. Some felt that the news should have been broken to them by the consultant, rather than delegated to a junior doctor or nurse. One said: '*I know how awful it is to break bad news, but really one of the doctors should have sat down and explained what happened The nurses were great and it is dreadful for them*'. One child's parents remember being told simply 'these things sometimes happen' when their child died after a failed resuscitation attempt. Several parents made complaints to the Panel of insensitivity by staff after their child had died. One parent remembers being asked: 'Do you want to come and see [him] now? By the way, he has just passed away'. In this case, the unfortunate doctor was not aware until they entered the ward that the parent had been unaware that his child had died.
- 10.5 Some parents felt unprepared by staff for what could happen: 'We were told to go for a walk, it could be a while. We went back, they took us into the staff nurses' office on the

ward and said that a mistake had happened. "It's not looking good. If you want to use a telephone you can". Then ten minutes later or so, [the doctor] comes up and says to us, exact words, "Things are not looking too good, I'm afraid he did not make it". All in one sentence, no breath, no nothing'.

- 10.6 Others felt they had to battle to get the truth out of the doctors: 'So we came back and at 11 o'clock I phoned through to intensive care to see if he was back, or to see how he was getting on and they said, "No, he is not back, give it another half hour to an hour", so we did. We phoned back at 12 o'clock and asked how he was, "Is he back?" "Oh no, if you just wait where you are he is coming up to his little bed now".... We go through the door and the surgeon comes out and asks us to come into a little room and I said to him "He is dead, isn't he?" And he said "If you calm down and sit down", and I said, "He is dead, isn't he?" And he said "Yes". I lost my temper. I swore, I shouted, I went ballistic, because they just told us he was all right. It is sick, sad'.
- 10.7 Some parents told us that in the PICU staff would avoid looking them in the eye and, in one case, the parents commented to the Panel: *'The minute he died, they could not wait to get us out of the unit'*. The parents of a child who died on the first day of the opening of the HDU told us that the nurse seemed to them very inexperienced, and remembered that there were difficulties and delays in bringing the resuscitation equipment in. Not only did that heighten their trauma, it also left them wondering whether their child's death might have been preventable. Again, we cannot validate this recollection, only convey the parents' experience.
- 10.8 In some cases, we were told that the parents left the PICU without anyone checking that they were all right, or were in a fit state to drive home. The parents in one case, on coming out of the nurses' office soon after their child's death, were shocked to see that 'on the board they just wiped his name off'. Several received a telephone call from RBH during the weeks after the child's death, which showed that the member of staff was unaware of what had happened. In one such case the parents were telephoned by a secretary who said it would be 'appreciated if you would bring [your child] to the Brompton for [visiting doctors from abroad] to look at her'. Six weeks later they received a letter asking them to bring their daughter to a medical conference. What was even more tragic in this case was that the child had written a note, to be given to the staff if she died, thanking them 'for all you have done to try to save my life'. In another case an appointment was received one

week after the child's death, asking her to attend on what would have been her second birthday. Another set of parents were asked, two months after their child's death, to take him for examination by medical students to the hospital that had made the original referral to the RBH.

10.9 Not all the comments made to us were adverse. The parents in one case said, despite all their concerns, that there were 'a lot of very good things at the Brompton We met some fantastic nursing staff and some very good doctors'.

Follow-up consultation and bereavement support

- 10.10 There are two ways in which the RBH provides support for parents after their child dies. The first is a follow-up meeting with the consultant. The second is attendance at a regular bereavement group, where parents can get together with trained counsellors a few weeks after their child's death.
- 10.11 Not all the parents whose cases were reviewed were offered the opportunity to meet the consultant. Practice at the RBH is for the clinical team to hold a 'mortality meeting' to evaluate the management of the child's treatment and find out why the child had died. We heard that, in one case, the parents were not told when the meeting of the clinical team was to take place or what conclusions had been reached. In another, at a follow-up meeting with the consultant, the parents were told that: '*he would get back to us [after the mortality meeting] with their findings …. We heard nothing*'. At one hearing we mentioned to parents that there had been a mortality meeting attended by 35 people from the RBH and the referring hospital; they said: '*We didn't know*'.
- 10.12 Parents' experiences and expectations of follow-up bereavement support by the RBH varied considerably. A parent in one case said: 'I cannot imagine somebody else sitting there telling me how I feel. It is not their child'. Similarly, another parent said: 'I think we were both brought up anyway that if you had a problem, you got on with it and you don't talk about it. That's how you tend to cope with it'. On the other hand, another parent commented: 'We were left to our own resources. We did not hear from the Brompton at all Perhaps the opportunity should have been given to us to come back and reflect and just talk about it and help with the grieving process. I think I would probably have liked somebody to contact us within maybe a month or so'. For the parents of another child, to

receive an invitation after one month to attend a bereavement meeting would have been too soon, and in one case the Panel was told that the parents could not have afforded the cost of attendance as they lived some distance from the hospital.

- 10.13 In several cases we were reminded of the impact of death on the child's siblings as well as the parents, and the difficulties of providing appropriate support. One parent told us about the distress experienced by all three of her remaining children: 'My daughter left home and went and moved in with her Nan, because she couldn't cope. She was the eldest one....she was 13. She moved out about two months after he died.....The worst one I think was probably the middle one [child's name]. He never speaks about it. Won't speak about [the brother who died]. You all get upset. [The third brother] just sort of ignored the whole thing, just totally ignored it, even the funeral'. Another parent said: 'To lose a child is obviously the worst thing that anybody could go through in their lives. Two years have gone by and we just live every day for every day really. The only thing that keeps us together is our other son [who was nine when his brother aged twelve died post-operatively]. We go to the cemetery every Sunday morning and he will not get out of the car'.
- 10.14 Some parents were distressed by being offered repeated invitations to attend a bereavement meeting or group. One family commented that returning for a meeting to the place where their child had been before going to the operating theatre had brought back agonising memories. The presence in the room of letters and photographs of children who had survived their treatment and, on the table, the child's case notes marked 'deceased', had seemed to them insensitive. The Panel was asked by several parents why meetings could not take place away from the hospital.

Post mortems

- 10.15 There are two types of post mortem:
 - A hospital post mortem where, although the cause of death is known, the medical staff wish to discover further information. Written consent from the next-of-kin needs to be obtained.
 - A coroner's post mortem, where the circumstances of the death fall within certain prescribed categories, or the medical staff do not know the cause of death. Consent

is not obtained at the hospital, as it is for the coroner to decide whether and when to call for a post mortem and, occasionally, to conduct an inquest. The coroner's officer is responsible for making the arrangements and notifying the parents and others.

- 10.16 Although post mortems are carried out to provide more information to medical staff, they are of critical importance to parents in understanding why their child died. As one parent said: 'We had gone home with a perfectly healthy baby, as far as we were concerned, and this happened in a space of ten days from giving birth to having the death of a baby'.
- 10.17 Yet evidence from several parents suggests that it was not routine for them to be informed of the outcome of a hospital post mortem or given more than the minimum necessary information. One parent, herself a doctor, told us: 'It was not until I saw the post-mortem report a few weeks later when the GP gave me her notes that I discovered that at 9.30 she had had a hypertensive crisis and actually needed resuscitating and external cardiac massage'. In another case the involvement of the coroner was not adequately explained, and we also heard that neither the hospital nor the coroner's officer told the parents of one child when the post mortem would be held, or its outcome. One parent, who wished to consider donating her son's cornea as a positive outcome from his death, said that: 'It just wasn't well handled I think that could be handled much more sensitively or positively'. These parents were also concerned that the consent form they were asked to sign for organ donation was in fact a form consenting to a post mortem examination, 'which was somewhat inappropriate as this was signed the night before surgery'. Another parent, when giving consent to a limited post mortem, had told the staff: 'We said we wanted a limited post mortem. I said "His chest already has this wound . If you are looking at his heart and lungs I do not want any other wound" and they agreed to it. When I held him again in the Chapel of Rest the day after the post mortem the wound from the post mortem was from his throat to his groin. I specifically said "Can this be done without another incision". They said, "Yes"'.

THE CLINICANS' RESPONSE

The moment of death

10.18 Regarding the immediate aftermath of the child's death, a doctor said: 'You have to put on a certain face and act, but when you walk away you feel terrible. In reality cardiologists remember all their deaths, even 20 years later, including the near miss cases You feel psychologically shattered because the child has died'. A consultant told us that staffing levels needed to be sufficient to enable the named nurse to spend an hour or two with the family. The current PICU did not provide a suitable environment for parental support. The Panel raised this issue with the Trust's Director of Nursing, and with two nurses from the PICU. We were told that the staff tried 'to give the parents quiet time with their child, and I know that this has been misconstrued and that parents have felt that we are sort of pushing them out of the way'. The Trust's procedure following the death of a child includes the instruction: 'Give the family all the time they need to be with their child'. The staff tried to take account of parents' differing needs. The nurse who had cared for the child retained that responsibility until the child left to go to the mortuary. Unlike some other hospitals, such as at Guy's and St Thomas' NHS Trust, where a full-time nursecounsellor is based on the PICU, the RBH does not have a designated bereavement specialist. In their meeting with us the nurses speculated that some of the problems recounted by parents might have been due to the relative inexperience of the staff available: 'even if you have the most detailed protocol in the world, if you get a member of staff who is inexperienced, or stressed all that goes out of the window'. The Director of Nursing considered that rather than introducing a new role into the PICU, more attention should be focused on the role of all staff involved in the care of children. In her view, the greater priority in relation to new posts was to develop a community-based service with liaison nurses rather than funding a specialist bereavement nurse in the PICU. We discuss this further in Chapter 22 about cardiac liaison nurses.

Communicating bad news

10.19 The doctors felt that the way in which parents were told about their child's death had improved over the years, but acknowledged that there was still room for improvement. A number of reasons were given for the perceived shortcomings. One consultant said: 'One always feels somewhat of a failure. Often times the child who died you would yourself

develop some level of attachment to them and you would have developed a certain attachment to the family It was less than what the parents were feeling, but you had your own feelings that you had to just abandon while you spoke to the family. I think we are very bad in general at telling somebody that their child has died, because it is not something one can ever get used to. The Brompton was as good as any other hospital in which I have worked'.

- 10.20 A cardiologist acknowledged that the death of a child was not always well managed, but that the doctor had to 'talk to the family, support staff, all of whom may be feeling very down. If somebody dies in the catheter lab whom I have been catheterising, I go and speak to the families, but it is devastating at every level. If there is a death I think that both surgeons stop operating, although it used not to be the tradition, they would go on and do the next case after. That doesn't happen now, it used to'. In some cases the child died after an operation that took two or three times as long as had been expected. It was for the surgeon to tell the parents, usually accompanied by a nurse. A surgeon commented to the Panel that it was not appropriate, just after the operation, to go into the 'nuts and bolts' of why it did not work. The parents would be trying to come to terms with the news of their child's death, and it was better for the nurses to take over, as they were 'very good at counselling parents in grief'. Another consultant said that: 'there should be a location away from the PICU in which parents can rest and also receive support The current PICU area is unsuitable for this purpose'.
- 10.21 The Medical Director acknowledged to us that training and support in breaking bad news was probably better for nurses and others than for the medical staff, but he pointed out that: *'there are some people who are and will remain better at this than others'*.

Follow-up consultation

- 10.22 The approach of consultants to offering a follow-up appointment varied considerably:
 - 'It would be taken as read that it would be possible for them to see me should they ask for it.'
 - 'I usually write a week or so after, saying we're very sorry, you may never want to come to the Brompton again, which is quite understandable. But if it would be of

help, I would be very pleased to meet either at the Brompton or where I do an outreach clinic.'

- 'I must say few of the parents who I have offered the opportunity to come and talk to me again about the events that led to their child's death have actually taken up the opportunity I think the same offer comes from the cardiologists as well and maybe they go back and see the cardiologists.'
- 'A follow-up consultation is imperative as it is difficult for parents to understand information when offered immediately after the loss of a child.'
- 'I always offer parents an appointment to come and see me, usually six weeks or so later, or at another time at our mutual convenience ... I am not sure that protocols can be strict in timing.'

Post mortems

- 10.23 When we raised the parents' concerns about post mortems with the clinicians, we were told that: 'consent should be obtained by a member of the team who is senior enough to understand all the issues'. It was better to avoid seeking consent in the period immediately after the child's death. One consultant at the RBH suggested that there probably needed to be a 'more focused and agreed way of handling that It would probably be better if we did not have to ask that question ten minutes after the child had died'. Another thought it appropriate for the hospital staff to tell parents why a referral was being made to the coroner.
- 10.24 We also asked the nurses about arrangements for obtaining consent to a hospital post mortem. One said: 'we have written information about consent for post mortem, which we have given out to bereaved families, but obviously shortly after your child has died is not the time to be dishing out literature I would say at some stage we may ask [a member of the medical staff] to come in and ask you about a post mortem. If it is not a coroner's post mortem I always tell them that they have the right to say no'. Another commented: 'you can imagine actually having to ask that question is very difficult and if you have been described as being abrupt in a way you can understand'.

THE TRUST'S POLICY

Follow-up consultation

- 10.25 Although practice varied between one consultant and another, we understand that the Trust's policy is for parents to meet the consultant six weeks after the child's death, as by then the results of any post mortem should be available. We note that a similar policy is in operation at, for example, the John Radcliffe Hospital in Oxford, where the ward staff inform the GP and health visitor immediately about the child's death, and ask them to visit the family if necessary. The Trust's policy states that the meeting with the consultant should be held away from the ward area, usually in the consultant's office. The experience at Edinburgh is that such discussions can take up to one and a half hours and parents often need to be seen on more than more occasion. A report on the RBH's bereavement service, reproduced at Appendix 8, states that additional parents' rooms have been requested as part of the development of paediatric facilities, which the Trust believes would be a better environment for follow-up meetings with parents.
- 10.26 We have seen that guidance from Health Services Accreditation on Service Standards for Care of the Dying (26) includes the following: 'Parents should be given an appointment to return to discuss the circumstances of the [child's] death and result of a post mortem with a member of the paediatric staff' and 'It will be important for [parents] to retain contact, at least initially, with a member of the paediatric team that cared for their child'.
- 10.27 The Trust Chairman confirmed that there was always an 'internal inquiry' after the death of a patient in hospital. He was referring to the mortality meeting, when all members of the clinical team review together the circumstances surrounding the death of a patient. The Medical Director confirmed that mortality meetings were seen as an essential component of the Trust's approach to clinical audit, which is detailed in Chapter 25.

Bereavement support

10.28 At the RBH there is a multi-disciplinary team whose role is to support the parents of a child with a life-threatening condition, and the parents and siblings of children who have died. The team comprises a paediatric social worker, paediatric psychologist, nursing and play specialists and others. The Trust's report on the current bereavement counselling

service operated by that team (see Appendix 9) states that: 'Following the death of a child, the parents are assisted by the PICU staff with such matters as registration of the death and any practical issues that they may encounter' and 'Before leaving the hospital, parents are given information both orally and in the form of the Hospital's booklet "When Your Child Dies" '. Parents are also told about the bereavement group meetings.

- 10.29 The Trust's report shows that between June 1994 and June 1999, 151 children had died while an inpatient at the RBH (see also Appendix 9). Only 43 (28%) of the families had attended a bereavement group meeting, one possible reason being the RBH's wide geographical referral area. In future, families are to be offered help with travel costs. The number of families attending the meetings ranged from one (13 groups) to seven (one group), the average attendance at each meeting being three. Except for those who had informed the hospital that they did not wish to participate, all English-speaking families were encouraged to attend as often and for as long as they felt necessary. Eighteen of the families attended only once, others attending for as many as 31 meetings. The Trust has recognised the inadequacy of provision for families who do not speak English, and in future a translator will be provided. The Chief Executive remarked that a 'five days a week' arrangement was not an adequate basis for running a bereavement service. We agree with him.
- 10.30 Training is provided for staff on how to deal with bereavement. We have seen the programme for a Bereavement Study Day, which covers a wide range of issues such as grief reactions, what to say to parents, and support for both parents and staff. It is open to all staff. We have seen from the Trust's report that bereavement training, at present attended mainly by nursing staff, and instruction on how to break bad news are to be made available to all members of the multidisciplinary team.
- 10.31 The Trust is currently updating its existing policy on bereavement support; this will take account of our findings and recommendations.

ORGAN RETENTION

10.32 Even where the family has managed to live with the death, the subsequent discovery that part of the child's body was retained after a post mortem re-awakens their pain and distress. The retention of organs after a hospital post mortem is an issue that has caused

considerable public concern over the past year. It emerged as an issue in the context of the BRI Inquiry and at other centres such as Alder Hey in Liverpool, but after our Inquiry was established. Nevertheless, the question of organ retention was raised with the Panel by parents in four RBH cases, and one Harefield case. To some families the discovery that the body they had buried was, to them, 'incomplete' was extremely distressing. One parent said: '*I have still not had a proper burial for [my child]*. It is not over now'. In another case where the parents had consented to removal of the cornea for donor purposes, the parents said: '*no one ever came back to us and told us whether that had been done or not*'.

10.33 Establishing whether an organ was retained in individual cases was not part of our remit and so we referred parents directly to the RBH management for specific answers to such questions. Although it was not for us to find out what had happened, we were able to tell one concerned family that none of their child's organs had been retained.

Policy guidance

- 10.34 The Bristol Royal Infirmary Inquiry issued an Interim Report on the *Removal and Retention of Human Material* (27) in May 2000. It provides a comprehensive review of the context within which the conduct of post mortems and the retention of human material took place in the UK. It states: '*Parents and the public were unaware that human material was routinely taken and used for a variety of purposes Fundamentally, there was a social and ethical time bomb waiting to go off*'.
- 10.35 The conduct of a hospital, as distinct from a coroner's, post mortem is governed by the Human Tissue Act 1961. The BRI Interim Report makes clear that, although the consent of parents is not required under the Act, such post mortems are commonly referred to as 'consent' or permission' post mortems. It also points out, contrary to what parents would suppose, that: 'the body, on death, does not become property and cannot, therefore, belong to anyone'.
- 10.36 The Interim Report referred to updated guidelines published in March 2000 by the Royal College of Pathologists (28). It regards the use in those guidelines of 'agreement' to describe the parents' involvement in the process as imprecise, the BRI Inquiry preferring to use the word 'consent'. The BRI Interim Report doubts whether guidelines *'issued by the*

very professional body seen by some as having lost trust, will suffice to recapture this trust'. It therefore recommends that such guidelines should come from Government.

- 10.37 Also in March 2000, the Chief Medical Officer issued 'interim guidance' (29) requiring the chief executives of NHS Trusts to put its provisions in place pending the final report and conclusions of the BRI Inquiry. At the time of writing this report, further guidance has not been published. Under the interim guidance, NHS Trusts are now required to designate a named individual who will provide support and information to families of the deceased where a post-mortem examination may be required. The guidance stipulates that this person should be trained in the management of bereavement and in the purpose and practice of post-mortem examinations. The designated individual is to be responsible for, among other matters, obtaining consent to post-mortem examination through a signed form which provides clear written information about:
 - What the examination entails.
 - Which organs and tissues may be retained and why.
 - How this might impact on the funeral arrangements.
 - Whether archiving for research or legal reasons is required.
- 10.38 Relatives are to be given time to consider '*what will take place and the opportunity to ask questions and talk the issues through before the post-mortem examination is carried out*'. The interim guidance emphasises that the word 'consent' is used to reflect everyday usage of the word, rather than any legal meaning or implication.
- 10.39 In October 2000 the British Medical Association issued interim guidance underlining the importance of obtaining consent before carrying out a hospital post mortem (30). The guidance, whilst welcomed by parents' groups, provoked concerns, particularly among pathologists, that this might lead to a significant reduction in the number of such examinations, to the detriment of research and the care of patients in the future.
- 10.40 In January 2001, following publication of the Royal Liverpool Children's Inquiry into the removal, retention and disposal of human organs and tissues (31), the health secretary announced a series of remedial measures. These include the establishment of an independent commission to oversee the cataloguing and return of organs retained by hospitals in England; a new law on informed consent; a review of the coroner's system;

and the employment of bereavement counsellors by hospital trusts to help relatives and champion their interests.

The Trust's policy

- 10.41 The Trust gave us their December 1999 press statement in response to enquiries about organ retention, which we forwarded to the relevant families. It states that any hearts and lungs retained by RB&HT are used solely for research and/or teaching purposes. '*The post-mortem consent form in use at our hospitals makes clear to the family both what they are and, even more importantly, are not permitting our doctors to do including the removal and retention of organs to help develop treatments to save other lives In earlier days, especially in the 1970s and 1980s, the law did not require the consent of patients' families before removing organs for research purposes, nor was it common practice for hospitals to seek that consent.... Today, no organ is retained without explicit information to and consent from parents.'*
- 10.42 The Trust's *Guide to the Post Mortem Examination*, dated April 2000, reiterates this: 'With your written consent the pathologist may also retain organs such as the heart and, in exceptional circumstances, the brain for later, more detailed examination If you wish to know further details about the procedure, please speak to your baby's or child's doctor or ask to speak to the pathologist'. The Guide explains that organs are retained to help other children in the future and to enhance the education of surgeons, paediatricians and nurses. On the duration of organ retention, it states: 'We would normally ask to retain it indefinitely beyond the time needed for diagnosis If you do not wish us to retain the organ indefinitely, we may ask you to allow us to retain it for up to two months'. The Guide concludes by explaining how any organ that is retained for only a limited period can be disposed of in accordance with the parents' wishes.

CONCLUSIONS

10.43 The perceived lack of sensitivity by staff in managing a child's death was a recurring theme in the concerns expressed by the 20 families whose child had died. It was clear to us, and not surprising, that the clinicians found this an immensely difficult part of their work. Medical and nursing staff are aware of the needs of the parents for information and understanding, but reminded us also of the distress and tensions which they themselves

experienced at the loss of a child whom they had been treating, perhaps over a period of months or even years. We recognise that breaking bad news is never easy, and that even the most empathetic, caring and experienced professional will not get it right all the time. Nevertheless we believe that on some occasions this may have resulted in an apparent brusqueness which, whatever the pressures, is not acceptable. It is also the case that every person being given bad news reacts differently – some accept the news quietly, others are open in their distress, whilst others still will express anger. Someone inexperienced in encountering such a situation may fail to respond appropriately, which may make the resolution of grief more difficult.

- 10.44 Wherever possible the responsibility for telling parents about their child's death during surgery should lie with the consultant or senior surgeon carrying out the operation. That should be done as soon as possible, in a room where the parents have privacy, and a nurse should be present to stay with them if that is wanted. We understand that, at the Royal Hospital for Sick Children in Edinburgh, the policy is that the parents of a child who has died should always be seen by the relevant consultant. Where the child dies after surgery, for example in the PICU, the responsibility lies with the most senior member of the clinical team available at the time. That is because the relevant consultant might be off duty, or involved in another clinical commitment, such as an operating list or attending a peripheral clinic away from the RBH. What is critical is that there should be minimal delay, and that the task should not be left to a junior member of staff. The family's GP and the referring paediatric department should also be informed within three days in order to ensure appropriate support locally. No bereaved family should have to endure the agony of receiving a telephone call or letter to arrange a hospital appointment for a child who has died.
- 10.45 Intensive care nurses are in short supply throughout the NHS, so there will have been times when staff in the PICU could not give parents the time and attention that they required despite their best intentions. We understand that agency nurses have been used in this and other wards and departments. They may not always have had the training or experience to handle bereavement, or be aware of the hospital's procedures.
- 10.46 Despite the Trust's policy regarding follow-up visits, this practice is not uniform. Many children with congenital heart disease will have been under the care of both a cardiologist and a surgeon. In our view it is their joint responsibility to discuss and agree who should

offer the follow-up meeting. We have noted that some consultants write to parents shortly after the child's death. Whether or not that is done, we consider that it is preferable for the parents to be contacted either by telephone, or by a cardiac liaison nurse, so that their wishes can be properly understood and respected. At the meeting, the consultant should go through any post-mortem report and the results of discussions at the mortality meeting. This should be followed up by a letter to the parents explaining what further information had been obtained or conclusions reached about why their child had died.

- 10.47 We commend the Trust for its arrangements for bereavement group meetings, and for its acknowledgement that they are in need of review. We are conscious that although these need to be sensitive to the wishes of individual parents, a tailor-made service for each family is unlikely to be realistic. The Chief Executive has said that a weekday service may not be adequate, and we consider that occasional weekend meetings would help parents to fit these in with work commitments. Some parents have expressed the preference to have the meeting away from the hospital. The Trust's excellent booklet *When Your Child Dies* states: 'If you feel that you simply cannot come back to the hospital, but would like to talk to someone, please contact any of the people listed on the next page. This applies too, to other family members for example, grandparents or siblings'.
- 10.48 Different people have different needs, and some families have their own support systems. The cardiac liaison nurses will also be able to ensure that the RBH's arrangements meet these different needs. They will need to liaise with the multi-disciplinary bereavement team, whose activities and role must be more closely integrated with the work of the clinical team. Many of the families attending the RBH will have been referred through a peripheral clinic, often at some distance from London. In those cases it is important to check that parents have access to support nearer to home.
- 10.49 With regard to post mortems, consent should be obtained by a doctor of sufficient experience and understanding to be able to explain why it is needed this sensitive task should not be left to a junior or inexperienced member of the team. We understand that this is the approach taken at The Royal Hospital for Sick Children in Edinburgh. We have examined the Trust's *Guide to the Post Mortem Examination*, which was issued in the light of the Chief Medical Officer's interim guidance. We consider it to be inappropriately lengthy and repetitive for distraught parents. It should be reviewed and re-written in plain English, with families involved in the re-drafting, once the DoH has issued definitive

guidance in the light of the final report of the BRI Inquiry. So far as arrangements for a coroner's post mortem are concerned, we accept that the RBH staff have no responsibility for these but this should not preclude them from passing on to the family any information about whether and when such an investigation is to take place.

- 10.50 We conclude that, in common with practice throughout the NHS, the parents of children who died at the RBH and Harefield were not generally made aware of, or asked in any meaningful way for consent to, the retention of organs or tissue after post mortem. Although their consent was not a legal requirement, we can fully understand why the discovery by some parents that human material was retained has caused them immeasurable distress. Because national policy on organ retention is to undergo radical revision (including a new law on informed consent) following the recommendations of the Redfern Report and the report of the Chief Medical Officer, we do not see any benefit in making our own recommendations on policy or procedural aspects. However, we would like to emphasise that, in the interim, 'consent' for organ retention should be obtained by someone appropriately trained, and that parents be given sufficient information, support and time to consider it carefully. In our view, it would do a great disservice to the development of new treatments if poor procedures resulted in a diminution in the availability of organs.
- 10.51 The overriding priority is for the Trust to extend the training of staff in handling death and bereavement. We have been told that, while many nurses receive this training, the medical staff rarely participate. There should be a clear policy that all staff are expected to enhance their skills, competence and self-awareness in talking to, and supporting, parents whose child has died. Consultants should attend training sessions both for their own benefit and as an example to junior staff. We understand that training at present takes the form of a one-day workshop, which is a strong deterrent, particularly for medical staff. A two-session format, occasionally using a late afternoon or early evening, may attract better support. One of the parents whose child's case we examined offered to help with bereavement training. We believe that such training would be greatly enhanced by involving parents who are skilled in communicating their experiences. Supporting the family should be viewed as an integral part of a holistic children's service, as the way that a death is handled has profound and long-lasting effects on its acceptance by the child's family and on the psychological health of all those involved. There would be great merit

too in senior management staff, and occasionally members of the Trust Board, attending training sessions in order to underline this essential message.

10.52 Finally, all staff should have access to a confidential counselling service, to help them cope with the death of a child under their care.

RECOMMENDATIONS

The Panel recommends that:

- 34. The Trust draws up a protocol for informing parents about the death of a child in hospital, and for passing that information with the minimum of delay to other hospital departments, the GP and any consultant who referred the child to the RBH.
- 35. The Trust ensures that, where both a cardiologist and a surgeon have been involved in the child's care, they agree between them who should give the parents the opportunity of a follow-up meeting.
- 36. Pending new government measures on organ retention announced in January 2001, the Trust ensures that consent for a hospital post mortem, and where necessary for retention of any organs, always be sought by a fully registered medical practitioner who is familiar with the child's case and known to the parents, who should be given enough information, support and time to consider what is being asked of them.
- 37. The Trust ensures that, at the follow-up meeting, the parents are told the results of any post mortem and the analysis reached at the mortality meeting, and that a letter is sent confirming the information given orally.
- 38. The Trust ensures that at least one of the nurses on duty for each shift in PICU and HDU is familiar with hospital procedures and experienced in dealing with bereavement, and that this be the responsibility of the nurse manager in charge of these units.
- **39.** The Trust more closely integrates the work of the multi-disciplinary bereavement team and the clinical team.

- 40. The Trust ensures that cardiac liaison nurses, when in post, work closely with the parents and the clinical team to ensure that the bereavement service is sensitive to the parents' needs.
- 41. The Trust seeks to identify and consult parents of children who have died, when reviewing their arrangements for bereavement group meetings and before finalising changes to current practice.
- 42. The Trust's policy and arrangements for bereavement training for staff involved in heart services for children be overhauled, as a matter of priority, to ensure:
 - The participation of all members of the clinical team, including medical staff at all levels.
 - Active interest and support by senior management and board members.
 - Input, where possible, from bereaved parents.
 - Access for staff to counselling support.
- 43. The Trust approaches a parent or representative group, such as Heartline, for assistance in revising its *Guide to the Post Mortem Examination*.

11. RESOURCES

INTRODUCTION

- 11.1 In reviewing the provision of paediatric cardiac services at the RBH over the period 1987-1999, the level of resources made available was a key issue, as this dictated the number of doctors, nurses and other clinical staff available to provide services as well as the physical environment in which these services were provided.
- 11.2 Although lack of funding is a straightforward explanation for why a particular service may not be made available to families, other factors come into play such as physical constraints, shortages in the supply of newly qualified clinical staff and difficulties in recruiting and retaining staff, especially nurses. In this Chapter we examine the overall level of funds made available during this period and the impact of external factors on the Trust's ability to provide high quality paediatric cardiac services.

FUNDING AND INVESTMENT

- 11.3 The Trust has provided the Inquiry with information that indicates that total expenditure on paediatrics at the RBH has increased annually in real terms. The figures for 1992-1993 to 1999-2000 in Table 1 show that expenditure rose from £2.6 million in the financial year 1992-1993 to almost £5.3 million in the financial year 1999-2000 and the number of staff in post rose from 74.9 to 124.5.
- 11.4 Paediatric expenditure has also grown at a faster rate than expenditure in other services. In part this resulted from the DoH's decision to meet the costs of neonatal and infant cardiac surgery from supra regional funding from the 1986-1987 financial year onwards for nine designated units across the UK including the RBH. The additional funds received from this source enabled the appointment of an additional surgeon in 1987 and a third cardiologist in 1991.

Financial Year	1992-93	1993-94	1994-95	1995-96	1996-97	1997-98	1998-99	1999-2000
	£	£	£	£	£	£	£	£
Budgeted Expenditure								
Paediatrics	2,569,693	2,475,200	2,806,488	2,983,774	3,108,674	3,840,103	4,756,656	5,264,806
Establishment								
Paediatrics	74.93	87.79	96.45	82.40	89.24	98.43	111.69	124.50

Table 1: Royal Brompton Hospital Comparison of Budgeted Expenditure and Establishmentfor 1992-1993 to 1999-2000

- 11.5 In response to an acute financial crisis in the early 1990s there was a period of retrenchment across the board but, as can be seen in Appendix 10, the second part of the 1990s was a period of growth in real terms for paediatrics. This primarily followed a decision by the then Trust Board to accept proposals from the Medical Director put forward in 1995 to increase funding for paediatrics to enable the recruitment of more consultant level doctors. The figures also show that since 1994-1995, and after taking account of inflation, expenditure per episode of care has gone up by over 60%. A calculation of cost per episode was made by comparing the relatively static caseload (see workload figures in Appendix 11) with the large expenditure growth.
- 11.6 The Trust puts these higher unit costs down to:
 - The increase in numbers of consultant staff dedicated to paediatrics.
 - The increase in the members of the patient and family support team.
 - The increase in the numbers of higher graded registered sick children's nurses.
 - The costs of new developments such as closure devices, trans oesophageal echo, the Careview computerised monitoring system, and bi-plane viewing systems.
- 11.7 We would add to this list the impact of higher survival rates, as the number of return and follow-up attendances rose from 1,295 in 1991-1992 to 3,117 in 1998-1999 (see attendance figures in Appendix 11).
- 11.8 The RBH's unit costs in paediatric cardiac work reflect not only expenditure within the specialities directly involved but also the financial performance of the Trust as a whole; poor performance in one business area had to be balanced by achieving a surplus in
another area. Although the Trust was allowed to subsidise expensive services from any surplus income achieved on other services, the scope for this was very limited as the Trust as a whole had to achieve an annual financial target set by the Treasury of 6% return on its capital assets.

- 11.9 Following the introduction of the NHS internal market, the DoH decided to end central funding of specialist services such as neonatal and infant cardiac services as this was incompatible with the new philosophy. In the first few years after supra regional funding ended in 1994, health authorities were in general prepared to meet the costs of paediatric cardiac services in full. However, those authorities which referred only very small numbers of patients for treatment were less prepared to accept the higher costs of referral to a specialist tertiary referral centre in London.
- 11.10 Following changes in contracting arrangements in the 1998-1999 financial year, most health authorities referring paediatric patients to the RBH with the apparent exception of the KCWHA were unwilling to absorb the impact of the hospital's cost pressures in 1999-2000. As a result, paediatric services (which had experienced real growth in expenditure since 1995-1996, reversing years of under-investment), along with every other clinical directorate within the Trust, had to make a 5% efficiency improvement in its budget in the 1999-2000 financial year to help the Trust meet its financial targets, although this was against a base which already contained provision for significant developmental expenditure. In addition, the ending of the extra contractual referral system which funded one-off cases, and its replacement by a more complex system for funding Out of Area Transfers (OATs), significantly reduced the 'earnings potential' of paediatric cardiac services.

PHYSICAL FACTORS

11.11 At the beginning of the Inquiry period in 1987 paediatric services were housed in the South Block of the RBH on the Fulham Road. The wards Rose and Amanda Jones (the intensive care unit) were on the second floor. The general ward had around 24 beds and the intensive care unit had six beds. One family room was available for play and waiting, with some three or four cubicles where parents could stay with their child or which could be used for isolation purposes. A family flat situated above the Rose public house opposite the hospital on the Fulham Road was offered to parents who wished to stay near their child, but this could accommodate only one family at a time. Accommodation was also made available for parents in the nurses' home, but usually only for the day of major surgery.

- 11.12 In 1991 the paediatric services moved to new purpose built accommodation in the Sydney Wing building in Sydney Street, with significantly improved physical provision and capacity, notably in facilities for families, additional cubicles, additional intensive care beds, a hospital school and dedicated play areas. The unit now consists of a ward of 24 beds, plus four beds for day cases, a four bed High Dependency Unit (HDU), plus seven beds in the PICU.
- 11.13 Other significant enhancements to the paediatric facilities during the late 1990s were the creation of an adolescent rest and recreation room, an increase in the number of rooms available to the school (to allow for a split between primary and secondary education), and the creation of two additional cubicles with en-suite lavatory and bathroom. Currently a fourth catheter lab is being developed.
- 11.14 During the Inquiry, a public consultation was held on the proposal to consolidate the Trust's paediatric inpatient cardiac services on the RBH site (13). As outlined in Chapter 5, our Inquiry was invited to submit evidence to KCWHA (reproduced in Appendix 7). In March 2000, the Health Authority reaffirmed its preference for the move, but asked for a detailed implementation plan to reflect our comments and those of others. This was eventually approved in July 2000. We understand that the Full Business Case will allow for an expansion of bed numbers and cubicles on the RBH site to accommodate the Harefield workload and ease current bed pressures. We were also told that a significant improvement would occur in the level of resources, in particular staffing and facilities going into paediatric services, as a result of the merger of the RBH and Harefield site services with significant investment planned on upgrading and adding to the facilities on the Brompton site. Additional parental facilities will also be provided with expanded accommodation for parents and space for privacy. The additional investment on the RBH site to accommodate the merged services is likely to be in excess of £3 million.
- 11.15 More recently, consultation has been launched for a new proposal which involves the rebuilding of St Mary's Hospital in Paddington and the building of a new hospital next door to accommodate the RB&HT within one purpose built hospital (14). A particular

feature of the Paddington Basin development is the co-location of heart and lung paediatric services with specialist services for children. The St Mary's building will accommodate children's services on the same level as those in the RBH and Harefield Hospital, enhancing the obvious benefits of physical co-location and allowing a much greater concentration of clinical and academic expertise.

STAFFING

- 11.16 The dramatic growth in paediatric cardiac services from a very low base in the 1970s to the current position has already been described in Chapter 5. In the first phase, which ran from approximately 1970 to 1987, the responsibility for the development of the service rested in the hands of a few very dedicated individuals who worked far in excess of their contracted hours carrying a workload in excess of 2,000 patients per annum and working a one in one rota.
- 11.17 During the period from 1987 to 1991, when the number of surgeons and cardiologists at the RBH doubled, each cardiologist saw between 2,500 and 3,000 children individually a year, jointly undertook around 500 cardiac procedures per annum, did a joint ward round every morning and evening on the PICU, and provided cover for each other on a one in two basis. The cardiologists also held joint outreach clinics at 24 different hospitals across the South East of England. During this period, the two paediatric cardiac surgeons were undertaking around 400 operations a year, increasing to around 550 by 1997-1998. Later in 1991 an additional cardiologist was appointed making three in all but it was not until 1997 that the first intensivist was appointed to manage the PICU, relieving the cardiologists of this task.
- 11.18 By the end of 1999 a further expansion in consultant numbers had taken place and the service was led by:
 - 4 consultant paediatric cardiologists.
 - 3 surgeons (one part-time for 4 sessions a week).
 - 2 intensivists (an additional intensivist was appointed in 1999).
- 11.19 Like most hospitals, the RBH faced a number of external constraints in recruiting and retaining key staff during the period under review. In the early days of the build up of the

service there was a shortage of trained paediatric cardiac surgeons or cardiologists. The various centres had to compete with each other to fill consultant posts from the small number of potential recruits as junior doctors completed their specialist training. The training took an average of eight years, which meant the service was hard put to keep up with the developments in surgical and management techniques that transformed paediatric cardiac services during the last 20 years.

- 11.20 The shortage of junior and middle grade doctors looking for promotion also reflects changes in junior doctors' hours and training requirements, which added to rather than detracted from the consultants' workload. The publicity given to the BRI Inquiry has also deterred some potential recruits from entering what is a highly visible specialty.
- 11.21 Interestingly, although under EU legislation junior hospital doctors' hours are regulated so that no individual can be required to work more than a one in three rota, similar rules do not apply in respect of consultants' workloads. Despite their greater level of competence, the requirements of the job make much higher demands on consultants' skills than applies in the case of junior staff. This reflects the fact that paediatric cardiac services are becoming consultant-delivered because of their highly specialised and complex nature.
- 11.22 The RBH paediatric cardiac service was much enhanced by the creation of the first dedicated paediatric social worker post early in the 1990s and further so in 1992-1993 by the creation of posts for play specialists, a paediatric clinical psychology service, and the 'establishment' of the Chelsea Hospital School which is the children's school on Rose Ward.
- 11.23 The 1990s saw a period of significant expansion with the start of the evening bereavement clinics led by trained children nurses and the paediatric clinical psychologist, the appointment of a registered children's nurse to lead paediatric outpatient services (still housed in the South Block), and in 1997 the creation of the four bed HDU with 12 additional nursing posts.
- 11.24 Other paediatric cardiac centres also faced difficulties in recruiting other members of the clinical team, especially highly trained paediatric intensive care nurses, leading to the cancellation of operations. A minimum complement of six paediatric intensive care nurses was needed to staff each bed over a 24-hour period. Such nurses were in short supply in the

London area throughout most of the period covered by the Inquiry with real problems in increasing the recruitment of these highly qualified nurses who typically train for four years. Whilst there is a role for less highly trained nurses in other parts of the health service, this is not the case in intensive care, particularly for children who have undergone complex surgery for congenital heart disease who need extra care and vigilance during the immediate post-operative period.

CONCERNS EXPRESSED BY PARENTS

Physical factors

- 11.25 Facilities for parents were poor in 1986 and in urgent need of upgrading. One parent said: 'We were told [in 1986] to leave the hospital and go shopping ... There needs to be some sort of relatives' room Your child is in theatre, you are out of your mind with worry, you are clock-watching all the time. I just feel there should be some sort of room that you can go to – some sort of facilities, not out on the street. We walked around kitchen reject shops sobbing'. Other parents who attended at this point in time commented on the lack of privacy and space in the outpatients clinic especially in the echo suite. The impending move to a new building meant that interim improvements were ruled out. Although the facilities in the new building were much better there was still scope for improvement.
- 11.26 However, the majority of parents whose children's cases were reviewed by the Panel attended the Brompton in the 1990s after the move to the Sydney Street site. For the most part they were satisfied with the standard of accommodation offered to them. However, one parent, describing a hospital flat in 1994, said: 'You don't expect luxury. All you expect is somewhere with a shower in it and a bed but it was like something out of "The Bill" where they go and find the drug pushers. You walked in under a shop and up this flight of stairs, dark and dingy. You opened the door. It smelt musty and old'. Even in the current building accommodation is limited, the hospital being unable to provide more than one room per family even when there was more than one carer of the child. For example, in one case a single parent shared responsibility for caring for his son with the child's grandmother. Although the parent was offered a room, the grandmother had to camp in the general waiting room, as there were insufficient rooms to accommodate her. Even where both parents were able to stay in hospital, the standard of accommodation sometimes left a lot to be desired. At least one set of parents pointed out that the space provided was very

limited: 'They have a top floor area for parents which is good really the room was fine for sleeping in but you do not want to spend any other time up there. Literally there was a bed, with another bed on the floor. Once the bed was on the floor, you could not walk around the room'. Space is likely to be more of an issue in the future as the traditional family is replaced by a range of parenting and caring options.

Staffing

- 11.27 As we discuss in Chapter 9, parents complained about repeated cancellation of their child's planned surgery. As one parent said: 'They cancelled him. He was set up. He was starved in the morning, right through and was supposed to be going down at 3 o'clock, and they cancelled him at the last minute. They said, "Sorry, something else had happened and a priority case has come in". The kid could hardly breathe, but this is not a priority'. Cancellations were generally due to inadequate resources, either in the form of a lack of funds to pay for more paediatric intensive care nurses or of the difficulty of recruiting them.
- 11.28 Parents were often told that a cancelled operation was due to a lack of beds, which they could not understand because beds in PICU were clearly unoccupied. No one had explained that this is a 'shorthand' way of saying there are insufficient nurses to staff all the intensive care beds. One parent, herself a doctor, said: 'What they said was that they had not got a nurse for PICU, and so because of the time, I was so desperate for this to go ahead I actually rang St George's because I knew someone who worked as an agency nurse but who was actually a trained PICU nurse but the Brompton said no'.
- 11.29 Other parents drew attention to the difficulties they experienced whilst on PICU in being able to talk either to the surgeon or their cardiologist, particularly in the earlier part of the period under review before the appointment of additional consultants. Even when they were able to speak to their child's doctor, parents were always aware that his time was precious which sometimes made communication very pressurised.

THE CLINICANS' RESPONSE

Funding and investment

- 11.30 RBH doctors interviewed by the Panel believe that paediatric cardiac services were seriously under-funded throughout the period under review and that these factors should be borne in mind by the Panel when reviewing the concerns expressed by parents. As one said: 'some of the perceived failures of communication should be seen against the workload that we undertook at the time'. Another doctor said: 'When talking to the Chief Executive or the Board I used to say paediatric cardiology at the RBH was a very expensive toy they had to decide whether they wanted to spend money on it. Because for most of us we did not want to have a sort of second division unit'.
- 11.31 All the doctors interviewed felt strongly about the lack of resources. The older doctors described how they had to manage one in two rotas earlier in their careers, which meant having to share a 24 hour on-call rota with one other doctor, increasing to being permanently on call when their colleague was on leave. As one said: 'For many years I was either effectively on call on my own or worked a one in two. Then it became a one in three. Throughout this time we were also responsible for the intensive care unit. We held outreach clinics in 24 different hospitals, four to six times a year. We taught, ran research projects, published more than 100 papers and lectured extensively abroad'. He contrasted the past situation with the current more generously funded establishment saying: 'New consultants in paediatric cardiology take for granted what will have taken their predecessors years to achieve. We now have four paediatric cardiologists, one electrophysiologist and two intensivists. The intention is to have four intensivists. When this is achieved resources will be more appropriate'. The younger consultants also complained about the onerous nature of their work.
- 11.32 In the earlier years, prior to the hospital achieving Trust status, the doctors told us that, although the RBH was generously funded as a Special Health Authority, the allocation of funds between the different hospital specialities disadvantaged paediatric services which were overshadowed by the needs of adult patients. As one doctor said: 'I enjoy going to work but when we had two paediatric cardiologists doing one in two, covering the intensive care unit every night, doing everything, there were 19 chest physicians, who

between them saw probably about the same numbers of patients as the two paediatric cardiologists, and whatever we did they sort of ignored us'.

- 11.33 Even in 1986-1987, when the RBH was successful in gaining supra regional funding, some doctors questioned whether all the funding received was actually spent on paediatric services. One told us: 'I actually believe very strongly, when the paediatric cardiology unit had protected funding from the Government as a supra regional specialty, they were not spending all that money on paediatric cardiology; they siphoned it off and spent it on other things, because for the same amount of money at the Birmingham Children's Hospital, or at many other institutions, they had bigger numbers of staff, greater numbers of beds, and a lot more nurses for sometimes less money. It was clear that that money which should have gone to paediatric cardiology from the Government did not come to us'.
- 11.34 The doctors believed that the position was exacerbated by being a children's unit in a predominantly adult hospital where insufficient weight was given to the needs of paediatric services. One former Clinical Director said: '*My view is that the share of the cake for paediatrics is too small. That would not be shared by any other member of the Brompton Hospital other than people who work in the paediatric department. They think it's too big. It is one of the difficulties, I think, of having a paediatric practice in what is predominantly an adult hospital'.*
- 11.35 The parallel he drew was particularly stark when comparing staffing levels at Great Ormond Street Hospital with the levels felt to be appropriate at the RBH: 'My view is that if you are going to do it, you have got to do it properly, and you've got to keep up with Great Ormond Street and Southampton and Birmingham and wherever. If you look at the number of additional staff that has been appointed at Great Ormond Street, for example, they have an enormous number of intensivists, and cardiologists. They have the ability to ventilate something like 24 children on their various intensive care units for paediatric cardiac surgery'.
- 11.36 This problem was not unique to the RBH but the creation of the 'internal market', with the increased emphasis on competition for patients, caused a certain amount of resentment amongst RBH doctors as different centres tried to maintain or increase their market share by investing in more staff: '...there was a very immediate and almost palpable change in London units; Guy's, for example, who at the time, let us say we were doing 350 surgical

cases a year – I think that is about right – they were doing 150 per year. We had three consultant staff; no intensivists. Over that two or three year period – forgive me if I get the numbers slightly wrong – they end up with five consultant staff, four intensivists and Uncle Tom Cobleigh and all, still at that time for 150 cases per year they provided a better service, they provided a retrieval service, and there was a certain frustration, I have to say, amongst all of us to see one of our competitors investing and improving while we were in effect standing still'.

- 11.37 This consultant pointed out that the workload undertaken by him and his colleagues, looking after in excess of 350 surgical cases a year and sharing the daily management of PICU, far exceeded that of paediatric cardiologists working in other centres.
- 11.38 The situation was further complicated by the fact that the RBH is a leading postgraduate centre in which teaching and research are fundamental to its work. The fact that the RBH is expected to be in the forefront of researching and developing leading edge treatments put additional strains on a group of doctors who were determined to maintain their position in the world league. As one indicated: *...there were other requirements on us that are not so pressing in other units, and that is an academic requirement. So at the same time we were all out of the hospital 12 weeks a year lecturing, going to meetings, and had a large additional research burden, and we all worked at the weekends to do that. I used to get up in the morning to do my NHS practice and get up at the weekends to do research. It was very stimulating and very fulfilling, but there were times when it creaked at the seams'.*
- 11.39 Given that the level of funding had such an adverse impact on paediatric cardiac services, the Panel was interested in ascertaining what efforts had been made by the doctors to advise the Trust Board and management of the urgent need to recruit and fund more staff. One doctor commented that: 'Over the last decade we have fought our case very aggressively with managers completely ineffectively, apart from over the last two or three years'.
- 11.40 Other more recent arrivals were less prepared to tolerate a system that they saw as grossly inadequate. As one doctor told us in 1994, after a few years in post, he was so disillusioned by the inadequacy of resources that he had contemplated leaving the Trust. However, after being advised by the Trust Chairman that the Board recognised the need and was prepared to invest in paediatric services to correct years of under-funding, he was

persuaded to stay and fight his corner. As a result of discussions with the Medical Director, he was invited to draw up a plan for investment over the next 3-5 year period. He informed the Panel that: 'I put together a sort of strategic plan, I wanted things to be better in 1995-1996 and so made a series of suggestions that were agreed by all of us with the Chief Executive, to improve the service. They were agreed and were being worked through'.

- 11.41 As a result of this plan, a consultant intensivist was appointed in 1997 to manage the dayto-day work of the PICU. This relieved some of the pressures on the cardiologists who had previously undertaken this task unaided. However, one additional post did not provide sufficient cover for a 24 hour, seven day a week service. The doctors continued to press for more intensivists to be appointed, pointing out that new developments in areas such as foetal cardiology were adding to the demands on their time.
- 11.42 The doctors also drew attention to the fact that, in August 1997, two of the PICU beds were closed, in their view, for financial reasons. They commented that this led to an increase in the number of cancellations and impeded the hospital's ability to respond to emergencies. The then Clinical Director informed the Panel that: '*I argued for many months in favour of reinstituting those intensive care beds but I was told it was impossible for financial reasons*'.
- 11.43 The Clinical Director informed us that two years later he became so concerned at the continuing shortage of clinical resources and the constant round of cancellations of operations due to the lack of intensive care beds that he invited senior clinical staff in paediatric cardiac services across the Trust to meet to agree a plan of action to tackle the constant shortages and identify the weaknesses, which he felt were undermining the performance and reputation of the unit. He pointed out that: '*Between October 1999 and the end of the year, the number of paediatric cases cancelled between myself and one of the other surgeons was running at 50% for a period of two months*'. The Panel noted that other paediatric centres occasionally experienced a run of cancellations due to the shortage of intensive care beds.
- 11.44 In December 1998, following a strategy meeting at Syon Park, proposals were drawn up to merge on one site the Trust's paediatric cardiac services at least in part in response to the funding problems identified by the clinicians. Doctors were broadly in favour of the merger as they recognised that even the current levels of resources, which were far

superior to those in place during most of the 1990s, were inadequate. As one doctor said: '...there is a need even now for more resources. All the PICU beds should be properly nursed and used. We should run a proper retrieval service and that requires staffing. We need further to develop foetal cardiology as in the next decade with increasing frequency, congenital heart disease will be diagnosed antenatally. The current percentage of about 20% will undoubtedly increase'.

11.45 A new Clinical Director appointed in April 2000 from another paediatric cardiac centre was given the brief of planning for the merger of paediatric cardiac services on the Brompton site. He advised us that he had flagged up a number of improvements, which he considered essential if the combined RBH-Harefield Unit was to continue to operate at the highest level. This ranged from the recruitment of more consultant level staff through to substantial improvements in facilities for parents. Although the level of investment planned for the new combined service had not yet been agreed by the Trust, he was confident that it would fund a significant improvement in services.

Physical factors

- 11.46 The doctors acknowledged that accommodation for parents was far from ideal, pointing out that the lack of space in both the consulting rooms and the echo suite made it very difficult to respond to parents' needs whilst at the same time teaching up to ten students. One doctor commented: 'In the mid 1990s when we moved to the new hospital we had a much better echo suite. We were able to take parents into an ante-room just off the echo room and so if there was bad news you would take parents in and sit them down and talk about what was going on'. He agreed that it was insensitive to have to break bad news to parents in front of a group of postgraduate students and junior doctors. He added that: 'In the last four or five years we had a nurse specifically for the echo clinic which was very helpful'.
- 11.47 Although the space available in the new hospital in Sydney Street was a great improvement on the old hospital, doctors acknowledged that there was still very little space to have a quiet word with parents or to comfort parents after their child had died.
- 11.48 Despite improvements, the current Clinical Director advised the Panel that more space was required: *'The physical resources, the environment at the Brompton are under-resourced*

in terms of the ward area in particular occupancy levels are very high and the fact that, in the ward area [PICU], the respiratory medicine and cardiology has to be accommodated means that both services are very pressurised in terms of the immediate environment. The relocation plans will increase the available ward area but it is no good having the space if you can't recruit people'.

- 11.49 He felt that additional space was required in the PICU and on the ward, especially for families. He pointed out that there were insufficient spaces to accommodate quiet areas for doctors to talk privately to parents, and to give parents facing a crisis privacy close to the PICU. He added that: '*Parent accommodation needs to be improved*'.
- 11.50 Doctors also found it difficult to respond to parents' requests to remain in the PICU during ward rounds as the lack of space around each intensive care cot made it impossible to speak to each set of parents confidentially, without others overhearing the discussion. Problems also arose in respect of teaching because there was no space adjacent to the PICU large enough to accommodate teaching requirements.
- 11.51 Although parents did not comment on the equipment provided in the PICU, we noted the doctors' concerns about the difficulties they experienced in obtaining new equipment, for example echo machines, during the period under review. This was also a problem in the peripheral clinics undertaken by the cardiologists, where the standard of equipment was often inferior to that available at the RBH, making accurate diagnosis more difficult to achieve. However, this problem was not unique to the Brompton. As one doctor with experience of a number of paediatric cardiac centres pointed out: '*I cannot remember working anywhere where an echo machine was bought out of hospital funds*'. He added that the majority of echo machines were purchased with charitable funds.

Staffing

11.52 All the doctors acknowledged that the cancellation and postponement of planned operations was a regular and highly regrettable occurrence. Clearly the doctors were very unhappy at having to apologise for events which were outside of their control. As one doctor commented: '*When the reasons for lack of nurses are financial constraints, perhaps it should be the business managers who go and apologise to the parents*'.

- 11.53 Although doctors were under immense pressure during the period under review, they indicated that the biggest problem was recruiting and retaining sufficient skilled nurses as the unpredictable effect of a shortage of nurses in intensive care seriously disrupted operating lists leading to cancellations at very short notice. The surgeons in particular were very critical of efforts made to attract and retain nursing staff, as one commented: *Recruiting was never a problem, it's when you reduce beds and you start cancelling patients and the nursing staff become dissatisfied that recruitment becomes a problem'.*
- 11.54 One of the areas that the Panel examined was the extent to which the Trust had instituted good recruitment and retention policies to retain its existing highly skilled nursing workforce and to recruit new staff when resources allowed. One doctor was very critical of management's efforts to deal with the ongoing nursing crisis saying: 'We were dealing with issues of nursing staff, like everybody else, but I felt in a rather uninspirational way'.
- 11.55 Doctors raised a number of criticisms as to how short-term considerations such as projected overspends were frequently allowed to disrupt the recruitment of nursing staff which led to cancelled operations with medical staff standing idly by as a result.
- 11.56 The doctors accepted that there had been a significant increase in staffing during the period under review but this still had left very little time available for talking to parents and being able to focus on their needs. As one doctor said: 'It was a great relief three years ago when we appointed our first intensivist and now we have two my own feeling is we have not kept pace in terms of reducing the work commitments of the cardiologists and the cardiac surgeons who all had significant adult practices for a long time only giving this up a few years ago'. He added: 'Throughout the period we have been in existence, there has been a desire to increase the number of consultants and when we reached three [cardiologists in 1990] it seemed like a luxury'.
- 11.57 Despite the significant increase in numbers, this was still not regarded as adequate by the doctors, who advised the Panel that they would like to see a minimum of three or four intensivists in post to cope with the current workload of around 500 operations. They also wanted to see an additional intensivist appointed for the combined unit, to manage the expanded workload following the merger of the RBH and Harefield paediatric cardiac services on the RBH site.

- 11.58 Another doctor pointed out that perceptions of the need for additional clinical resources have changed over time: 'One of the things that happens is that if you work somewhere for 25 years, at the end of that time, where the hospital has reached is the starting point for the next group of consultants coming in somebody coming in from a different era and different expectations expects more'.
- 11.59 The Panel was advised that the consultants also wished to see an increase in middle-grade doctors as they felt that more junior doctors provided less back up nowadays than had hitherto been the case. As one doctor said: *'They actually have less experience and they know less. Our SHOs now do a lot less than they used to do because they are less experienced, and our registrars do much of what the SHO used to do. The consultant staff find themselves having to take on duties and responsibilities which maybe in the past a senior registrar would do'.*

THE TRUST'S RESPONSE

Funding and investment

- 11.60 We also discussed resources with the Chairman and non-Executive Directors of the Trust Board, the Chief Executive, the Medical Director and the Head of Service Development and Planning. The Chairman accepted that a shortage of resources had in part given rise to the concerns being reviewed by the Panel: 'Of course we are very aware of the fact that we are under-resourced and we, as a Board, are under an obligation to balance the books, which we have done'. However, he denied the accusation that the Board had ignored these issues adding: 'You say we are not aware of doctors' misgivings about lack of resources in their own departments, but that would be a total misconception'.
- 11.61 The Board members were very surprised at the suggestion that the paediatric cardiac services had not received their fair share of resources, saying that this view would not be universally shared by managers and other consultants at the RBH. As one said: 'I believe that the rest of the hospital staff would feel very strongly indeed that the paediatricians have had more than their fair share of cake. We would dearly like more resources. Within the resources we have I can assure you the allocation consistently favoured paediatrics quite properly Would the paediatricians wish for more? Of course they would'.

- 11.62 The Chief Executive pointed out that although supra regional funding was allocated by the DoH for paediatric cardiac surgery, this was specifically for operations and related costs and did not cover paediatric cardiology, despite representations made by the Trust. This led to dissatisfaction and anomalies. For example, heart lesions treated with closure devices as part of the interventional cardiology service were not included whereas the costs of operations to correct the same lesions surgically were met by supra regional funding.
- 11.63 The Chief Executive also pointed out that the early part of the 1990s had been taken up with the move to the Sydney Street building and the organisational changes required to achieve Trust status. By 1994 the Trust recognised that paediatric services would need substantial additional investment, as it was clear that the RBH unit was falling behind other paediatric cardiac units which had invested in more clinical posts and in better support services for parents. In reviewing the increase in resources over the last six years, the Chief Executive advised the Panel that: 'It is quite clear that we have invested in paediatric services as distinct from investing in other services, or proportionately to a higher level than in other services'. He pointed out that in a fast-developing specialty like paediatric cardiac services there was a constant need to invest in more up-to-date equipment. The rapid advances in surgical techniques had also had a knock-on effect by generating a higher level of demand for surgical services, which in turn increased the demand for beds in intensive care. Taken in conjunction with the need to respond to parents' expectations for accommodation and support facilities, this represented a need for significant investment. He added: '... there was a recognition that, in the early 90s, the service we were providing – although it was delivered by individual doctors of really quite substantial reputation – nevertheless, had every appearance of being under-invested, and that we were likely to slip, both in terms of our clinical capabilities and our ability to generate knowledge'.
- 11.64 Turning to the closure of two PICU beds in 1997 for financial reasons, the Chief Executive pointed out that the position was more complex than it appeared and needed to be put in context. Despite an increase in the budget for paediatric cardiac services of £600,000 in the 1997-1998 financial year, by the end of July 1997 it was clear that if no action was taken there would be a considerable overspend by the end of the financial year. A decision was therefore made to close two PICU beds on the basis that the recent investment in establishing the HDU with four beds would help to compensate for the loss of PICU beds by absorbing some of the demand which might otherwise have been placed on them.

- 11.65 Notwithstanding the cutback in PICU, hospital records show that the number of cases taken to theatre in the 1997-1998 financial year was 546 compared to 461 in the 1996-1997 financial year. In other words, the amount of surgical work undertaken in 1997-1998 was higher than in the previous year, despite the loss of two PICU beds. The Trust accepts that the workload would have been higher without the cut in PICU beds but the Chief Executive pointed out that, like other parts of the NHS, the Trust had to balance its books and tailor the workload to available resources.
- 11.66 The Trust refutes the assertion that the closure of two PICU beds had in itself increased the number of cancellations, as records demonstrate that the number of operations cancelled due to the unavailability of a PICU bed averaged eight per quarter (or less than one case a week) in the last nine months of 1997, increasing to 16 for the first quarter of 1998 when there was a slight blip, as a consequence of which the two closed PICU beds were re-opened.
- 11.67 Turning to the question of whether the needs of a research institution took priority over the needs of patients, the Chief Executive pointed out that: *`...it is absolutely as much an objective of Brompton to contribute to research and development in the medical arena as it is to provide patient care. But our unique contribution I believe is the addition to knowledge in the field that we provide. The pressures coming through suggested that we were becoming, or going to become, unable to sustain that leading edge clinical and research capability, unless we invested'.*
- 11.68 The Trust readily acknowledged that despite increased investment in the paediatric service, not all of its ambitions for the service had been met. However, the forthcoming merger of paediatric cardiac services on the RBH site provided an opportunity to consolidate services and re-invest any savings in creating a centre that would once again be at the leading edge.
- 11.69 The Trust also pointed out that funding for the NHS is not open ended. Spending has to be controlled in relation to the resources available internally and to the external funding environment, with the Board's decisions restricted to the division of the Trust income between the different service sectors.

Physical factors

- 11.70 The Chief Executive pointed out that although his predecessors had invested heavily in a new hospital on the Sydney Street site, the buildings were designed in the 1980s when the need to include facilities for parents was not widely recognised. Although resources were limited, the Board had tried to respond to the needs of families by appointing clinical psychologists, establishing a hospital school for older patients, and improving play facilities for all age groups. However, managers recognised that there was a need to expand on current facilities.
- 11.71 Turning to the question of equipment, the Trust recognised that a substantial amount of equipment was purchased each year from charitable funds but that its responsibility for purchasing new equipment in peripheral clinics was a moot point. '*There is an absolute limit to which a hospital like the Brompton can say "Don't worry, we will pay for all the new equipment at [X hospital]". What we try and use is our clout and our input to try and persuade them that it should be a priority investing in these specialist services*'. The Chief Executive agreed to consider whether the Trust should be doing more by way of quality assurance to ensure the effectiveness of peripheral clinics and monitoring whether there is adequate back up in terms of diagnostic capabilities.
- 11.72 One useful development which had occurred as a result of the Inquiry was to establish contact for the first time between Heartline, which had given evidence to the Panel, and hospital managers. As a result, the Panel was informed by the Trust's Head of Service Development and Planning: 'I had a very useful meeting with the people from the Heartline Association who gave some views on what they would like to see as parents, the kind of facilities. Not all of these ideas involved a need for more space, some were more about creating privacy for parents on the wards'. He pointed out that: 'The idea parents can come into paediatric units, that they should be more welcoming and have some facilities has been an astonishing change. A lot of centres have not been able to keep up with the pace of change'.
- 11.73 In the longer term, the Trust recognised that the creation of a virtual paediatric hospital on the St Mary's site with all tertiary paediatric services co-located, presented a first class opportunity to share resources such as a larger paediatric intensive care unit and to foster close collaboration with other paediatric disciplines. Although a number of doctors were

concerned at the potential loss of independence by moving to the Paddington Basin site, the Chief Executive advised the Panel that: *....being closer to sub-specialty advice in other disciplines is in the interests of patients and it's potentially in the interests of research and education as well'.*

Staffing

- 11.74 We were informed that the decision to increase the number of doctors working in paediatric care in the period under review was indicative of the high priority that the Trust attached to enriching the service, but it had only been possible to do this as resources allowed. The Trust acknowledged that consultant cardiologists had been under extreme pressure prior to the appointment of the first intensivist in 1997 and that there was a need to improve upon the current position of having two intensivists in post. The Chief Executive pointed out that the prime motivation for the merger of paediatric cardiac services was a desire to strengthen the clinical input to these services by concentrating resources on one site.
- 11.75 The Director of Nursing acknowledged that the cancellation of planned operations was undesirable and informed us that, like most other paediatric cardiac units, the Trust had experienced considerable difficulty in recruiting nurses to staff PICU during the period under review. The problem was that too few nurses had been trained in the 1990s and even smaller numbers had chosen to undertake additional specialist training in paediatric intensive care nursing. This meant that there were more posts than people to fill them, especially in the London area where potential staff had a choice of units. The Director of Nursing pointed out: 'We have a national recruiting problem which is compounded by being a very small specialty requiring the very skilled top per cent of nurses in terms of their abilities, qualifications, post registration courses completed and so on'.
- 11.76 In the early part of the period under review only the ward sisters working in paediatric cardiac services were paediatrically trained with a large number of nurses who were not registered sick children's nurses (RSCNs) working in the paediatric area. This reflected the fact that many of the services were based on an adult model of care and were not geared to meeting children's needs.

11.77 The Director of Nursing informed the Panel that the Trust had made considerable efforts in the last eight years to recruit more trained paediatric nurses, partly as a response to national guidelines on the care of children in hospital that required Trusts offering paediatric services to recruit more RSCNs. The Trust is currently setting up a specialist Critical Care Practitioners programme coupled with an MSc in Critical Care Nursing for nurses who want to specialise and develop their interest in critical care. It is hoped that this would attract and retain nursing staff who were at the top end of the market.

CONCLUSIONS

- 11.78 We were asked to report on whether parents were offered the level of service at the RBH appropriate to their child's needs. It is clear that the shortage of resources in the early period of our review impeded clinicians' efforts to provide a comprehensive service to parents, making it extremely difficult to meet requirements for a more family-orientated service. It also placed unfair pressures on a small group of dedicated and highly motivated doctors who tried to respond to parents' needs. Many years later, when the doctors drew attention to the gaps in resources, it was clear that they had all shared a deep concern at the way in which the shortage of resources had undermined their ability to provide a high quality service.
- 11.79 It could be argued that in the early 1990s the Trust and its predecessors were too slow to respond to the demands being placed on its doctors and failed to provide adequate resources for the paediatric cardiac service. However, to put this in context, this was a period which saw the move to the new hospital in 1991, the creation of the Trust in 1994, and significant organisational change as a result of the introduction of the NHS internal market, which diverted managerial resources away from services into corporate planning and external issues. The 1990s was also a period when public expenditure was tightly controlled, with continued pressure on the NHS.
- 11.80 The RBH was no different from other large specialist and teaching hospitals during this period in being forced to make frequent adjustments to its recruitment policies in order to meet its financial targets. This led to cancellations of surgery as a result of the closure of intensive care beds. The consequences for some parents of children needing urgent heart surgery were potentially serious, with several sets of parents left wondering if their child would have survived if he or she had been operated on sooner rather than spending several

months on a waiting list. The Panel regards the frequent closure of PICU beds, which led to cancelled operations for children awaiting surgery, as regrettable. We note that from 2002, under the NHS Plan (5), when a patient's operation is cancelled by the hospital on the day of surgery for non-clinical reasons, hospitals will have to offer another binding date within a maximum of the next 28 days or fund the patient's treatment at the time and hospital of the patient's choice. We welcome this commitment but there are problems inherent in implementing this policy in such a complex surgical area, which we refer to in Chapter 9.

- 11.81 Unfavourable comparisons were made by the doctors between Great Ormond Street (GOS) Hospital and the RBH. As a result, the Panel undertook a survey of all paediatric cardiac centres currently operating in England which is reproduced in Appendix 12. This shows that although GOS does have more PICU beds than the RBH, provision at the RBH is not significantly out of line with that available in most centres. However, this should not be taken to imply that this is sufficient as all centres experience occasional problems in sourcing intensive care beds, resulting in cancellations of planned surgery. It is not our remit to propose standard numbers of intensive care beds for hospitals providing paediatric cardiac services, but we note the absence of guidance from the DoH on standards.
- 11.82 Likewise the Panel is unable to comment on funding decisions made by other Trusts delivering paediatric cardiac services, but it is clear that the level of service a child and his or her parents experience should not be markedly different between hospitals as a result of different levels of investment. The Panel believes that in order to achieve greater geographical equity, the DoH should take a lead in defining a National Service Framework for Paediatric Cardiac Services, setting out minimum intensive care bed and staffing requirements for paediatric cardiac centres, recognising that if the existing network of centres cannot be supported, this may lead to a concentration of services in fewer larger units.
- 11.83 It is creditable that, in 1994, the Trust recognised the need to invest substantially in improving both the staffing and physical resources for its paediatric services and drew up a plan for investment over the next three years agreeing that, if necessary, money would need to be diverted from other Trust services. The new developments included opening a four bed HDU, recruiting an intensivist in 1997, and recruiting two additional cardiology posts in 1999.

- 11.84 However, we note that this did not happen at a fast enough rate to satisfy the doctors. The doctors all shared a deep level of concern at the way in which the shortage of resources had affected their ability to provide high quality services.
- 11.85 We recognise that improvements in the working hours of junior doctors, whilst desirable in themselves, had an adverse effect on the working hours of consultant staff who were expected to fill the gap without any additional staff being appointed. We were surprised to find that there are no formal limitations on the number of hours a consultant is required to work and be on call. The consequence of this is that most consultants have to subordinate their families and social lives to the demands of the job which, in the case of paediatrics, includes the need to set aside significant amounts of time to talk to families and deal with the psycho-social elements of care.
- 11.86 Several of the consultants working in paediatric cardiac services are approaching retirement and their successors may well be reluctant to take on a workload where a 12-16 hour day appears to be the norm. This, coupled with the adverse publicity arising from the BRI Inquiry, could lead to a crisis in recruitment over the next 5-10 years. We regard it as essential for the DoH to conduct an urgent review of the medical personnel required for the specialty over the next decade so that resources can be strengthened to meet future needs.
- 11.87 We recognise that the recruitment and retention of sufficient trained paediatric nurses is a critical area for the Trust. It was clear from our meeting with nursing staff that the Trust did appear to have put in place a comprehensive package of policies designed to attract key nursing staff and that the appropriate steps were being taken, including the provision of child care and funding of educational bursaries for their retention. However, this is clearly not sufficient in a position of intense competition for the small numbers of RSCNs with intensive care training.
- 11.88 Although the merger of paediatric services on the RBH site is desirable, we remain concerned that many Harefield nurses may not choose to make the daily journey to the Brompton even if door-to-door transport is laid on. The Trust is in the process of ascertaining what benefits would be required to retain Harefield nurses, many of whom are very experienced in this field. In these circumstances, we suggest that more work is needed

on issues such as the provision of subsidised housing to address the problems of living and working in London and applaud the Trust's efforts to tackle this problem.

- 11.89 Turning to cardiac liaison nurses, we were pleased to note that the recruitment of two fulltime cardiac liaison nurses additional to the existing staff complement was underway with one candidate already appointed. We understand that funding for further posts will be considered next year following evaluation of the first two posts. In our view, two posts are unlikely to be sufficient to offer a full service, given the view of the Clinical Director that 4-5 cardiac liaison nurses are the minimum required to meet current needs and the Director of Nursing's plans for a team of eight. We deal separately with the role of these posts in Chapter 22.
- 11.90 In reviewing the resources allocated to the paediatric cardiac services, we noted that they shared a business manager with another directorate for most of the period under review. However, the Chief Executive pointed out that this was a very senior and experienced manager and in his opinion paediatric services had high visibility from 1995 onwards. He acknowledged, however, that more senior management resources would be required to facilitate the merger and the planned Paddington Basin development. To this end a designated manager for paediatric cardiac services was appointed in October 2000 who is responsible for co-ordinating the move of Harefield paediatric services and integrating and planning the move to the Paddington basin site if this goes ahead. These tasks will be in addition to managing the day-to-day work of paediatric cardiac services and provide a focal point for addressing any future concerns parents might have about the services. We also welcome the appointment in May 2000 of an Associate Director with a nursing background to strengthen the role of nursing in the directorate.
- 11.91 The Trust Board has not designated one of the non-Executive Directors with responsibility for paediatric cardiac services. We noted that none of the non-Executive Directors appeared to have specialist expertise in relation to children and we believe that the appointment of a Directorate Manager should be balanced by the designation of one of the non-Executive Directors to take specific interest in and responsibility for paediatric cardiac services.
- 11.92 We understand why the Trust could not exempt paediatric services from contributing to its savings target in the 1999-2000 financial year. However, we are concerned that some

planned developments, principally the expansion of the number of intensive care nurses and the development of a cardiac liaison nurse service, might be constrained. We hope that the Trust will place a high priority on implementing the recommendations of this report, some of which, but by no means all, indicate the need for additional resources.

- 11.93 Turning to the merger of paediatric services, the Panel accepts that the concentration of services on the Brompton site will increase the clinical input to services to the benefit of families. However, we accept that in moving to the Brompton site, Harefield staff will be giving up excellent physical facilities. It is therefore imperative that the planned investment to increase and improve facilities on the Brompton site is sufficiently generous to meet the needs outlined by the Clinical Director in full, including a significant increase in facilities for parents.
- 11.94 Provided that the opportunity is taken to create a state of the art facility which genuinely reflects the needs of children, their parents and the clinical staff, the Panel is confident that some of the physical constraints which have impeded the provision of high quality patient-centred services in the past will disappear. However, similar expectations were raised in the late 1980s prior to the move to the Sydney Street building, which were not realised. The reality of NHS Capital Planning is that all too often non-clinical areas are cut back as building costs rise and the hoped for improvements do not materialise. This is always disappointing but, in the case of paediatric services, a failure to provide adequately for parents' needs in a specialty where children are highly vulnerable is likely to give rise to more complaints of the types considered by this Inquiry.

RECOMMENDATIONS

The Panel recommends that:

- 44. The Department of Health issues a National Service Framework for Paediatric Cardiac Services within the next 12 months setting out the national standards which parents have a right to expect when using these services.
- 45. The Trust publishes a clear statement of service outlining what standards parents have a right to expect in terms of:

- Accessing information (especially on risks upon which to base their decision about whether or not to proceed with life threatening surgery).
- Residential accommodation in the hospital on the night before surgery and whilst their child is in intensive care.
- Follow-up care for children after they have been discharged from hospital.
- 46. The Trust ensures that the Clinical Director assumes responsibility for annual service audit, reporting to the Trust Board on how far these standards of service have been met, setting out the reasons for any under-performance and highlighting what, if any, resources, particularly increases in staffing levels, are needed to enable the service to meet these standards.
- 47. The Trust Board Chairman designates a non-Executive Director to be an advocate for paediatric cardiac services at Board level taking specific responsibility for ensuring that services are regularly reviewed and that they meet the needs of children and their parents.
- 48. The Trust Board ensures that, in redesigning services for the merger of the RBH and Harefield paediatric cardiac services on the RBH site and their potential further relocation to the Paddington Basin development in 2006, the physical space allocated to the service is increased and improvements made in line with the recommendations set out in the Panel's interim report to the Kensington & Chelsea and Westminster Health Authority dated March 2000, reproduced at Appendix 7 of the main report.
- 49. The Trust Chief Executive investigates the effectiveness of peripheral clinics and assesses whether enough back up is available in terms of diagnostic capabilities.
- 50. The Trust investigates what package of benefits is needed to recruit and retain nursing staff, particularly intensive care nurses for the merged paediatric cardiac services, and considers re-investing part of the savings arising from the merger to fund accommodation options for nursing staff in Central London.

Part Three

ISSUES AT HAREFIELD HOSPITAL

12. SERVICES AT HAREFIELD HOSPITAL

INTRODUCTION

12.1 Harefield Hospital currently has 17 beds in the Harefield Paediatric Surgical Unit, including three or four intensive care beds. The PICU has six beds but is only funded to provide three or four beds at any one time. The ward accommodation consists of one four-bed unit plus six single rooms. The unit also has two well-designed and well-equipped playrooms (one of which has external space), a schoolroom, four rooms for parents and one family room, which are of a very high standard. In 1999, the number of cardiac procedures were as follows:

•	Inpatient surgery, including operations to the heart	130 operations
•	Day case and inpatient investigations	438 admissions
•	Outpatient heart services	2,089 attendances

- 12.2 The ward area contains a number of single rooms with no patient having to share a room with more than three other children. The Panel was particularly impressed by the generous accommodation in the PICU, funded from charitable sources, which contrasts very favourably with the PICU on the RBH site.
- 12.3 Since the inception of the paediatric service, Harefield has acted as a specialist referral centre where patients with complex cardiac abnormalities are sent by other centres in the UK and abroad. In addition, from 1984 to 1988-1989, Harefield was the only centre in Europe carrying out heart transplants in children. Early success at Harefield brought increasing numbers of patients to the centre without a matching increase in resources. This put doctors under immense pressure, making it very difficult for them to devote sufficient time to respond to parent's need for a more family-centred service that provides regular opportunities for discussion with consultant staff and joint decision making about their child's care. This was a particular problem in the 1980s when, prior to the appointment of a second cardiologist, there were only two part-time consultants working in the unit, although both worked far in excess of their contracted hours.

DEVELOPMENT OF PAEDIATRIC CARDIAC SERVICES

- 12.4 The history of the development of Harefield as a paediatric cardiac centre is one of serendipity and opportunism in which strategic planning in resource allocation played little part. Although other centres were developing services in parallel, Harefield was at the leading edge of new surgical treatments now taken to be standard the world over. As we show later in this Chapter and in Chapter 20, the gap between resources and medical innovation had a marked effect on the delivery of a holistic paediatric cardiac service at Harefield during the period under review. Despite the best efforts of staff, it was not possible to meet consistently parents' need for support because funding was inadequate, and the service relied on soft monies for the majority of the unit's buildings, equipment and facilities.
- 12.5 The service began with the appointment of Professor Magdi Yacoub in 1969 to the post of Heart Surgeon at Harefield, which was a former sanatorium on the edge of London. It should be noted that his appointment covered both adult and paediatric services. In late 1973 he was appointed to the National Heart Hospital for two days a week with the rest of his sessions being held at Harefield Hospital. At the time of his appointment, Professor Yacoub was supported by Dr Malcolm Towers, an adult cardiologist of considerable standing and experience who specialised in services for adult patients and had no paediatric experience. In 1971, Dr Rosemary Radley-Smith was appointed to the post of consultant paediatric cardiologist, initially on a part-time basis of four sessions per week. The paediatric service was developed and run by Professor Yacoub and Dr Radley-Smith for the next 30 years, both being constantly on call right up until the mid 1980s, except for holidays which appear to have been relatively short and infrequent. Although Dr Radley-Smith worked around the clock, she was not given a full-time contract until 1987.
- 12.6 Harefield's name was placed firmly on the map when Professor Yacoub undertook the first successful switch operation for correcting transposition of the great arteries in 1975, introduced the adult transplantation service in 1980 and launched transplant services for children in 1984. This was a remarkable achievement for a centre that lacked the back up found at most other paediatric cardiac centres. Together with Dr Radley-Smith, he developed a service from a very low baseline to one which undertook 150 to 200 operations per year with outstandingly good results. However, no additional funding was

made available in the period 1971 to 1987 to meet the costs of recruiting additional paediatric cardiac surgeons, paediatric cardiologists, and middle grade staff for the centre.

- 12.7 The lack of clinical resources was compounded for Harefield as it was a stand-alone hospital and did not have access to the additional teaching and research funds enjoyed by teaching hospitals, despite being a leading centre of research and innovation particularly in adult and paediatric transplantation services. Interestingly, Harefield's achievements in this particular respect were recognised nationally through supra regional funding which was made available for the transplant services until 1997 with some additional funding for nurses also provided. The number of paediatric transplants carried out at Harefield ranged from an average of 20 per annum in the early years of the programme rising to around 30 per annum in 1989-1991, then dropping back to an average of 15 per annum in the 1990s.
- 12.8 In some quarters Harefield was seen as being run by a 'maverick' set of consultants doing their own thing but the reality was far more complex. The shortage of funding forced a group of innovative doctors to become ever more entrepreneurial in order to continue their vital research. Perverse though it may seem, it was the shortage of central funding and lack of recognition in the UK, which created the dynamic force to build an international centre of excellence accessing patients and donations globally and enabling Harefield to maintain its innovative research programme. It is doubtful whether Harefield would have survived as an independent centre for so long without the existence of a wealthy group of donors who were prepared to fund new developments.
- 12.9 One of the factors that could have relieved the economic pressures on Harefield was the introduction of supra regional funding for specialist services other than paediatric transplants in the early 1980s. In 1984 nine supra regional centres were designated by the DoH as centres for surgery of congenital heart defects for neonates and infants. A Joint Working Party, established between civil servants at the DoH and representatives of the medical profession devised a system which proposed that central funds be allocated in 1985-1986 to meet the costs of a small number of high cost specialities. A Supra Regional Services Advisory Group (SRSAG), comprising representatives from the DoH, the medical profession and the NHS, was responsible for overseeing the designation and operation of this and other very specialised clinical services that had previously been unable to secure adequate recognition and funding. The Group worked closely with the relevant Medical

Royal Colleges, Societies and Associations. When it came to considering which centres should be designated, the advice of the relevant Medical Royal College was sought.

- 12.10 The history of funding for Harefield Hospital differed from that at the RBH. Hillingdon Health Authority, which managed the Hospital, applied for recognition and funding for neonatal and infant cardiac surgery in 1986. Harefield was competing with three other centres in the London area The Royal Brompton Hospital, Great Ormond Street Hospital and Guy's Hospital which were already designated as national centres for paediatric cardiac care, and there was strong resistance by policy makers to funding a fourth centre in London no matter how good its clinical outcomes.
- 12.11 As a result, the SRSAG advised ministers to reject Harefield's bid for funding in 1984-1985 and 1985-1986, and in 1986-1987 suggested that Harefield might wish to consider a strategic alliance with one of the other London centres. Although these decisions may have appeared reasonable at a national or strategic level they left Harefield very exposed. A service which was increasingly being valued and acknowledged across the world largely had to rely for its survival on the continued acceptance by clinical staff of wholly unreasonable levels of commitment. In addition there was some resentment over Harefield's ability to attract media attention and achieve publicity for its excellent research data which showed that the centre was achieving extremely good results.
- 12.12 This unacceptable situation changed in 1986 when Professor Yacoub was appointed to the Chair of Cardiac Surgery at the National Heart and Chest Hospital and he accepted an appointment as a part-time consultant surgeon at the RBH. Eventually, following a great deal of lobbying, the SRSAG agreed to encourage a joint programme between the RBH and Harefield. Additional funding for Harefield was therefore included in the RBH allocation for 1987-1988. Subsequently, both centres came to be recognised in their own right. The additional funding, although less than that received by all the other designated paediatric cardiac centres, was used to fund additional sessions to pay the cardiologist the salary due for her actual full-time appointment. Eventually in 1991 a second consultant paediatric cardiologist was appointed.
- 12.13 Capital resources were also in very short supply in the period under review, with Harefield having to compete for funds each year in the annual bidding round to North West Thames Regional Health Authority, which had more hospitals than any other NHS region. The

Authority's decision to go ahead with funding the new Chelsea and Westminster Hospital constrained severely the amount of capital available for new buildings and equipment across the rest of the region. However, from the start, Harefield doctors adopted a dynamic approach, successfully publicising the centre's groundbreaking work and raising substantial charitable funds. As a result, freed from the constraints of NHS cost limits, the physical facilities available today for patients and their families are far superior to those in most NHS hospitals.

- 12.14 In 1992 Harefield became an independent NHS Trust subject to the disciplines of the internal market with health authorities contracting directly with the Trust for individual patients. Although this should have benefited Harefield as it was no longer having to compete with local hospitals for funds, this was not the view of the doctors, who complained that they were still having to release savings to fund any expansion in hospital staffing. However, the Trust did attract some additional funds for research from the national Service Increment for Research funding scheme.
- 12.15 In Harefield's case a large number of patients came from outside its home region. Treatment for these patients had to be funded as an extra-contractual referral (ECR) by the purchaser health authority in the area where the patient lived. In March 1999 the ECR system came to an end, and was replaced by a less generously funded scheme for OATs.
- 12.16 During the period 1992-1997 the Harefield Trust performed reasonably well in meeting its financial targets. However, changes in the external environment, such as the implementation of the new contract for junior hospital doctors and changes in the accreditation arrangements for training hospital doctors, encouraged the Trust to seek a strategic alliance with another heart centre to create a larger Trust capable of withstanding these pressures. Harefield recognised that the volume of paediatric work was too small to be viable in the long term and that, in the aftermath of the BRI Inquiry, trends in paediatric cardiac surgery were likely to lead to the creation of fewer larger centres with a requirement for the appointment of full-time paediatric cardiac surgeons. Moreover, there was insufficient volume in the Harefield workload to justify the creation of a full-time post for a paediatric cardiac surgeon when the current surgeon retired in 2001, especially as the additional referrals attracted by his reputation were unlikely to continue after his retirement.

- 12.17 In April 1998, the RBH and Harefield Trusts merged into a single organisation working in tandem with the Imperial College School of Medicine and the National Heart and Lung Institute. The aim of the merger was to optimise the use of academic and financial resources, and create a cardiothoracic centre of excellence which would be pre-eminent in the UK and the equal of any in Europe. One of the benefits of the decision in 1997 to proceed with the merger was the appointment of a third consultant cardiologist/intensivist for the Harefield paediatric cardiac services in 1997, providing dedicated management of the PICU and reducing the on-call commitments of the other two cardiologists to a more reasonable level. In addition, one of the Harefield cardiologists was appointed as the single Clinical Director for paediatric cardiac services in December 1998 to be responsible for clinical work on both sites.
- 12.18 Early on in the life of the Royal Brompton & Harefield NHS Trust (RB&HT) it became clear to the Board and management that the Harefield paediatric centre was underresourced in staffing compared to the RBH paediatric centre. It was anticipated that this situation would be compounded by the retirement of the surgeon at Harefield Hospital in 2001, because of the difficulty of recruiting a full-time replacement in such a small centre in line with the recommendations of the Society for Cardiothoracic Surgeons that all such posts should in future be devoted solely to paediatrics. A decision was therefore made to proceed with plans to relocate the Harefield services to the RBH site, both to achieve economies of scale and to provide better access to paediatric general services at the nearby Chelsea and Westminster Hospital.
- 12.19 The establishment of our Inquiry coincided with the launch of a consultation exercise carried out by KCWHA on the proposed co-location of the two paediatric services on the RBH site (13). We were asked to contribute to this consultation on the basis of its findings to date. Our response is discussed in Chapter 5 and set out in Appendix 7. In summary, we welcomed changes which would increase the viability of Harefield's paediatric cardiac services by co-locating them on the RBH site; we also suggested the need for considerable improvements to be made in the services currently on offer at RBH given the superiority of the facilities available to parents on the Harefield site. These include the appointment of additional staff, such as cardiac liaison nurses, and improved day room facilities and overnight and consulting rooms for families and doctors.

- 12.20 In July 2000, the Panel was advised that the KCWHA had agreed the merger, which is planned to take place in spring 2001, prior to the retirement of Professor Yacoub at the end of September 2001. At the same time the health authority announced plans to consult on the eventual re-location of the entire service at the RBH and Harefield hospitals in 2006 to a new site adjacent to St Mary's Hospital, London, as part of the Paddington Basin redevelopment scheme. As far as paediatric cardiac services are concerned, the logic of this proposal is that it will facilitate the co-location of services with specialist tertiary paediatric services, which have been reorganised as part of the West London Review. This will considerably improve access to specialist services such as paediatric neurology and children's renal services for those children with complications arising from their surgery.
- 12.21 Harefield Hospital was separately designated and funded centrally as a heart transplant centre in 1986-1987 although, from 1997-1998, heart transplant services were funded by health authorities from a separately identified allocation. At the time of writing the future location of paediatric transplant services is still being considered by Ministers advised by the National Specialist Commissioning Advisory Group that replaced the earlier SRSAG.

13. THE ISSUES

INTRODUCTION

13.1 The seven cases we reviewed, all of which occurred in the period 1990-1999, though few in number, have provided a consistent picture of parents' concerns that contact with senior medical staff at Harefield Hospital was inadequate, especially in the post-operative period. In six of these cases the child died while in hospital for surgery, and in the other case the child suffered severe neurological impairment. The concerns raised with the Panel echo, and in some instances reinforce, those raised by parents in respect of the RBH Inquiry. This is not unexpected, as any centre finding itself under the spotlight is likely to generate similar concerns.

COMPLEXITY OF CASES

- 13.2 Six of these seven cases are, however, different from the majority of the RBH cases in two important respects.
- 13.3 First, the clinical condition and management of the children was much more complex than most of the RBH cases reviewed by the Panel, and the majority had complex abnormalities or clinical presentations.
- 13.4 Second, they include five cases treated by other paediatric cardiac centres and referred to Harefield as one of the few centres with a track record in handling this degree of complexity. As such, they presented a high-risk group of patients with unusual complications, some involving lengthy stays on PICU, which parents found deeply upsetting and, at times, extremely traumatic.

CONCERNS EXPRESSED BY PARENTS

13.5 In reviewing these cases we adopted the same objectives and guiding principles, procedures and methods of working as for the RBH Inquiry. Copies of these are set out in Appendix 3. The parents' main concerns include:

- Not meeting the surgeon before or after the operation, sometimes neither.
- Not understanding the diagnosis properly, or the nature of clinical and surgical management.
- Not understanding the surgical procedures.
- Not understanding why their child had died.
- A belief that things had been kept from them.
- Nobody having the time to explain anything in detail.
- Inadequate support after a death.
- Lapses in hygiene standards on the PICU.
14. DIAGNOSIS

INTRODUCTION

14.1 Five of the cases concerned children who had already been seen by another paediatric cardiac centre and who were referred on to Harefield either for a second opinion or as a result of the complexity of their case.

CONCERNS EXPRESSED BY PARENTS

- 14.2 Four sets of parents felt that the nature of their child's diagnosis and treatment options had not been explained adequately, or in terms that they could readily understand. One parent said: 'I knew only the problem with him was a hole in the heart, but I did not know what I am reading now. I was not told he had more complications he was just a normal kid'.
- 14.3 A number of parents would have liked more information. One said: 'I have not got a medical background but it struck me that it might be good practice that for planned surgery where it was not acute and an immediate emergency that as much information as possible should be achieved before surgery is undertaken'. Some suggested, for example, that they should have been given access to a computer, details of relevant websites and the hospital library so that they could search out information on innovative forms of treatment. One parent said that: 'access to a library and the internet would have been helpful to obtain more information about my daughter's condition'. She added: 'Is the hospital publishing mortality and morbidity data? It should be made available to parents now because we did not have anything clear at the time. That would be very, very useful'.
- 14.4 This parent was also concerned at the absence of dietary advice in terms of helping her child gain weight, as this was the key factor in the decision when to operate, saying: 'It's very much left to the local hospital, but the local hospital is not the specialist in children with heart conditions, because the scheduling of [child's] surgery was to a certain extent going to be determined by her weight gain as one of the factors, it was so surprising to me that there was no dietary advice available in that first year and indeed on development aspects as well'.

14.5 Several parents felt that the initial consultation was not long enough for them given the complexity of the issues involved. One parent, whose child had a rare chromosomal condition, questioned whether children with a complex diagnosis requiring the input of other specialities would be best served by being referred to a general hospital such as Guy's or a children's hospital such as Great Ormond Street, saying: *'At such hospitals specialists are immediately on hand to treat the whole child and not just the heart'*. This parent felt that such a referral *'would have allowed for better continuity and co-ordination of care'* than was possible in a single specially hospital like Harefield.

THE CLINICIANS' RESPONSE

- 14.6 The Panel asked doctors what arrangements could be put in place to make diagnostic interviews less pressurised and more informative for parents. One doctor pointed out that: *'five of the cases came to us having been through at least one other centre, therefore they as well as Harefield should have been responsible for explaining the diagnosis and to a certain extent why they were being sent to us we do spend a lot of time with these patients, trying to explain what we are proposing it is a concept of what is taken in'.*
- 14.7 The cardiologists commented that they spent a lot of time with parents trying to explain what is often a very complex diagnosis, drawing and using heart models to get their message across. As one doctor said: 'Every patient goes away after diagnosis is made carrying away a diagram of the congenital heart defect, with somebody spending time with the parents explaining what is wrong with the heart and what the consequences are for future management, treatment, surgery'.
- 14.8 All of the Harefield cardiologists indicated that they were prepared to offer parents an opportunity to come back for further discussion once they had overcome the initial trauma of learning that their child had complex congenital heart disease and especially where treatment options are not clear cut. As one doctor said: '*This [initial diagnostic session] is usually reinforced with an invitation back at any time to discuss it further and in a fairly short time, between that first visit and the next outpatient visit'.* However, it was not always easy for parents to understand the complexities of congenital heart disease especially when a condition is comparatively rare. As one doctor said: '*Two problems: one is how much time we spend with them and then how much we can make them*

understand. They are capable of understanding, but sometimes they are not willing to understand maybe we should try harder, but there is no magic procedure'.

- 14.9 The doctors indicated that, more recently, parents who are computer literate had been encouraged to use the internet to access technical literature and more specialist information on their child's condition. As one doctor said: '*I always ask them what their profession or occupation is You get a fairly clear idea quite quickly as to who you need to go into a great deal of detail with, including internet access etc'.* The doctors were happy for parents to be given access to the medical library on site especially as many parents travelled long distances to come to Harefield and could not readily access their own home computers.
- 14.10 Doctors told us that they tried to be open with families rather than giving an evasive response to questions: 'We are open with families and say We cannot be exactly sure in a great deal of detail as to what [the surgeon] will do at the time of operation because it will depend upon his findings on the table, and this is something we cannot predict'.
- 14.11 The surgeon pointed out that: 'Most of the time I try and see them myself and draw pictures and show everything as much as I can sometimes they want three or four people to do the same thing and try and compare what people have said and, at the end of the day, they still want to believe what they want to believe. So there is a problem, How can we improve that? I honestly do not know There are pictures, there are ideas, we go through each procedure, the advantages and disadvantages and why we think that the very best thing for this child is this route we cannot offer permanent long-term solutions. They always say "Is she going to have children?" What we are concerned about is the next three years, two years or even the next week, and let us take it bit by bit, but they want full solutions'.
- 14.12 The Harefield cardiologists were happy to consider any suggestions for improving their diagnostic interviews with families. One doctor suggested that: *'the only way is taping it. Because you don't have time to transcribe it'*. She added that if a case was particularly complex, she would arrange for a nurse or psychologist to sit in on the consultation and act as a resource to the parents after the session. She also pointed out that, in recognition of the fact that Harefield was the only European paediatric transplant unit for much of the period under review, the hospital had gone to great lengths to translate its explanatory leaflets into other languages including Arabic and French.

14.13 The doctors pointed out that in the case of parents needing access to dietary advice, this is always shared with the local DGH as they have specialist expertise and it may not be appropriate to keep recalling patients to Harefield, especially when this would involve a long journey. A dietician is available on the Harefield site and their input was frequently sought in the management of cases.

CONCLUSIONS

- 14.14 We accept that it was reasonable to expect that, prior to arriving at Harefield, parents of children who had been referred from another heart centre would already have been given a detailed explanation of their child's condition and possible treatment options. We noted that this information was reinforced by Harefield clinicians. Nevertheless, in some of these exceptionally complex cases, there was still a gap in the parents' understanding of their child's condition. We suggest that research would be useful to evaluate different methods of trying to convey complex clinical information simply to parents and in a form that they can retain.
- 14.15 We welcome the suggestion that diagnostic interviews should be taped for parents to play at home before returning for a further appointment with any queries. We note that this is an area in which cardiac liaison nurses will be expected to make a difference by helping parents understand more about their child's condition. We also support the involvement of the psychologist right from the start in particularly difficult and complex cases.
- 14.16 We also welcome the action being taken to give parents access to the hospital library, and in particular a computer, to enable then to obtain more specialist information on their child's condition. We welcome the fact that doctors are increasingly encouraging parents to use the internet to access information on their child's condition. This should include guidance on how to find and evaluate medical information. However, not all parents are able to use the internet, have access to a computer or are fluent in English, which is the most common language used on the internet. More thought needs to be given to meeting the information needs of these parents.

RECOMMENDATIONS

In addition to the recommendations set out in Chapter 7 the Panel recommends that:

- 51. The Trust commissions research to evaluate different methods for conveying complex clinical information to parents in a form which they can easily understand and retain.
- 52. The Trust ensures that the paediatric clinical psychologist continues to be involved in difficult and complex cases right from the start, and that this service is periodically reviewed to ensure that sufficient resources are provided to enable this to happen.
- 53. The Trust puts in place arrangements for parents to be given access to a computer and helped to use the internet for the purpose of obtaining further information on their child's condition. This should include guidance on how to find and evaluate medical information.

15. CONSENT

INTRODUCTION

15.1 In order to cope with the increasing numbers of patients, a decision was made to maximise the surgical input of Professor Yacoub so that he could operate on each of the three half days of his contracted time for paediatric cardiac services at Harefield. As indicated earlier, the lack of surgical resources meant that it was not possible for every surgical case to be seen the night before surgery by the surgeon or to be consented by the surgeon. Instead, the other tasks in respect of holding outpatient clinics and obtaining consent were undertaken by the centre's consultant cardiologists. This was not unusual; a number of other paediatric cardiac centres did not have surgeons undertaking outpatients' clinics at this time as they considered that the best use of the surgeon's time is in the operating theatre or in managing post-operative patients.

CONCERNS EXPRESSED BY PARENTS

- 15.2 The majority of parents expressed concern that there was no opportunity for them to meet the surgeon before their child's operation and that the surgeon was not available to obtain consent from parents, leaving it to the paediatric cardiologists.
- 15.3 As in the case of the RBH parents, the majority of Harefield parents had considerable difficulties in appreciating that the treatment being offered to their child was difficult, dangerous and potentially life threatening. As one parent pointed out: *'if a surgeon quotes a particular percentage success rate, there are all different kinds of interpretations of what success means for a surgeon and what parents might think is successful'.* Another parent told us: *'If I was told [the] full diagnosis, I could have thought differently they should have informed me more [and] give more time to parents the consent form I signed it when they were taking him to the operating theatre'.*
- 15.4 One parent made her decision to proceed with surgery at Harefield on the basis of being informed that the procedure carried an 80% success rate as opposed to the reported 50% two years previously. She was also informed by the senior consultant at Harefield that

there was a possibility of a transplant if things went wrong. 'At the time we felt or at least I felt it was the right choice my partner did not want any operation at all I phoned my partner in Munich and I said "Well this is the situation" he said "80%, 80%, that is wonderful".'

- 15.5 A number of parents found it hard to understand and retain the complex information they were given on risks, especially when only one parent could be present at the meeting to discuss giving consent to surgery because of family or other commitments. As one parent whose child actually had a very rare condition said: '*The odds seemed so good.* 95% or 90% seemed to be a very good basis to make a decision to go It was a green light and I, as a teacher of mathematics, worried that the medical profession are very hooked on this 95%. You know, the 5% significance'. For these parents, the percentages quoted were subsequently felt to be meaningless as the number of operations undertaken for their child's rare condition was very small less than one a year. They felt that the figures quoted by Harefield gave them false hope, which made their daughter's eventual death all the more painful.
- 15.6 Some parents wished to protect their child from the harsh realities of discussions about risks and would have liked to have the opportunity to discuss the operation first with the doctors without their child being present.

THE CLINICIANS' RESPONSE

15.7 The cardiologists who undertook the task of obtaining consent on behalf of the surgeon accepted that this was not ideal as consent should normally be obtained by the person undertaking or capable of undertaking the operation. However, in Harefield's case this was not possible as the surgeon also spent two days a week on the RBH site and he faced extreme pressures on his time, particularly in respect of combining running a transplant programme where surgeons usually operated at night with a normal daytime operating schedule. As one doctor said: '[The surgeon] is special – in the best way – in that he is very over-committed. [The surgeon]'s time with the families is not as good as it ought to be but I think the social side which has become increasingly important over the last five or ten years has lagged behind. He does not have time to see patients as it is at the moment pre-operatively routinely. Even if he is doing the operation the next day. In an ideal world, no question that the surgeon should be involved with the final consent

procedure but he has become more and more well known and therefore his commitments are far greater than they were even ten years ago'.

- 15.8 Although the surgeon did not routinely see the parents on the day before surgery, he always made time to visit the child prior to surgery and he discussed potential courses of treatment for each child with the relevant doctors prior to surgery. As one doctor said: 'We have clinical conferences every Friday where we discuss cases and if the Professor cannot attend, we tend to discuss the particular case separately with him on another occasion when we manage to speak to him, and spell out what the strategy for surgical treatment is going to be. I do not think there is a patient who will go for an operation where the case will not be discussed with the Professor beforehand'.
- 15.9 All of the doctors felt that a delicate balance has to be struck between being open about the potential risks of an operation and giving parents confidence in the competence of the surgical team.
- 15.10 One cardiologist indicated that she often used a line of ten soldiers when explaining surgical risks and, for example, one soldier is knocked down to explain a 10% risk. Although parents appeared to understand this graphic demonstration of risk they would still conclude the consultation by saying '*but my child will be all right, won't she, doctor?*'.
- 15.11 Another doctor said: 'The way I put it is, if there is a 3% risk of complication, that if one hundred children go for an operation, three out of them are likely to suffer an adverse incident. If they look at it from the more optimistic side, there is a 97% probability that their child will have a complication-free treatment'. He added: 'I encourage them not to sign the consent form if they have any doubts about anything I said or they read on the consent form'.

CONCLUSIONS

15.12 We accept that the shortage of surgical resources made it almost impossible for the surgeon to meet parents in advance of surgery on their child. Given the very limited clinical resources available, it made sense for Harefield to allocate resources in the way that they did, maximising the surgeon's time in the operating theatre. Although this was not unusual at the time it seriously restricted the opportunities available for parents to meet with the surgeon prior to their child's operation, which was the source of a number of complaints made to the Panel. This could be interpreted as denying parents the opportunity to give fully informed consent. We strongly believe that surgeons should not operate without a greater level of involvement with both their patients and the parents, including a requirement to attend case conferences with other members of the clinical team before making a decision to proceed with surgery.

- 15.13 Certainly there was no dispute amongst the doctors that it would have been desirable for the surgeon to obtain consent possibly jointly with the cardiologists if more surgical resources had been forthcoming. However, given the resource constraints, we accept that the alternative would have been for Harefield to cut back on the number of surgical procedures performed. This would have led to longer waiting lists, which would have been equally unacceptable to parents. We hope that this is one area that will benefit from the concentration of resources on the RBH site, thereby allowing more time for parents to meet the surgeon both as part of the consent process and immediately after surgery.
- 15.14 We acknowledge the dilemma for doctors of deciding just how much information should be given to parents. There is a tendency for doctors to focus on the success factors and perhaps to underplay the risks of death and neurological injury because it is not part of the culture to represent cardiac surgery as difficult and dangerous. We believe that when giving parents information about risks, the doctors should indicate how these figures are arrived at and whether they relate to their own, the Trust's or the national record. Even when doctors do try to be more explicit we accept that there is an understandable desire for parents to downplay the risks and focus on the probability of a successful outcome.
- 15.15 Heart surgery is never entirely risk free, although mortality and morbidity risks have reduced dramatically for most procedures over the past decade. We note that few parents appeared to appreciate that, even in a centre with outcomes as good as those of Harefield, it is not possible to guarantee that any particular child will respond well to surgery without complications. We acknowledge that openness about risks can be stressful for some parents but believe that this is essential, as in those cases where something catastrophic does occur during surgery or in the immediate post-operative period at least parents will be better prepared to cope with and come to terms with such an outcome.

RECOMMENDATIONS

In addition to the recommendations set out in Chapter 8 the Panel recommends that:

- 54. The Trust reviews the operation of existing protocols on consent at Harefield Hospital to ensure that parents, and the child where appropriate, have an opportunity to meet the surgeon prior to giving consent for surgery.
- 55. The Trust ensures that all cases of children requiring surgery at Harefield Hospital are fully discussed by the surgeon with other members of the clinical team prior to a decision being made to proceed with surgery.
- 56. The Trust ensures that doctors, when giving information on risk factors, include how these figures are arrived at and provide parents with comparative information for their own outcomes, the Trust as a whole and the national position.

16. DAY OF OPERATION

INTRODUCTION

- 16.1 The day of operation is a time when parents are understandably very anxious and in need of a lot of support. The majority of parents remain on the hospital site during the operation, as Harefield is rather isolated from other facilities. However, the hospital does have extensive grounds and quiet places where parents can wait during their child's operation but remain in touch with staff through the use of hand held bleepers.
- 16.2 Like other paediatric cardiac centres, Harefield was under great pressure during the period under review in respect of the availability of intensive care beds. This was largely due to the shortage of appropriately qualified nurses available to staff these beds. This inevitably led to cancellations of planned surgery.

CONCERNS EXPRESSED BY PARENTS

- 16.3 Although the facilities for parents were far superior to those available in most NHS hospitals, in one case a parent complained: 'I was asked to stay on the ward with [my child] the night before his operation. I was given a rickety camp bed on the floor, sharing a ward with a patient who had undergone minor palliative something, and her mum was also on the ward with her. She woke up in the night and of course was crying I had my child with me on the floor because he was frightened and he could not sleep in his bed. So we were both on the floor with a screaming toddler and her mother who was trying to calm her down I might have got two hours sleep or something, and we were woken up at 6 a.m. because the operation was scheduled for 10am. The trolley finally arrived at 1pm!'.
- 16.4 This parent complained that, as a result of a delay of several hours in her child going down to theatre, the pre-medication had worn off and her child had to be taken down to theatre and administered an anaesthetic in a very disturbed state. *'He was kicking and screaming and shouting "No, no, take me home, Mummy, please take me home". I have had nightmares about this. An hour before I was holding him in my arms and he was sleeping and I thought, thank God he is going to go there peacefully, and by the time the trolley had*

arrived he had woken up.' This was very distressing for all concerned and added to the parents' grief as their child died post-operatively.

16.5 Some parents described having been ill informed and reliant on nursing staff for scraps of information at the time of the operation. They complained at the lack of access to the surgeon to discuss any problems.

THE CLINICIANS' RESPONSE

- 16.6 The doctors told us that when giving parents the date for their child's operation, they always pointed out that this may have to be changed because Harefield only had 3-4 staffed intensive care cots at any one time although space for six cots had been built. As one doctor said: 'Because I am well aware of this, when I give patients dates in outpatients, I always tell them that this may move because of emergencies, transplants etc. And most families are quite happy with that. We have had cancellations more than once, two or three times because of different things coming up. Somewhere in the middle the child might get a cold and therefore they get postponed for that reason'. A doctor also pointed out to the Panel that: 'We are only funded for a certain number of intensive care beds and we have struggles with management. Even if we have nurses available sometimes, historically we have had to say no [for financial reasons]'.
- 16.7 The admission of any child as an emergency, including a transplant, could mean the postponement of that day's planned or elective surgery, often at very short notice. Other problems could arise as a result of difficulties during the operation itself when highly complex surgery can take longer than planned and upset the timetable for the rest of that day's operating list.
- 16.8 Doctors accepted that where it became obvious during surgery that an operation was likely to take much longer than planned, parents should be informed that there would be a delay in their child going down to theatre, saying this happened routinely at Harefield. Ideally the person giving this message should be the surgeon but, since he is likely to be fully occupied in theatre, it was important that a senior doctor or nurse known to the family was on hand to explain the reasons for the delay. As one doctor said: *'I think this at Harefield was quite bad. Strictly speaking it should be the surgeon, but the surgeon who is in the middle of the operation cannot. So then it needs to be someone of senior standing.*

Whether it is a doctor a senior nurse I am not sure. Strictly speaking it should be a doctor but sometimes I think the nurses do it better'.

- 16.9 Delays in surgery as a result of unforeseen complications with the previous operation were regarded by the doctors as an unfortunate inevitability; if there were problems in theatre, the best place for the surgeon to be was in theatre sorting out the problems. 'I think there is a role for the surgeon to talk to the parents, but I feel that, if things do not go right in the operating theatre, then the best place for the surgeon is in the theatre taking care of the patient.' As the surgeon himself said: 'We try very, very hard to do the operation and deliver what we can but sometimes there are clashes with what we have in hand. We feel the primary responsibility is for the patient on the table or for the emergency coming in dying needing an artificial heart or whatever. I honestly make it a point that at the first opportunity, I rush out of theatre and go to the ward and inform the parents what is going on and why and how and when we can do it and apologise for what has happened. But this will happen when I can safely do that'.
- 16.10 The doctors told the Panel that the paediatric transplant programme did have an adverse impact on operating lists where an overnight transplant admission to the intensive care unit would effectively block the bed for a planned surgical admission, disrupting the next day's operating list. As one doctor said: '*[if I were starting from scratch] I would ask for more facilities and dedicated beds. The problem comes in transplantation and artificial heart and ECMOs (extra corporeal membrane oxygenation) have a habit of being unpredictable. You cannot keep the beds open in anticipation. And you cannot anticipate when they will arrive [usually at 3 a.m.] so it is an impossible situation'. Ideally, it should be possible to plan for such an eventuality but the availability of donor hearts, which often arrive at night requiring immediate surgery, is highly unpredictable.*
- 16.11 Turning to the question of whether or not a distressed child should have been anaesthetised, the doctors agreed that in these circumstances it would have been preferable to wait until the child was composed, delaying the start of the operation and avoiding anaesthetising a child who was obviously distressed.
- 16.12 The doctors accepted that there had been problems in responding to parents' concerns during most of the period under review, prior to the appointment of a dedicated consultant intensivist in 1997 with responsibility for the day-to-day management of the intensive care

unit. We were told that it was now his responsibility to stay in touch with the theatre and ensure parents were informed if things did not happen according to plan. 'This is one of the roles of the intensivist. The intensivist should be present if not for all the course of the operation, but at least for the concluding parts of it and be able to convey messages to parents if things do not develop the way everybody would hope they would.' The intensivist pointed out that: 'At the moment it is the practice at Harefield there is a named nurse for each patient going for an operation, a surgical procedure, who keeps in touch with the operating theatres and gets a regular update which is then conveyed to the parents'.

CONCLUSIONS

- 16.13 The day of the child's operation is a highly stressful time for parents. They are understandably anxious and in need of support during the period when their child is in theatre, especially if the operation takes longer than expected. It is clear from the evidence we heard that the failure to appoint an intensivist before 1997 meant that many parents did not get the support they needed at this critical time.
- 16.14 We recognise that there has been a significant improvement in managing parents' anxieties with the development of the named nurse concept in April 1992 and the appointment of the intensivist in 1997. It is regrettable that these developments did not occur earlier in the decade when the majority of the children whose cases we considered were attending Harefield.
- 16.15 If Harefield was to continue as a separate centre, we would regard it as essential that a second intensivist and either a full-time surgeon or a second surgeon be appointed for the paediatric cardiac service. As it is, the Panel accepts that the forthcoming merger will improve paediatric cardiac services by concentrating resources in this vital area.
- 16.16 Finally, we note that all the doctors are in agreement with the need to revise the anaesthetic protocols to ensure that in future no child is anaesthetised when obviously distressed and that in such circumstances time is allowed for a child to return to equilibrium before proceeding.

RECOMMENDATION

In addition to the recommendations set out in Chapter 9 the Panel recommends that:

57. The Trust reviews anaesthetic protocols to establish what should happen when surgery is delayed and a child's pre-medication has worn off before the child has been anaesthetised.

17. POST-OPERATIVE CARE

INTRODUCTION

17.1 The quality of post-operative care at Harefield was the issue that generated most complaints to the Panel. For most of the period under review, management of the intensive care unit was the responsibility of either the sole cardiologist in the period from 1987 to 1991 or the two cardiologists from 1991 to 1997, in addition to their other work. Given that each doctor needed to take the occasional holiday and study leave this meant that on such occasions each cardiologist was effectively on call for 24 hours a day. Matters reached a crisis in 1997 when one of the cardiologists threatened to resign unless another consultant was appointed to manage the intensive care unit, as he was no longer prepared to tolerate such a burdensome workload. Shortly thereafter, in 1997, an intensivist was appointed specifically to manage the intensive care unit and to provide additional support to the cardiologists. However, since he could not be on duty 24 hours a day, the cardiologists were still responsible for providing cover to the intensive care unit.

CONCERNS EXPRESSED BY PARENTS

17.2 As stated above, the largest number of complaints concerned the quality of post-operative care. One parent said: 'From a parent's point of view, I felt there were a number of areas where they were falling down and they could do with some help either from other professionals with expertise in infection control or from changes in management, systems and procedures'. Some parents expressed disappointment at not being able to see the consultant surgeon immediately after the operation to hear how it had gone but he was often not available to see them. 'Once the operation is done, he would do very well. He would live a normal life. There would not be any problems with him. The operation itself, for people like us, we are not medical people so we just understand the operation is done and the doctor, when he comes to us, well you see your son is fine, he is coping with the operation. He will not tell me much in detail. We should have been told the details; what is happening day by day'.

- 17.3 Some of the parents were satisfied with the operation but considered that the management of care following surgery was wholly inadequate with very little evidence of teamwork. One parent told us: 'One of my concerns at Harefield is that they are so focused on surgical outcomes. There was not much in the way of support services available'. Another parent, a qualified nurse herself, pointed out that it was not clear exactly which consultant was in charge of her daughter's care, saying: 'there were no particular doctors assigned to intensive care. There were three SHO's, two registrars and two consultants plus the surgeon but there was no one person in charge of her case'.
- 17.4 Several parents told us there was a failure to respond speedily enough to a crisis and many queried whether this was because the consultant surgeon and paediatric cardiologist were not always on site. Three families referred to the fact that the consultant cardiologist on call at some weekends lived in the next county and was one hour away by car. One family accepted that this cardiologist had already been on call for three consecutive weeks covering for her colleague who was on annual leave. They did not question her commitment but asked why more senior doctors were not employed to provide holiday cover.
- 17.5 One family whose daughter spent a long time in intensive care was particularly concerned at the lack of knowledge demonstrated by a new team of senior house officers who, they said, appeared to have very little experience of either intensive care or paediatric cardiac care. 'The young SHOs were actually left in charge without registrar back up. The three junior doctors who were there had very little experience of intensive care and should not have been left alone in charge of the unit at any time.' These parents added: 'We felt we needed to be there to keep an eye on what was going on. We almost took on the responsibility of overseeing her treatment. We were very anxious that no one seemed to be in charge'. In this case the parents ended up relying on the experienced nurses. As the father said: 'You would tend to have conversations with nurses about important matters and not trouble the SHO the nurses would be the people who could make a judgement and say right we need to get somebody in or this needs to happen. So I ended up with great admiration really for the nursing staff. Well, we had admiration for everyone there. There just did not seem to be enough people around. There seemed to be too much responsibility on junior shoulders'.

- 17.6 Families referred to the shortage of staff on PICU saying that there were too few nurses and that nurses often worked a gruelling double shift. One parent commented that 'there was a complete lack of co-ordination' on PICU. Parents questioned whether resources were spread too thinly at Harefield, saying: 'It is an accountant/management saving that is costing the lives of children'. One parent, who was concerned that staff were working a full shift and then volunteering to return six hours later to do a half shift due to staff shortages, said: 'We felt the unit was not being adequately resourced. There clearly was a need. Funds have been spent. What was stopping the hospital from taking on staff it needed clearly to staff those beds? The staff were working above and beyond the call of duty. Six hours sleep, including travel time, is not enough when you have to do a 12 and a half hour shift with children who are very, very ill'.
- 17.7 Four families expressed concern over what they believed were poor levels of hygiene on the PICU. Two parents alleged that senior nurses did not always wash their hands between activities. One parent said: '*The rules for letting parents and families into the intensive care ward and the amount of washing, the regulation that people did wash, did seem to me to be pretty loose*'. Another parent said: '*My main concern is that the sister on duty did not wash her hands after removing a pile of dirty linen from one bed and then going over to my child's bed. She started pressing his tummy to drain off fluid he had a peritoneal dialysis and this was on the second post-operative day, and the pedal bins did not work. Therefore, you had to open the lid, touch them and put stuff in, and she went over to him at that stage, and I went up to her, and I said, "I am sorry, please wash your hands". There was a big notice by the bed, "Please wash your hands before you touch me"'.*
- 17.8 Parents referred to a lack of infection control procedures for the ward complaining that neither parents nor visitors were required to gown up and wear masks to prevent the spread of infection. One parent said: 'We had the experience of two other hospitals in Munich where no one was allowed on the intensive care unit without a white gown. I mean, you not only washed your hands, you had to disinfect your hands. Sometimes I also had to wear a mask if I had a slight cold or something'. She also raised concerns about visitors to the intensive care unit, where children are very ill and vulnerable to infection. In part, this complaint stemmed from differences in practice between the UK health system and that of Germany with which she was familiar. She pointed out that after her son died: 'My partner blamed me for this hospital, because he had not been there with me on the two

previous occasions, saying, "How could you have even thought of handing over our son to a place that is worse than hospitals in Third World countries".

- 17.9 In two cases the child developed post-operative complications requiring urgent treatment by other specialities which were not available at Harefield and not readily accessible elsewhere. In one case this related to a child with neurological injuries requiring access to specialist neurological advice: 'What worried us was it took six whole days after that before [my child] had a scan at Charing Cross Hospital'. (This case is discussed further in Chapter 21.) In the other case, a child required urgent admission to a respiratory intensive care bed on the RBH site but this could not be made available for six days, by which time she was too ill to be moved, and she died four to five weeks later. 'I was very frustrated that [my child] could not get a bed at the Brompton in a specialist intensive care unit when consultants at Harefield felt she needed to be there as it was no longer a cardiac problem This is a child with a very severe respiratory problem within the same Trust. There were staff that were willing to go to the Brompton to staff the beds if necessary. What the heck was happening to stop her going down to the Brompton?' This left her parents with the terrible question of whether the outcome for their child may have been different if she had had access to care in a specialist respiratory unit at the right time.
- 17.10 One of the most deeply disturbing and shocking cases considered by the Panel raised questions about how far measures that might be considered heroic should be used to try to save a child's life in the post-operative period. The child's mother considered the highly traumatic post-operative treatment of her child to have been prolonged unnecessarily beyond the point when he was capable of surviving.

THE CLINICIANS' RESPONSE

17.11 The doctors acknowledged that many of the parents' complaints were justified during the period under review saying: '*[this was a] valid criticism at the time that most of the patients came. We did not have an intensivist for most of them*'. However, they did not accept that the Harefield did not provide high or consistent standards of post-operative care, saying: '*To medical and nursing staff post-operative care is understood as the actual management and care of the child. We do not believe that this type of care to the children was sub-standard and feel that none of the children died because of lack of care'.*

- 17.12 The Clinical Director at the time accepted that the lack of a single individual in charge of intensive care for most of the 1990s meant that disagreements on the management of patients could arise saying: ' there was a cardiologist round and an anaesthetic round and there was not always agreement'. However, she added: '.... I do not think it is anything near as bad since we have had an intensivist'.
- 17.13 Although the doctors readily acknowledged the difficulties of providing full medical input during the decade leading up to 1997, they did not accept that there was a delay in responding to arrest calls. As one doctor said: *'There are always people on-site who can do the arrest call. It is not practical for the consultant to be there to cover the arrest call we have much better back up on-site now I would say half an hour for an emergency I suppose an hour maybe for a routine'.*
- 17.14 The doctors agreed that the unit had experienced a number of difficulties due to the shortage of nurses, pointing out that the NHS had experienced severe problems in recruiting and retaining nursing staff, especially those in intensive care, for much of the period under review. A nurse told us: '*The problem is there are an inadequate number of nurses in the specialty and more jobs around than there are individuals, and that it is that stage of somebody's career, particularly the sort of D and E grades it is a time of life that is often mobile, working one place, try somewhere else, and so the turnover is quite high'. Double shifts were a relatively common way of responding to these problems. We discuss further the impact of the shortage of nurses in Chapter 20.*
- 17.15 In response to parents' complaints that they found it difficult to gain access to the surgeon, the doctors told the Panel that the surgeon often visited his patients in intensive care during the night when he was in the hospital to perform a transplant and when the parents may not have been present, saying: '[The surgeon] actually does see the patients post-operatively often in the middle of the night when the relatives are not there'.
- 17.16 We were informed that the surgeon also maintained contact when he was not at Harefield, telephoning three or four times a day to monitor the condition of his patients. However, we were told that in post-operative care the majority of decisions do not normally require a surgical input into decision making although it was always helpful to have the advice of someone of his seniority and experience.

- 17.17 The doctors acknowledged that there were problems when new teams of junior doctors came in to post with little or no knowledge of the area they were working in. This was not unique to Harefield, however the lack of middle-grade staff exacerbated these problems. This was ameliorated to some extent by the fact that many of the senior nurses working in intensive care were very experienced, having worked at Harefield for many years. As one doctor said: 'I think all the sisters, and there are certainly more than two or three of them were all well experienced and working to the highest standard one can expect'. However, a nurse told us: 'I think the doctor has a level of decision-making about the care that nurses do not have, and that does bring with it huge responsibilities that in a way it is easier for the nurse not to dissociate from, but the buck stops with the doctor, and that I do think makes a huge difference in how the groups operate'.
- 17.18 The doctors were very surprised at the parents' allegations about the low standards of hygiene at Harefield, as regular audits of infection rates throughout the period under review had shown that rates of infection on the unit were very low and there was no evidence of any infection on the wards during the 1990s when all the cases reviewed by the Panel attended the hospital. One doctor said: '*There is no excuse for not washing hands, and this has not changed since Nightingale in that sense and should not happen There has been an audit done of the infection rate and ours, as I understand it, is very good'.* Another doctor indicated that there was an infection control sister in post who was responsible for the entire hospital for the whole of the period under review.
- 17.19 The doctors noted parents' concerns about the absence of protective clothing on PICU, saying Harefield had discontinued the policy of requiring parents and visitors to wear protective clothing even on the transplant unit some years previously as research had shown that infection control was not improved by wearing gowns.
- 17.20 The doctors responded to parents' concerns about high-risk surgery saying Harefield had pioneered many innovative treatments over the years which were now regarded as standard with a high chance of success. Given the complexity of the cases referred to Harefield, including a number requiring the correction of earlier surgery which was failing, it was not unusual for doctors to be faced with the need to undertake pioneering surgery which carried a relatively high degree of risk. However, in most cases, without surgery the child would have died in the near future. In these circumstances the doctors said it was seen as ethical to attempt high-risk surgery with the consent of the parents and where appropriate

the child as, in addition to meeting the child's needs, such surgery provided the opportunity for surgical advances to be made. The doctors also believed parents wanted to fight to save their child's life and were prepared to consider high-risk surgery if the alternative was the premature death of their child.

- 17.21 The Panel sought advice on what factors need to be borne in mind when doctors decide to pursue heroic treatment or to determine that the point has been reached for discontinuing treatment. For the most part this was seen by the doctors as a team decision with all members of the consultant team and parents participating equally in decisions on difficult cases.
- 17.22 The doctors pointed out that these considerations also applied to post-operative care in that it is only by attempting new procedures and new drug therapies that progress is made. The doctors accepted that the effects of heroic treatment on children in the post-operative period may be devastating for parents, and that it was important that families were supported and helped to come to terms with what had happened in the event of a prolonged and traumatic stay in the intensive care unit which ended in the child's death.
- 17.23 The doctors acknowledged that, in one case, there were delays in obtaining specialist external advice and arranging for the transfer of a child to a specialist respiratory intensive care bed. As one doctor said: '.... access to expert paediatric or general paediatric care, renal support team or so on is readily available the hospitals where the paediatric intensive care unit is an integral part of the children's hospital have much easier access to those expert opinions but I do not think that this expert opinion was denied to the patients treated at Harefield Hospital'. The Panel was advised that, as the child in question was very sick her transfer to the RBH site would not have been without significant risk, as it would have been unwise to transfer her by ambulance until she was completely cardiologically stable. As one doctor said: 'Equally some of these children, although we could transfer them over, are often very sick and to transfer is not without risks'. Although access to other specialist respiratory advice and services was less than ideal in this case, the doctor informed the Panel that it would probably not have affected the eventual outcome.

CONCLUSIONS

- 17.24 We accept parents' concerns about the weekend on-call arrangements, particularly in the period before the appointment of an intensivist in 1997. Clearly a balance was needed between the doctors' responsibilities for being on-call and their need to have a life, and this was not entirely achieved. The Panel noted that in one case the consultant cardiologist had been on call for the previous three weeks while her consultant colleague was on annual leave. It was intolerable for her to be placed in this position especially as she was then expected to cover the following weekend as second on call. We believe that the on-call arrangements were seriously deficient and yet another justification for the appointment of the intensivist, who joined Harefield shortly thereafter.
- 17.25 We consider it self-evident that a surgeon appointed for three half day sessions a week spread across three days cannot be expected to devote to each case as much time as a surgeon appointed for paediatric work on a full-time basis. In our view the responsibility for this state of affairs does not lie with Harefield staff but with those managers and politicians who declined to fund additional surgical input to Harefield during the period under review.
- 17.26 The allegations about the poor hygiene practice of a 'senior' member of the nursing staff surprised us as nursing staff were highly praised by the majority of parents participating in both Inquiries. We established that records show that there was no evidence of any infection on the ward in 1993 or in 1999, the specific years to which the complaints related. However, we felt that if several families complained of poor hygiene standards in PICU, there must be some basis for their concerns. The Panel is quite clear that if there were any instances of poor hygiene on an intensive care ward there can be no excuse for this.
- 17.27 In discussions with the nursing staff we accepted that it was difficult to follow up complaints about an individual nurse not washing her hands before touching a patient in the absence of any details identifying the individual concerned. The nurses pointed out that it was impossible to obtain independent verification of the parents' concerns, especially as a number of bank or agency nurses worked on the intensive care unit during the period under review.

- 17.28 Turning to the question of when is it right for doctors to pursue heroic options, it is not appropriate to discuss the circumstances of a particular case, but it does raise an important issue of principle. It will undoubtedly be the case that on rare occasions clinical staff pursue both established and pioneering methods to try and save a child's life, in the belief that they have a duty to their patient to grasp every possible chance to ensure their survival. But whenever high-risk, heroic treatment is considered, it is imperative that the clinical team is open, honest and transparent with parents in order to avoid any misunderstandings or false expectations about what is achievable, reasonable and in the child's best interests. Particular care and attention also needs to be paid to respecting the wishes of parents about ceasing treatment and allowing a child to die with dignity.
- 17.29 As with other deficiencies that we have noted, the proposed merger of paediatric services on the RBH site will improve access to specialist advice either from the respiratory physicians at the RBH or from the tertiary paediatric services at the Chelsea and Westminster and St Mary's Hospitals.

RECOMMENDATIONS

In addition to the recommendations set out in Chapter 9 the Panel recommends that:

- 58. The Trust reviews medical staffing structures to ensure that adequate cover is provided to cope with staff sickness and holiday arrangements without requiring consultant staff to work a more than one in three rota.
- 59. The Trust ensures that new junior doctors coming onto the paediatric wards are given specific focused training in intensive care before being left in charge of the paediatric intensive care unit, even for only a short period.
- 60. The Trust considers reviewing specialist sources of advice in respect of known complications likely to arise from paediatric cardiac services, with the aim of ensuring that named doctors are identified who can respond promptly within 24 hours to requests for advice. A synopsis of these sources of advice should be made available to parents on their child's admission to hospital so that they are fully informed of the hospital's links with key sources of specialist advice.

61. The Trust continues to review its infection control policies and ensure staff are aware of the need to maintain vigilance.

18. PARENTAL INVOLVEMENT

INTRODUCTION

- 18.1 The way in which Harefield involved parents and used its limited resources coincided with a major shift in the expectations, rights and responsibilities of patients and parents in terms of the need for information and full involvement in decision making. What may have been regarded as acceptable in 1987 is no longer the case. Parents request more information, better communication and more time with the consultant when making difficult decisions, for example in respect of giving consent to major heart surgery.
- 18.2 As will be clear from the preceding sections, the main casualties of a service which was severely under-resourced were children and their parents, because senior medical staff did not have sufficient time to respond to the needs of parents in a manner consistent with a modern day paediatric cardiac service, especially in the difficult post-operative period when parental anxiety is at its highest.

CONCERNS EXPRESSED BY PARENTS

- 18.3 Many parents were concerned that their observations seemed to be dismissed by staff although these observations were subsequently seen as critical indicators to the progress of their child in intensive care. As one parent said: '*They were not responding to parents*' concerns if they do not, how are they making improvements, how are they moving forward if such a vital element is not being addressed?'.
- 18.4 One parent told us: 'It is important for a hospital to understand the family whose child they are treating, and in what sort of environment they are living and how they will cope with it I made the right decision but if the bereavement happens ... I was not fully aware or prepared for this outcome'. This parent was also concerned at the lack of support offered to him and his wife after their son had died in intensive care saying: 'We had to travel home in our own car, from Harefield to It is a long way when something like that happens. But that is the problem you see: they do not understand the problems of parents'.

18.5 One parent pointed to the lack of support offered by the surgeon after their child who had had a successful transplant at Harefield died two years later in intensive care. Another parent, who was herself a qualified nurse with experience of the adult heart transplant service, suggested that one way of reducing parental isolation would be for Harefield to establish a scheme to identify a volunteer rota of 'experienced parents' who had already been through the system and match them up with parents whose children were currently on the list for surgery. 'I do think either a volunteer advocate – or a paid advocate someone with medical knowledge should be there to support the parents and perhaps help them to get better information. Because as a parent you do not think of asking the questions that you need to ask at the time. Because you are swept along and obviously the pain of it all.'

THE CLINICIANS' RESPONSE

- 18.6 The doctors acknowledged the importance of taking into account parental views. As one doctor said: 'We certainly should be taking into account parental views. If they are saying there is a problem with their child, we should be taking their comments seriously and they should be voiced and documented'. They also accepted many of the parents' concerns regarding the unavailability of the surgeon. One doctor remarked that Harefield parents had a clear choice to make, saying: '.... if I am a parent and I want the operation to be done by a world renowned, world class surgeon, there may be a concession to make; that the surgeon may not spend as much time with me and my child before and after the operation. I do not know what the right answer is to settle for second best and have all the time available'.
- 18.7 The doctors pointed to the role of the clinical psychologist who had a major role to play in identifying vulnerable families and giving them additional support, especially when they were far from home and their usual support networks. As one doctor said: '.... psychologists have acted as family support and they have been very good. They will go in and spend hours sometimes with the patients, both pre- and post-operatively'.
- 18.8 The doctors welcomed the suggestion of setting up a parents' support programme saying: 'We have had a similar system with the transplant patients we have them put in touch with a family of similar background and similar locality to act as a mentor'. The doctors were interested in trying out new approaches but pointed to some limitations in respect of

the intensive care setting, where it was not always clear whether a child was likely to survive and each case was different.

18.9 The doctors informed the Panel that Harefield had tried to implement a more familyfriendly service saying: 'We tried our very hardest all along to make it patient-orientated. Instead of starting outpatient clinics at the usual 9 o'clock or 2 o'clock in the afternoon, outpatient clinics started at 11.30 in the morning so that patients [parents] could get their other children off to school and the ones that were coming a long distance could get there and be free to pick up their children. So even though resources were short we tried to make things as patient-friendly as we could'. It also meant that that those travelling long distances could travel at a reasonable time to their appointment and avoid putting undue stress on their child.

CONCLUSIONS

- 18.10 As stated earlier, parents' desire for fuller involvement in decision making has grown considerably over the last decade. It was clear to us that there was a serious mismatch between parents' expectations and the support available for them at Harefield. This is not to say that no time was allocated by the doctors to meeting parents as this would be patently untrue. Indeed, the evidence reviewed by the Panel indicates that doctors gave parents a significant amount of time at the important diagnostic stage to ensure they understood and agreed to the often complex diagnosis and treatment options.
- 18.11 We heard that the task of supporting parents currently relied largely upon the input of one clinical psychologist and felt that this individual could not be expected to provide support to parents unaided on a 24 hour, 7 days a week basis, especially as her work also involved providing support to adult heart transplant patients. A temporary second half-time appointment of a psychologist had been made in 1993 to cover maternity leave. Given the importance of the psychology service in providing support to parents, we believe it is essential that the staffing of this service be reviewed at the earliest opportunity.
- 18.12 From the cases we reviewed, we conclude that for much of the period under review Harefield doctors were not able, mainly for resource reasons, to meet parents' reasonable expectations in terms of psycho-social support in the difficult post-operative period. We were surprised to note that insufficient consideration appeared to have been given to the

role of the local authority's social work team in complementing the work of the clinical team and providing specialist support in this area. We noted that back up was provided by the local authority social work team only for children who actually lived in the London Borough of Hillingdon. Children who did not live in Hillingdon were therefore at a disadvantage as they were denied access to the level of social work support they could reasonably have expected in their home area. Given the nature of a tertiary referral service, we believe that this is an issue that should be considered by the DoH, as these children are falling through the net just when they and their parents most need support.

- 18.13 Many of these problems should be resolved at least in part by the proposed merger of paediatric cardiac services on the RBH site where there will be a larger pool of senior medical staff on which to draw. The appointment of a team of cardiac liaison nurses for paediatric services will also help considerably to reduce parents' anxieties by providing dedicated support throughout the process. A full description of the work of cardiac liaison nurses is included in Chapter 22.
- 18.14 Although it could not be a substitute for proper input from the doctors, we note the helpful suggestion of a parent that a volunteer or paid parents' advocate scheme be established. We acknowledge that some form of peer group support could be a valuable way of complementing the role of staff in providing support to 'new' parents, and that this idea is worth exploring in more detail.
- 18.15 In general the facilities made available to parents whose children were in intensive care were excellent. In planning the relocation of Harefield's paediatric cardiac services to the RBH site, we believe it is essential that generous provision is made for parental accommodation, play and school room facilities and quiet rooms where parents, who are faced with coping with the death or disability of their child, can be counselled in private and are not reduced to coping with distressing information in a public place.

RECOMMENDATIONS

The Panel recommends that:

- 62. The Department of Health reviews arrangements for the provision of social work support to children attending tertiary referral centres and ensures that all children are provided with an appropriate level of support.
- 63. The Trust revises existing protocols to ensure that parents are fully involved in decisions on their child's care and treatment, particularly where this involves the adoption of heroic measures, and that such decisions be discussed at a full team meeting allowing the full range of options to be considered. In the event of there being any dissent within the team on the right way forward, the parents should be given the option of seeking independent advice from the Trust's Clinical Practice Committee on the course of action proposed.
- 64. The Trust assesses whether it is possible to establish a volunteer scheme on a readily accessible database to provide mentoring or peer group support from 'experienced' parents to parents whose child is undergoing planned surgery. In the case of emergency admissions, consideration to be given to whether a similar scheme would work in these more difficult circumstances.
- 65. The Trust ensures that early attention is given to reviewing the staffing levels for the clinical psychologist service so that the injection of additional resources can be considered in the next financial year if required.

19. WHEN A CHILD DIES

INTRODUCTION

- 19.1 The main focus of the Harefield Hospital bereavement counselling service is on giving families support, care and information after the death of a child. It is also used to support staff who have to cope with death often in very difficult circumstances. Harefield was one of the first centres to recruit a clinical psychologist for paediatric cardiac services in 1988 but her role also encompassed work with transplant patients. Much of her work and that of a half-time colleague appointed in 1993 was with newly bereaved parents. Parents were routinely offered a follow-up appointment with the child's cardiologist and/or the intensivist and the psychologist six weeks later.
- 19.2 In the majority of cases where a child died on the PICU, the consultant intensivist and/or the consultant cardiologist were responsible for breaking the news to the parents. If the clinical psychologist was not present when a child died she offered parents the opportunity of attending a bereavement counselling meeting and kept in touch by telephone. Harefield has a very well developed bereavement counselling service, which is now co-ordinated by the Patient Liaison Officer appointed in June 1998, who also acts as a provider of advice and support to parents when their child is in the hospital. Contact was made routinely with local DGHs or original referring hospitals, to ensure that they were aware of an individual child's death and the need for parental support since this was best provided locally.
- 19.3 The follow-up meeting was an opportunity for parents to discuss their child's case in the light of the post-mortem or pathology reports, usually with the intensivist or one of the consultant cardiologists accompanied by one of the clinical psychologists. The doctors saw this as an opportunity to try to answer parents' many questions and to obtain feedback on parents' views of the service they and their child received. Meetings were also arranged at a later date if parents were too distressed to attend and needed more time to adjust to their loss.

CONCERNS EXPRESSED BY PARENTS

- 19.4 Most of the parents seen by the Panel experienced the death of their child in hospital. Parents were deeply traumatised but did not necessarily blame the hospital for their loss. As one parent said: 'Parents can accept that sometimes things do go wrong. But if you know what went wrong and the acknowledgement of it and they admit it, it helps parents enormously'. Another parent said: 'When you lose a child, it is difficult to raise questions as you do not necessarily want to speak directly to the staff involved because it is very traumatic, no matter how highly you regard their care'. In another case, where a child died 18 months after a heart transplant, the parents said: 'Immediately after [our child] died, the day after the post mortem Harefield wanted to send flowers to the funeral. But we did not actually have a proper funeral as such. We had a very, very small family affair. I did not want flowers from Harefield. I actually think counselling from the hospital where your child has died is inappropriate'.
- 19.5 In several cases, parents who had spent a very long time in the intensive care unit expressed their disappointment at the lack of support, both practical and psychological, offered to parents during this period. One case we reviewed concerned a teenager who died two years after receiving a heart transplant. In this case the parents would have liked to have been offered access to a non-medical contact to discuss their continuing concerns.
- 19.6 A number of parents were concerned in retrospect that they had not been asked to agree to a post mortem. As one parent, who was not asked to give consent to a post mortem, said:
 'I think we would have liked someone to look at her heart we did not think it at the time obviously to see exactly the state of her heart. And also to look at, I suppose, her other organs, just to see what it was that happened in the end'.

THE CLINICIANS' RESPONSE

19.7 All the doctors accepted that improved staffing levels were needed to offer parents much better follow-up support services especially when a child had died. They pointed out that although Harefield offered bereavement counselling this was not suitable for parents who lived in other parts of the country. In these cases parents were referred to local services but such support did not always materialise. Doctors also pointed out that bereavement
services are rarely geared to meeting the needs of siblings who are often very traumatised by the death of a much loved brother or sister.

- 19.8 The doctors saw it as important to give parents support after their child had died and were ready to answer their immediate questions, but for the most part parents were too distressed at this time to be able to think coherently. So the most useful time to do this was at the follow-up meeting approximately six weeks later. As one doctor said: '*I certainly do not feel personally at this stage that parents are left unsupported or without any information …. this is an extremely distressing time for the parents …. and they may not take in all the information given to them. That is why I think offering them the opportunity to come back later on, as many have done, to discuss the case, discuss what went wrong, what the result of the post mortem is, if there was a post mortem, and also give us feedback about what they felt was not right, what they perceive as weakness of the service or where they feel the problem was'. He usually urged parents to agree to a post mortem as it was not always easy to see why a child had died, particularly when the operation had been anatomically successful.*
- 19.9 The doctors told us that, in the rare event of a child dying on the operating table, the surgeon's first duty is to explain personally to parents in as much detail as they can absorb, what happened, what went wrong and to try and support them at this difficult time. As one doctor explained: 'Because all the medical and nursing staff take every possible way or time to spend with the parents of the child who died or who has suffered some irreversible damage I hope it is not the perception of the parents whose children died at Harefield that they were left without any follow up and support'.
- 19.10 The surgeon said: 'The ones who die if I am in the hospital, I make a point personally, immediately after a child dies, my first duty is to go and explain in great detail how I see things, what happened, and try and support them as much as I can'. But he acknowledged that this is a very difficult time for parents adding: 'We try and explain everything in a very, very honest fashion and then say that we expect you to feel free to come and talk to us again'. A doctor said: 'It should be the consultant in charge of the case who should go through things with the families be a staged approach, because there will be both the initial death in hospital and there will be a follow up at times at the time of death, the amount of information one actually absorbs and takes in is limited, but they still want to hear it all. So it is important to have the follow-up visit'.

19.11 The doctors pointed out that around one in three transplants fail so the risks of death as a result of organ rejection are very high. Although important advances in treatment have been made over the last fifteen years, a transplant is a treatment of last resort; the evidence to date shows that the majority of transplants in children will need to be re-done after a period of around ten years. Commenting on one case a doctor said: *'They allowed themselves to believe that transplantation means immortality. Transplants [only] buy a bit of time'*. The doctors drew attention to the difficulties for parents of coping with a transplant including the rigid maintenance of the immuno-suppressant drug regime which their child would have to follow indefinitely and constant fears about their child's long-term survival on a day-to-day basis.

CONCLUSIONS

- 19.12 In general, the Panel was impressed with the level of facilities provided to parents coping with the death of their child. However, we were concerned that some families are falling through the net. Given the fact that many parents travel long distances to Harefield, we felt there was scope for a much more co-ordinated approach to ensuring that such families obtain bereavement counselling in their own localities. We noted that on three occasions parents whose child had just died were left to make their own arrangements to travel home although they were in no fit state to do so. We believe that this is an area where a more sympathetic approach would be appropriate, with a member of staff or competent lay volunteer helping families make arrangements to return home safely.
- 19.13 We also noted that Harefield provides a dedicated foetal echocardiography service to all parents who have had congenital heart disease themselves or a baby with congenital heart disease, when they became pregnant again. In cases where there is a genetic component, parents are routinely referred to a clinical geneticist, if appropriate, by their local DGH as this is outside the remit of a specialist hospital like Harefield.

RECOMMENDATIONS

In addition to the recommendations set out in Chapter 10 the Panel recommends that:

- 66. The Trust ensures that there is a member of staff or competent lay volunteer who will make all the necessary arrangements to ensure that, in the immediate aftermath of a child's death, the family are able to get home safely.
- 67. The Trust, in its current review of bereavement services, pays particular attention to the needs of children living in other parts of the country to ensure that ongoing sources of specialist advice are available to parents.
- 68. In cases where there was a genetic component to a child's illness and subsequent death, arrangements should be made for parents to have an early meeting with a foetal cardiologist so that they can discuss monitoring arrangements in respect of any future pregnancies and with a clinical geneticist so that they can make informed decisions about future pregnancies.

20. RESOURCES

INTRODUCTION

- 20.1 It is apparent from the preceding pages that almost from the inception of the paediatric cardiac service in 1971, Harefield faced a constant struggle to secure sufficient resources. The issues raised by parents were seen as valid by both the Trust Board and clinicians. They reflect day-to-day life in a centre that, for much of the period under review, was delivering high quality care within severe resource constraints. Inevitably this meant that some corners were cut.
- 20.2 It is by no means exceptional in the NHS to find examples of a brilliant doctor pioneering new techniques and delivering a new service, but this is normally within a teaching hospital environment where the availability of teaching, research and Special Trustee funding can help to cushion any problems. These options were not available to Harefield, as it was not a teaching hospital, therefore it was obliged to seek charitable donations from the local community and wealthy philanthropists.
- 20.3 In the seven years up to 1997 when most of the parents involved in our Inquiry attended the hospital, medical staffing was a particular problem. A one in two on-call rota operated except during holiday periods when the on-call commitment was increased to a 100%, putting almost unbearable strain on the two cardiologists. Although in other specialities it could be argued that hospital managers should have recruited a locum to cover holiday periods rather than expecting dedicated staff to cover for each other, the fact is that such locums are rare in this small field; the only way of coping would have been to recruit additional permanent members of staff on a sessional basis.
- 20.4 Although it could also be argued that there was insufficient surgical input to the unit the gaps were not as great as they might have been as the surgeon put in considerably more hours than required and was a noted workaholic. The main workload pressures were experienced by the cardiologists as they were responsible for the management of post-operative care, in addition to undertaking their other duties, for most of the period under review until the appointment of an intensivist in 1997.

20.5 By 1996-1997 this led doctors to the view that, although technology was improving and they could continue to do good clinical work, the centre was small in relation to other centres and needed to undertake a larger number of operations to justify the appointment of a dedicated full time paediatric cardiac surgeon and the increased staffing levels seen as essential to modern day paediatric practice. Changes in junior doctor staffing meant that the days of small centres such as Harefield were numbered. In addition, the imminent retirement of Professor Yacoub in 2001 would make it difficult to recruit a replacement specialist paediatric surgeon to undertake that part of his workload. As we noted earlier, a decision was therefore taken to promote the merger with the RBH service.

CONCERNS EXPRESSED BY PARENTS

20.6 Parents raised a number of concerns about the lack of resources at Harefield, such as the paucity of doctors and the shortage of PICU nurses, most of which have already been discussed in earlier parts of this report. One parent's comment sums up simply the concern expressed by all parents on the issue of resources: 'There is no doubt that Harefield were under pressure at the time there are so many operations being done I do not think there was the back up They are stretched. When somebody goes on holiday it really is a problem'. She added: 'I have been able to make a lot of observations and suggestions due to the length of time that my daughter was at Harefield. The staff are very dedicated and I am very grateful there are people willing to do such a distressing job. I believe that I made many friends there but that they do need help to ensure that sufficient resources are available so that all aspects of care, great and small, are not overlooked last year staff were very demoralised by the impending move to the Brompton and [by] the Bristol Heart Staff need good morale if they are to work effectively in such a stressful Inquiry. environment'.

THE CLINICIANS' RESPONSE

20.7 Doctors told the Panel that, in their opinion, despite its excellent results and reputation Harefield was not encouraged to thrive by the North West Thames Regional Health Authority or by the DoH. One doctor said: 'We were not a local service – we were actually funded as a DGH and we did not get any of the supplements – that the teaching hospitals, the postgraduate, the special health authorities got because we were not *meant to happen. We were not planned'.* She added that: 'In those days [1980s] there was no question – services grew in hospitals in those days like Topsy and there was no rationale or no planning and there were all sorts of centres trying to do it'.

- 20.8 The situation improved in 1987 with the unit being recognised and awarded supra regional funding. As one doctor said: 'We were recognised in the end in the late 1980s [1987-1988] as there was supra regional funding for neonatal and infant cardiac surgery'. However this only lasted for a comparatively short 7-year period until 1994, when new arrangements were put in place by the NHS Executive for commissioning specialist services such as paediatric cardiac services on a regional basis. Doctors at Harefield were disappointed at the withdrawal of supra regional funding. As one said: 'Why get rid of something which has been successful?'.
- 20.9 Doctors accepted that they were not able to spend as much time responding to parents legitimate concerns as they would have wished. One said: 'I had to threaten to resign I am not prepared to do a one in two anymore I decided I should have a life'. However, the position eased with the appointment of a second cardiologist in 1991 and a consultant intensivist in 1997. One doctor pointed out: 'The strength [of Harefield] is the expertise where particularly complicated cases were treated which were quite often refused surgical treatment at other centres and a thriving heart and lung transplantation programme with a dedicated team of staff who worked very hard in the past in conditions which nowadays would be found quite unacceptable'. However, one doctor pointed out: 'Yes, it is historical the NHS has run at the expense of consultants for a long period. Junior hours have come in, in a big way And we have managed to employ more juniors on the back of that Consultant hours have yet to hit the mark'.
- 20.10 The doctors pointed out that despite its excellent results Harefield had been threatened with closure on a number of occasions. However, they now had to accept that Harefield was no longer viable. As one doctor said: 'I have fought tooth and nail to keep the unit at Harefield. But with patient care paramount, I feel that we cannot do that'. The doctors were not happy about giving up the generous facilities available at Harefield, as one doctor said: '.... we will be going into much more cramped facilities. I am prepared to fight in terms of patient accommodation, that adequate resources are made [available] for this It is not going to be easy and it is not going to be as good as we had hoped hopefully, when we all get to St Mary's, if we do, then it will be good'.

- 20.11 Whilst the doctors accepted the need for the merger, the surgeon pointed out there were losses as well as gains, saying: 'It has functioned well, it has a special type of expertise and magic the people, the community around who support the hospital all these ingredients you cannot suddenly reproduce'. He accepted that the move would happen but added that: '....the Harefield site and the support of the community should be used for the benefit of the NHS. It should not be just destroyed'.
- 20.12 Other doctors were very concerned about whether the nursing staff would move from Harefield to the Brompton site, saying: 'There is obviously not the morale among the nursing staff in particular we would all like to see, and it is not surprising because most of the nurses live around Harefield, who have families and who are not happy that the unit where they have worked, many of them for years will close down. They will find it extremely difficult to commute to the Brompton'. Another doctor who was concerned about losing some of the Harefield nurses on the transfer of services said: 'If we had more money, that is where we would be channelling it to a large extent. It is very difficult getting nursing staff countrywide for intensive care and perhaps added incentives accommodation, are necessary'.
- 20.13 The doctors pointed out that, although they faced great pressures in responding to the demands on their time, the key problem faced by the unit in the 1990s was the difficulty in recruiting nurses, particularly for the intensive care unit. As one doctor said: 'We need more people, we need more senior people, we need more nurses. What we need is a nurse who can nurse and do intensive care. We need adequate funding for nurses but even with the adequate funding for nurses unless they improve their pay scales quite considerably. The involvement of the nurses with these patients is considerably more harrowing than it is for the doctors and yet they get paid a pittance. They are there the whole time. We just float in and out'.
- 20.14 The Panel was advised that no capital costs at Harefield were funded by the NHS in the period 1971 to 1997-1998. As one doctor said: 'Until the last two or three years not a single bit of new building or equipment was government funded. The extension that you saw to the intensive care unit at Harefield even the adult intensive care unit was charitable funding and all the equipment, the echo machines, the ventilators and things came out of fund raising'. Although funding from wealthy benefactors and local charitable

sources was used to make good these deficiencies in capital funding, it was rarely used to meet the costs of funding additional staff as this required a revenue commitment over a two or three year period.

THE TRUST'S RESPONSE

- 20.15 The Trust did not acquire responsibility for Harefield's services until the RBH and Harefield Trusts merged on 1 April 1998. Nevertheless, the Chief Executive was clear that Harefield had been historically under-resourced and was potentially not viable due to its size: 'Paediatrics had two problems, primarily on the Harefield site. One was a resource problem, that it was clearly under-resourced and it was going to be very expensive to try and build it up to the level even equivalent to that of the Brompton in addition the Brompton site was continuing to press for additional resources with perfectly good arguments for them. Secondly the reducing number of paediatric units the simple smallness of the unit at Harefield felt that it would inevitably become very difficult to provide adequate cover, especially medical cover for it'.
- 20.16 The Trust recognised that there was a problem throughout the NHS in recruiting nurses for intensive care but the Director of Nursing said Harefield was better placed than many units as it had a number of experienced long-serving nurses who would be difficult to replace if they chose not to move with the service to the Brompton site. In describing what attempts the Trust was making to improve the nursing situation she said: 'What do we do about it? We have done and continue to do just about everything you can think of: national and international recruitment, support for education, bursaries, fought to keep the accommodation as good as possible, tried to have flexible working We go to open days, we take our students, we recruit from students. I seriously do not think there is anything magic that we should be doing that we have not done, both to try and recruit and to retain [nurses]'.

CONCLUSIONS

- 20.17 We recognise that the Trust can only be held responsible for the level of resources made available for paediatric cardiac services at Harefield Hospital during the last two years, as the Harefield NHS Trust Board and Hillingdon Health Authority were responsible for budget allocations prior to the merger. Press headlines on Harefield tended to focus on the miraculous advances in cardiac surgery without any acknowledgement that new equipment was almost entirely funded on soft monies and that the dedication of existing staff masked a chronic shortage of clinical and support staff.
- 20.18 We believe that there was a significant failure, both in terms of planning and resourcing, to establish a proper paediatric cardiac service at Harefield Hospital, particularly in the period 1971 to 1986-1987, when the unit was led by two consultants dealing with 150 operations per year, whose combined contractual hours amounted to the equivalent of less than one full-time post. Although the appointment of a second consultant cardiologist in 1991 and much later an intensivist in 1997 eased the position, the pressure put on the two cardiologists in the period from 1991-1997 was unacceptable. We conclude that the previous Hillingdon Health Authority failed to respond to the needs of the paediatric cardiac services in a professional and accountable manner and that this compromised the quality of services available to patients.
- 20.19 Even when part of the service was recognised for supra regional funding in 1987-1988, little attempt was made to cost properly what was by then acknowledged internationally as one of the leading centres in the world for paediatric cardiac services. We accept that the future of the Harefield centre was raised as an issue by regional planners on a number of occasions in terms of whether it should continue to survive as a stand-alone unit, but on each occasion the doctors fought off the threat of closure. With the benefit of hindsight, it is clear that a decision should have been made by senior NHS managers, DoH policy makers and politicians either to resource the centre adequately or to insist on an earlier merger with the RBH or Great Ormond Street Hospital to create a viable single unit.
- 20.20 In highlighting Harefield's resource problems we are aware that a number of other paediatric cardiac centres also suffered from under-funding during the period under review. It seems to us that little attention appears to have been paid at the national policy level to the real costs of funding paediatric cardiac services, with no attempt to define what

services should be provided or at what level. The SRSAG's criteria, which applied in the period 1984 to 1994, setting out the standards that units should aspire to, appear to have been ignored in the case of Harefield. Despite the requirement to have two full-time surgeons and cardiologists in post, Harefield had three paid sessions a week of surgical input throughout the period under review and four paid sessions of cardiological input, although the latter was increased to a full-time post in 1987, a second cardiologist was appointed in 1991 and an intensivist was appointed in 1997.

- 20.21 We needed to evaluate what difference, if any, the lack of resources made to the provision of services at Harefield Hospital. The question of whether surgical outcomes were adversely affected by the lack of resources has been reviewed contemporaneously by the Hunter Review, which assessed the outcome of paediatric cardiac surgery at Harefield Hospital between 1984 and 1998. It proved difficult to identify an appropriate comparator because no other hospital's mortality data has been subject, during the period under review, to similar scrutiny and external validation. Despite this shortcoming, the results have been compared with the HES data and with the annual returns to the Society of Cardiovascular and Thoracic Surgeons. Any inferences drawn need to take this into account.
- 20.22 In general the results were comparable to those reported by other units in the UK. In two periods, one in the early 1990s and the second in 1998, a small increase in mortality was identified by the clinical audit process: these resulted in a change in procedure in the first, and in practice in the second. In both cases the Hunter Review felt the problem was not great and the response timely and appropriate.
- 20.23 Our remit, which was focused more broadly on the parent's concerns, largely centred on post-operative care. Another key issue for us was whether patients had suffered as a result of the absence of locum care. We found no evidence to suggest that there was any delay in responding to arrest calls or that the medical care received by patients was deficient. However, we do accept that parents were extremely disturbed by the knowledge that a consultant was not always available on site at times of need or medical crisis. We believe that sufficient staff should have been recruited at this level to overcome these problems and enable consultant staff to go on annual or study leave without forcing their colleagues to be permanently on call during their absence.

- 20.24 Similarly, we accept parents' criticisms of on-call arrangements for the intensive care unit during the period under review and believe that the senior medical staff should, ideally, live within ten miles or 30 minutes drive of the hospital. However, we acknowledge that it was difficult to insist on this requirement when there was a single cardiologist in post from 1971 working more than full time whilst receiving less than half pay for the first 16 years of her appointment. The Panel considers that this dedicated and gifted individual deserves recognition and credit for having given significantly in excess of her contractual hours throughout the period under review.
- 20.25 Turning to the merger of sites, we conclude that it is appropriate for the Trust to proceed with the rationalisation of paediatric cardiac services on the RBH site, as the concentration of services should enable more clinical time to be devoted to patients. However, it is essential that the improvements to facilities referred to in Chapter 11 are implemented in order to provide a first class unit and make up for the loss of the excellent physical facilities present on the Harefield site.
- 20.26 We hope that, if the new development does go ahead, the opportunity will be taken to create a new centre of excellence in paediatric cardiac services, both in terms of the clinical facilities, and in terms of the facilities made available to patients and their families. Panel members noted that the experience of NHS capital development showed that all too often the initial plans agreed immediately following a public consultation exercise, which include all the necessary facilities, are gradually whittled down in the course of a five or ten year building contract until they bear little relation to the original plans. We hope that the issues highlighted in this report and the lessons of this Inquiry are fully incorporated in planning the new development.
- 20.27 The National Specialist Commissioning Advisory Group (NSCAG), which advises the DoH on the specialist services which should be designated and provided nationally for the whole of the NHS in England, has proposed that there should be one combined adult and paediatric transplant unit based in London. At the time of writing, no ideal site for such a combined adult and paediatric unit has been identified. The most likely long-term prospect for a major centre with all the necessary support facilities would be the redevelopment of the Brompton Hospital on the Paddington Basin site if this goes ahead. Pending this development, interim arrangements have been agreed for both the paediatric cardiac

transplant service and the adult cardiac transplant service, which will take effect from 1 April 2001.

- 20.28 From that date, the adult programmes currently provided by St George's and Harefield hospitals will be combined on the Harefield Hospital site. Following agreement by the Secretary of State that paediatric cardiac surgery performed by the Trust will in future be centralised at the RBH, the paediatric cardiac transplant programme currently provided by Harefield Hospital and Great Ormond Street Hospital will be combined on the Great Ormond Street site. In both cases, staff wishing to continue in transplantation will, as far as possible, be accommodated in a combined team. This should ensure that the specialist expertise built up at Harefield and Great Ormond Street Hospitals remains available to NHS patients.
- 20.29 Harefield Hospital can be credited with a remarkable achievement in developing paediatric cardiac services to such a high standard of clinical excellence. However, in some respects it failed to respond to parental needs and concerns, particularly in the post-operative period, due to the chronic lack of resources available for parental support services. Harefield doctors cannot be held responsible for this as they continually drew attention to the lack of funds and engaged in charitable fund raising to make good some of the most glaring deficiencies. However, welcome as this funding was, the business of fund raising placed additional demands on the workload of committed staff who were already working at full stretch.
- 20.30 The establishment of a world class centre which led the field in transplantation services for children is testament to the skills, commitment and entrepreneurial flair of two outstanding consultants and the fact that the centre thrived in the face of adversity was due to the commitment and dedication of core staff.
- 20.31 Our criticisms of the lack of support given to parents are directed at those ministers and senior policy makers in post during the period 1971 to 1997-1998 who, in determining the levels of resource allocation, failed to address the nature or needs of the service being provided by a small and dedicated team at Harefield. The Panel hopes that lessons will be learned from this Inquiry about the importance of resourcing new services adequately and that, in future, the provision of 'high tech' NHS services such as paediatric cardiac services

will be planned at a strategic level. It is, in our view, an abdication of responsibility to turn a blind eye to the demands of a pioneering clinical service. The price of such failure is, at least in part, the shortcomings in communication which parents have identified in our Inquiry and which have caused them so much distress and pain over the intervening years.

RECOMMENDATIONS

In addition to the recommendations set out in Chapter 11 the Panel recommends that:

- 69. The Department of Health gives early consideration to ensuring that the skills and expertise of staff currently working in the Harefield paediatric transplant service and the associated scientific research programme be retained within the NHS.
- 70. The Department of Health ensures that the development of any future highly specialist or complex paediatric services is funded in a way which recognises the need to include funding for parental support services.
- 71. The Department of Health ensures that, when considering the rolling out of any future innovative paediatric services, these services are added to the relevant National Service Framework, and that mandatory guidelines are issued as to the resources required to fund such services, including the number of clinical staff who must be in post to secure the provision of safe, family-centred services of a uniformly high standard.

Part Four

ISSUES AFFECTING BOTH HOSPITALS

21. CHILDREN WITH NEUROLOGICAL INJURIES

INTRODUCTION

- 21.1 In seven of the 49 cases heard by the Panel the children suffered serious lasting neurological damage as a result of cardiac surgery, ranging in severity from paraplegia to the most serious cerebral palsy, spastic quadriplegia. Six of these were operated on at the RBH, one at Harefield.
- 21.2 All open heart surgery carries a risk of injury short of death. The procedures of cardiopulmonary bypass and complete circulatory arrest each carry danger to the brain and internal organs.
- 21.3 However, most cardiac abnormalities can be corrected at relatively lower risk than 30 years ago. This extraordinary progress has been achieved through the dedication and skill of the medical and nursing staff involved, and staff at the RBH and Harefield have played a significant part in this. However, it has also been achieved at great cost along the way to children who have suffered death or injury.
- 21.4 In the cases we heard we did not find from the medical records that there had been a formal investigation of the causes of the neurological impairment of the child. In some cases no satisfactory explanation for this was given to the parents. We accept that in some cases it may be impossible to establish a cause.
- 21.5 Most of the parents highlighted the lack of co-ordination in accessing other necessary acute services not provided on the Brompton or Harefield site. Others complained that doctors were not open or honest with them and did not advise them of what had happened at an early stage. Several complained that their child was discharged with no advice on aftercare and no apparent agreement whether the RBH or Harefield or the referring hospital was responsible for subsequent clinical management. The families' concerns can be summarised as follows:

- Some felt that better explanation of dangers before the operation would have enabled them to cope better when things went wrong.
- Some were concerned about the delay in acknowledging that their child had suffered injury.
- Some felt rejected by the hospital when the disaster did occur.
- Some were concerned that no treatment appeared to be available to deal with neurological injury either after an event where neurological injury was a possible outcome but before the brain had sustained the resulting injury, or else after symptoms had appeared.
- Some were concerned to know why their child had been so unlucky as to develop such injuries and they wanted a full investigation into that and to have it fully explained to them.
- They wanted to know what was being done to prevent such injuries in the future.
- They almost all had difficulty accessing services locally to help them deal with the disability.
- They wanted acknowledgement of the tragedy from the hospital and they wanted compensation for their child and financial help in providing accommodation, care and equipment for his or her care.

HOW MANY CHILDREN WERE INJURED BY CARDIAC SURGERY?

- 21.6 We would have liked to know what proportion of heart operations cause neurological injury, whether this is a significant cause of brain injury generally, and whether numbers of children affected at the hospitals involved are typical of those of other centres performing such operations. But there are no statistics kept which would answer any of these questions.
- 21.7 We were able to derive some basis for making a guess about the probable numbers of children who suffer cerebral palsy (not other forms of neurological injury) from the work done by the National Perinatal Epidemiology Unit in Oxford. They were able to tell us, relying on work done by a number of academic groups which keep records of cerebral palsy incidence in different parts of the country, that probably about 1,300-1,600 children in the UK develop cerebral palsy, of varying degrees of severity, every year. Most either develop it in the womb or acquire it through the birth process. Only about 7-10% of the total acquire the injury after the first month of life. Of these, it is estimated that about 10-

16 new cases a year are probably surgically caused. If these guestimates are right, only a tiny proportion of children suffering cerebral palsy, at least, can be heart children. There is no way of estimating the numbers for other forms of neurological injury.

- 21.8 A paper published in 1995 analysed the records of 523 children operated on at Great Ormond Street Hospital in the year from November 1990 to indicate which suffered neurological problems (32). It concluded that neurological events were recorded in 31 children out of 523, at least 15 of whom suffered lasting neurological damage of which about half were very seriously disabled. Another survey by Ferry in 1990 seeking opinions from paediatric neurologists and cardiac surgeons reported a prevalence of neurological morbidity ranging from 2% to 25% (mean 8%) at six major paediatric cardiac surgery programmes in North America (33).
- 21.9 It seems unlikely that the RBH and Harefield Hospital produce more injuries proportionate to their caseload than do other centres. It may be, in fact, that the numbers are diminishing overall. When we talked to clinicians about this, some talked as if this were still a common problem and described how they dealt with it, but one said: 'In the past I think a lot of neurological injury probably occurred as a result of events that occurred during the operation or during cardiopulmonary bypass. I think now these events are very unusual'.
- 21.10 We found it perplexing that no central record is kept, nationally, of how many children every year suffer these terrible injuries. The perinatal and peri-operative death registers record deaths arising from birth or surgery; why are there no perinatal and peri-operative morbidity registers? We believe that records should be kept centrally so that the answers to these questions are known in relation to every operating centre.

THE CAUSES OF BRAIN INJURY IN CARDIAC SURGERY

- 21.11 Neurological damage to the children whose cases we considered had a variety of precipitating events which appear to be, respectively:
 - (a) Stroke.
 - (b) An ischaemic event (causing a shortage of oxygen) of unknown aetiology, possibly a series of strokes.

- (c) Post-operative cardiac arrest of unknown cause (presumably the damage was caused during the time it took to resuscitate the child, which was done quite promptly).
- (d) An unknown cause arising probably from a long but acceptable period on circulatory arrest and then bypass during a complex procedure.
- (e) Rupture of stitches on the aorta, resulting in haemorrhage and arrest.
- (f) Unexplained injury following uneventful complex surgery.
- (g) Post-operative removal of a pulmonary artery line followed by blocking of an endotracheal tube associated with two cardiac arrests from both of which the child was resuscitated.

In only one of these cases, the last, did the Panel's clinicians have any criticism of the hospital's clinical management.

21.12 Several of the RBH doctors have been demonstrating concern for this group of patients for many years. In the last two decades Mr Christopher Lincoln, a former RBH surgeon and Dr Michael Scallan, consultant anaesthetist, have conducted many clinical research trials on the causation and prevention of brain injury in cardiac surgery in infants and young children. They have contributed many research papers to international peer reviewed journals and organised an international symposium on brain injury in cardiac surgery held at the RBH in 1993 (34). Dr Elliot Shinebourne and colleagues have also researched other aspects of this problem (35).

THE LACK OF PRE-OPERATIVE WARNINGS

21.13 We are satisfied that clinicians now do warn about the risk of brain injury. However, all the children whose parents contacted us were operated on between 1990 and 1996. The Panel's clinicians felt that around 1990 many cardiac doctors would not warn about the possibility of brain injury when obtaining consent (though it would always have been best practice to do so) because at that time the main focus was still on living or dying. By the middle of the decade professional and public awareness and expectations had changed and such warnings became generally required practice. But those parents whose children were operated on at the beginning of this period and then suffered neurological injury felt they should have been given better advice.

21.14 Many of the parents wanted to be prepared for what might happen. One whose child sustained serious brain injury acknowledged that had she been given full warnings she and her husband would still have gone ahead because of the acute nature of her child's condition, but she said: '*I want to know everything, because I prepare myself by knowing*'. Parents were shocked when their child seemed to have survived surgery well but was then injured in the post-operative period, when they had reduced their anxiety. They felt they would have been better able to cope had they known how dangerous the post-operative period was.

DISCOVERING THE DAMAGE – DELAY IN ACKNOWLEDGEMENT

- 21.15 Some of the children apparently suffered some injury in the course of the operation although no precipitating event or cause could be identified; some had a definite precipitating event. However, even where there had been such an event almost all of the parents complained that the hospital staff were slow to acknowledge that damage had occurred and felt that their own observations about their child's condition were ignored.
- 21.16 It appears that babies and children who have undergone heart surgery may suffer neurological damage and have symptoms, some quite acute, but much of this is transient and the children fully recover. In the early days after the operation, when children are extremely ill and usually sedated, it is difficult to separate the serious irrecoverable injuries from the symptoms that will disappear. This led to clinicians denying that there has been damage and in one case, reassuring the parents that *'it's just post-op blues'*. Parents understandably became very angry and upset when it transpired that they were right all along and their child had suffered serious damage. Unsurprisingly, it was the parents of children who did not recover who came to the Inquiry.
- 21.17 The problem is compounded when nurses or junior doctors, who are probably seeing much more of the patient, are more worried or more frank than the consultant is. We deduced that this is because the junior doctors at least will be less experienced. The consultant will be reassuring himself or herself and everyone else on the basis of experience of children who have recovered unscathed from such conditions, but the juniors will not have so many of these reassuring memories to draw from. The result is that parents get confusing advice. In one case of catastrophic damage the child had suffered two cardiac arrests; brain injury must have seemed a likely possible outcome to the clinicians involved, but the mother told

us that no one acknowledged this to her except that the nurses hinted at it, saying: "she is not the same" and the way that they said it, they were kind of nudging me into doing something. But I was denying it and I was rejecting having to fight with anybody and trying to be grateful for saving her life, and it was very hard'.

- 21.18 One of the clinicians on our panel explained his own approach to this. 'Some children have an irritability and abnormal movements following surgery. At the time when you are looking at them, you are never quite sure as to whether they are going to be of great significance or not. I think that to assume they're totally benign and will get better is as wrong as saying that they are definitely bad. I would always tell parents that are worried about this that there are some neurological abnormalities because not many babies get neurological abnormalities, some do but not many.' A clinician now at RBH (but who was not there when these cases arose) made it clear that he would always acknowledge injury as soon as he himself suspected it.
- 21.19 The way information is conveyed is important. One family had a long period of observing apparently obvious brain injury, which was not acknowledged by staff. The father discovered that it was thought that the child had had a stroke as a result of overhearing what the consultant said to a nurse. The father told us: *'When he walked off, I said "What did he say? What did he mean by CVA?"*. *She said, "Oh, a series of strokes on the left hand side"*. *That is how I found out she had had strokes'*.
- 21.20 As the neurological damage begins to become apparent, it will still often be unclear to what extent the child will be disabled. Doctors may disagree and sometimes the cardiac specialists go on hoping for recovery but this does not happen. As both RBH and Harefield are single specialty (heart and lung) hospitals, no neurologist will be on site; they will have to come from other hospitals. In one instance, a neurologist wrote that she feared there was anoxic brain injury and that the prognosis would be very poor. The surgeon who had performed the operation wrote in the notes the next day that he felt that there was a definite chance of full recovery. It would be wrong to spread 'gloom and doom', which could have an influence on her care. Unfortunately the doom and gloom were only too well founded and the child suffers from the most severe disabilities.
- 21.21 The Panel wondered if more sensitive and empathetic handling and better neurological advice and management might not have allowed some parents to deal with the disaster less

painfully. We discussed this with one couple whose child is now catastrophically injured, cortically blind and totally dependent, fed by gastrostomy tube, without intelligible speech and suffering much distress and frustration. We asked these parents whether anything would have made this easier and the mother replied 'to be told the truth' and 'someone to put an arm round you'.

- 21.22 We felt that staff should be better trained in how to deal with disaster and how to make the parents' experience of it less traumatic. We did not hear from any of the children referred to in this Chapter about how they felt and generally they seem to have been too ill to understand what was happening. Severe distress in a parent must presumably affect any child who is conscious. Parents should be aware that most children do recover (but a tiny minority does not) and should understand before the operation takes place that it may be difficult to tell the difference between recoverable and irrecoverable damage. When their child does develop symptoms clinicians should be frank about the uncertainties.
- 21.23 Parents spoke about feeling very alone in this predicament and not knowing what to expect. This point was emphasised in the Menezes and Shinebourne paper cited above (35). Parents felt it would have been helpful to be put in touch with other parents with a similar experience.

TREATMENT FOR NEUROLOGICAL INJURY

- 21.24 Injury to the brain itself is generally caused by a period of interruption or reduction of the supply of oxygen; this results in an 'insult' to the brain. But the actual damage is caused by the brain's response to this during the period which follows, when it swells and reacts to the insult, resulting in the injury which is later so disabling. Observing the development of this kind of injury, however, some families naturally conclude that it is being caused as they watch and that nothing is being done to prevent it. Parents were therefore concerned by the lack of emergency action when it became apparent that their child might have suffered such damage. The planned move to the Paddington Basin development adjacent to St Mary's Hospital should make it easier to recruit the necessary specialties into the treating team.
- 21.25 Doctors, on the other hand, were aware that usually by the time the damage was evident it was too late. Only in one case was there an indication that some treatment might have

helped. The child suffered from cerebral oedema but no diagnostic scan was arranged until four days after this was suspected. Only when the child returned from being scanned were fluid-reducing drugs prescribed to reduce the oedema. It is not clear to us whether earlier action would have made a difference.

- We discussed this problem with clinicians. One of the RBH clinicians said that to get a 21.26 paediatric neurologist to come was quite difficult; they were all too busy and to see one case took a long time. The child had to be examined, the examination written up in detail and then there had to be a discussion with the family, and he added that there was a shortage of neurologists 'in this half of London' (and he could have added, almost everywhere else in the country, too). Another said: 'There is often a delay before the neurologist comes. The neurologists, you know, do not regard neurological opinions as emergencies because they often cannot influence the outcome anyway by seeing the child early, so they don't get there within 24 hours sometimes I think they deliberately stall coming to see the child. They will say, "stop all sedation, I will come in 48 hours" because by the time they come maybe then it's clear to them what is going on'. Another doctor said: 'It is nice to have those investigations done as soon as possible [but] do they influence the way you manage the child at that time? Hardly ever'. Another (not at RBH during the period when these cases arose) said he would always do his best to get a neurologist to see the child.
- 21.27 The clinician members of the Panel also felt that paediatric neurologist involvement would not often result in a change in clinical management. Nevertheless, the Panel felt it was unacceptable that paediatric neurology time was in such short supply and had to be obtained on an *ad hoc* basis from other hospitals. Even if intervention might make a difference in only a tiny proportion of cases, the economic and personal cost of brain injury is so high, both to the family and to the NHS, that any chance of averting it or ameliorating it must be taken.
- 21.28 The relief when the truth is known is sometimes tremendous. The parents of one child, who had a very obvious and dramatic stroke, waited four days to see a neurologist. The stroke occurred very early on a Friday morning shortly after his operation; the neurologist arrived at 10 or 11 p.m. the following Monday. The parents told us: '*It was as if the clouds lifted when she came to see us, because she looked at him and no one had [We] were trying to find out what was his prognosis. Were we now going to be left with a doubly*

disabled child in a wheelchair? And no one could tell us that [The neurologist] looked at him and said "this child will walk" because by that time he was moving his left leg a little bit'. She was right about this; he does now walk. This story indicates that, if neurological time is scarce and a neurologist coming from another hospital can only make one visit, and all the neurologist is likely to be able to do is to provide a prognosis, a few days after the event is the right time to come – but this is extremely hard on the parents (and the child if he or she is conscious). The Panel felt that a family to which such a terrible event has happened is entitled to be cared for by the appropriate clinician and one who is on the hospital site, able to monitor progress and answer questions.

- 21.29 We asked the Trust what the present arrangements for dealing with neurological damage were and were told: 'At both hospitals, parents have been told at an early stage, usually as soon as the medical staff have concerns about a child's neurological state, that there may be damage'. In both hospitals it has been standard practice to confirm the extent of damage by a CT scan of the head. At Harefield, prior to 1995, patients had to be moved to another hospital for this but since that time they have been done 'in house'. At the RBH scans have been performed on site since the mid 1980s. A consultation with preferably a paediatric neurologist or failing that an experienced general paediatrician is then arranged. This is not usually done as an emergency but more for prognosis and future planning for aftercare. These consultants usually have a long discussion with the family after they have seen the child. As soon as the child is fit enough from the cardiac point of view, the physiotherapists begin an intensive and ongoing course of treatment. However the physiotherapists in both hospitals are not experts in the rehabilitation of cerebral palsy and similar conditions.
- 21.30 We think the experience of the parents we talked to demonstrates that these arrangements are not adequate. Whether they are working better now (the last case we heard from occurred in 1996) we do not know.

Investigation

21.31 In our view the prevention of such outcomes is of primary importance and naturally parents felt the same. In order to prevent them, we need to understand why they happen. One mother said to us, explaining why she had contacted the Inquiry: 'My husband asked me "What's the point?" I said to him you know the point is it is nothing for us but for

every child that goes to an operation. They have a right for the best. If things go wrong, they go wrong: but not if things are going wrong for the wrong reason all these cases need to be looked at and decided upon and cleared up, so it does not happen again and again and again'.

- 21.32 These families felt they were entitled to an explanation, and were reluctant to accept that none was available. They had taken into hospital a neurologically healthy child but had to take home, in the worst cases, someone who hardly resembled their own child, who had in some cases no capacity for response, a child completely dependent on care for every activity of life. 'Our daughter went into Harefield as a chatty, assertive, mobile, sane, innocent child. She came out of hospital four months later, cortically blind, unable to communicate, incontinent, gastrostomy fed, spastic quadriplegic wheelchair user, requiring total adult supervision (24 hrs) as she is now completely dependent in all areas of life. If any of us as car drivers are involved in an accident, there follows an investigation and insurance is involved. Our family is now 'disabled' due to what has and hasn't happened at Harefield.'
- 21.33 Another family wrote: 'We still don't know what happened, we have never been told what went wrong'. We were not able to tell this family what went wrong as it was one of those cases for which no explanation presents itself; there was no identifiable adverse event, nothing to distinguish the treatment from that of children who escape unhurt. Even parents to whom our Panel clinicians were unable to explain what had happened said they had 'got more understanding' from the hearing (as one father put it) than in all the years since the injury occurred. These parents told us that no one from the Brompton had ever sat down with them for a talk about what had gone wrong in an attempt to explain things. As a result, the family felt very angry and resorted to lawyers to try to sue the Trust, assuming that the hospital must have something to hide. One of the clinicians remarked that nowadays one could expect that the parents of every child with neurological injuries will sue; we felt that this might be because this was in some cases their only method of getting an explanation.
- 21.34 The extent to which the clinicians had tried to explain what had gone wrong varied from case to case. One clinician had made every effort to explain a case to the child's parents, but he was not the consultant responsible for the child's treatment. He took the parents to a separate room and said: '*Ask me any question you want*'. They clearly felt he had helped

them a lot to come to terms with their child's injury. This contrasted starkly with another case of catastrophic injury where the mother asked for an appointment with the surgeon to discuss with him what had gone wrong. She told us that the staff would not let her see him, but arranged for her to see another doctor as the staff suggested to her that the surgeon concerned felt that what had happened was too complicated to explain.

- 21.35 We felt that a central database, such as there is, for example, in the case of perinatal mortality (36), would be likely to lead to faster identification of the causes of neurological injury. As it is, children could be being neurologically injured at RBH in exactly the same way as other children in Newcastle, for instance, but unless the clinicians concerned happened to report the case and compare notes no one would ever know. This is not to say, of course, that no effort is made to find out why the disaster has occurred, but this is internal and often not apparent to parents. These cases cause a great deal of concern among clinicians. We heard from those who came to see us how hard they have tried to discover why each disaster occurred. We believe there should be a specific agreed procedure for doing this and for notifying the parents, and a requirement to report to some central body which could track similar incidents at every centre.
- 21.36 This procedure should require incidents to be reported and investigated close to the time when they occur. We understand that this procedure was put in place in 1997 at RBH and some years earlier at Harefield Hospital. The requirement should be to investigate internally, with statements and information collected by an investigating officer, within, say, 28 days, to hold a meeting to discuss it, to report the incident to the national database and to hold a meeting with the parents to report on all this (and supply them with copies of the report). The central agency should review the evidence annually and publish their findings.
- 21.37 This is an inexpensive procedure which, compared to the cost in human suffering and financial costs of care, accommodation, medical treatment, equipment and special education that quite a small group of these cases can inflict on the children, their families and the State, is relatively small. As one mother said: *'You know we cannot bring back our daughter as she was, or as she would have been if things had gone well. But I think we'll go more peacefully to the grave if we are clear and it is resolved'.*

21.38 It may well be that one factor in the reluctance to carry out such an exercise is the fear of litigation. The Panel felt that as a matter of principle this should not affect the family's right to a full explanation.

Accessing services following neurological injury

- 21.39 It is always invidious to compare one form of suffering with another, but we did feel that the heart children with neurological injury had particular problems, both emotional and practical, which meant that they needed additional specific forms of help. We came to the conclusion that this small group of children need financial and psychological help to overcome these difficulties.
- 21.40 Cerebral palsy at birth involves severe care problems for the parents who have to gradually come to terms with what this means. Generally, the parents will find ways of coping and sources of practical help and support as the child grows. However, where this happens to a child who was previously neurologically able, the family is forced to face these changes very suddenly. The need to grieve is often overtaken by the immediacy of practical considerations and the shock is devastating. At that point, there is no time to adapt to the change in status of the child and the family, because of the need to harness the necessary equipment, transport and accommodation to enable their child to be looked after in their newly dependent state. (The children we heard about ranged in age from three months to ten years when they acquired their neurological disability). One doctor said: 'I continue to see children who are severely brain damaged and my heart sinks when I know they're coming, I see the name, and I am often very moved by the family's steadfastness at every level, even coming back to the place where this disaster happened'.
- 21.41 These cases cause severe psychological problems. The children had lived in the family as neurologically healthy members of it, and went into hospital without abnormalities except for their heart condition. Such children left hospital unrecognisable to their parents and siblings. The older ones had been returned to babyhood, but a babyhood from which they would never grow up, totally dependent again on their parents. This amounts to a bereavement for both parents, siblings and the child itself as such it affects each individual member of the family and the family as a whole. Grief is entirely appropriate and is essential for the family to remain intact and supportive, but this is seriously challenged by the huge obstacles confronting them and the enormous stress of coping with

a child in a disabled condition who may now never change. How this affects parents and siblings depends on their circumstances and requires very skilled support services, including counselling throughout the forthcoming years. The grief therefore is ongoing. When a child dies, the grief is acute but usually, in a healthy situation, it will moderate and resolve over time. In families with neurologically injured children, the grief will be chronic because it will continue without end while the child lives, grows up and reminds them all of the child they once had and the adult that should have been.

- 21.42 An additional emotional problem is that these parents have consented to the operation their children underwent and which has caused such damage, so they often have feelings of doubt and guilt as to whether they should have agreed, whether they should have asked more questions, whether they should have been more careful in the choice of hospital. They feel they should have been able to keep their child safe from injury.
- 21.43 Even parents whose children were injured as babies had acute problems adjusting to the change in them. One mother whose child was a few months old found him very difficult to feed when he went home and told us he did nothing but cry constantly. She wrote: '*We were sent home with no support at all it was like having a different baby*'. Even worse were the difficulties that families of older children faced in trying to access the help they and their child required following such injury. They needed suitable accommodation and equipment (otherwise parents found themselves carrying a child of ten or 12 up the stairs or lifting him or her in and out of baths or cars, with inevitable injury to themselves). They needed respite help from the constant burden of care. The children needed therapy and communication equipment.
- 21.44 One child was injured when she was eight years old. A nurse told them, before her discharge from the hospital, that they would have to start all over again with her, as if she were a toddler. The difference of course is that toddlers grow up this child will never grow out of her problems. She is now registered blind, wheelchair bound, unable to speak, communicate or use any communication aids, does not have any hand function or any cognitive skills. Her mother said: '*She has to be toileted, fed, washed, dressed and she has woken and needed attention between two and five times every night we have been left to pick up the pieces emotionally, physically, mentally and financially'.*

- 21.45 It is not only the physical functions of the child that are a problem. Most of the children we heard about were too severely injured apparently to have much awareness of the catastrophe that had overtaken them but some were distressed. One child was intellectually preserved but suffered mobility problems. She was seen by a psychologist at Harefield but her mother said she was too confused to benefit; all she knew was that she went in to hospital for a heart operation and came out unable to walk. She didn't want to talk to anyone about it.
- 21.46 Parents also suffer and some need treatment. In the case referred to in 21.44, the mother's GP wrote to the child's cardiologist describing her problems: 'by [two years after the operation] I was seeing her with depression severe enough to need antidepressant treatment the depression also gave way to symptoms of an anxiety state with panic attacks and this needed intensive support both physical and mental symptoms have always had as their focus [the child's] condition'. This mother was said to be: 'bereaved of the pre-op [child's name] but cannot grieve and has to struggle with reality of present and future'.
- 21.47 We suggest that before the proposed move to the Paddington Basin development in 2006 there should be some liaison arrangement in existence with local facilities. The hospital (and all hospitals carrying out high-risk procedures that may cause neurological damage and other serious disabilities) should provide a designated social work post to help families to understand what facilities they will need and put them in touch with such facilities in the area in which they live if this emergency arises. This post holder will need training in the benefits available to and the legal rights of a disabled child and its parents, together with the skills and knowledge to make care assessments and access services quickly in the child's home area. Liaison with relevant social service departments needs to be established while the child is still in hospital so that services can be planned appropriately for the child's return home.
- 21.48 The Menezes and Shinebourne paper referred to above (35) came to a similar conclusion, but no action appears to have been taken to implement it. They concluded that: 'It seems that a co-ordinator of services for acutely brain injured children after cardiac surgery could be beneficial for families. The person concerned could provide independent emotional support and practical guidance on how best to access support services. Nothing takes away the reality of what has happened, but providing the opportunity for families to

explore what this means to their subsequent lives is something for which the paediatric cardiologist or surgeon is not necessarily well equipped, particularly when they feel in part accountable for the outcome'.

21.49 We asked the Trust what the present arrangements are for helping families to access services and they said: 'Unfortunately, there are extremely few dedicated children's rehabilitation centres and all have long waiting lists and may be far from the patient's home. Depending on where the patient lives, arrangements may be made with Chailey Heritage or Tadworth Court for patients from the Royal Brompton and Stoke Mandeville for Harefield patients. Very often these centres are unable to accept the children and arrangements have to be made with the local (District General Hospital) Prior to discharge at the Royal Brompton a case conference is convened and, in conjunction with the parents' needs and wishes, the child's future management is discussed by a multidisciplinary team, including occupational therapists, physiotherapists, nurses and a hospital social worker, who liaises with the community health services where the child lives. At Harefield the approach has been less formal, and more on an individual basis with arrangements for discharge, again with full consultation with the parents, made together by the medical and nursing staff and most importantly the psychologists who act as family support'. The Trust points out that after that responsibility for these arrangements must lie with the community. We cannot comment on how these arrangements are working as none of the families we have seen appear to have benefited from them.

HOW SHOULD SUCH CHILDREN BE COMPENSATED?

- 21.50 Losing the ability to function normally as a human being is something to which money is almost irrelevant. Compensation for injuries such as these is no compensation at all.
- 21.51 What the families who talked to us wanted was the money to pay for help in looking after their child and to provide accommodation, equipment and therapy which would help the child and the family live some approximation of a normal life. Many wanted this mainly because they were anxious about who was going to pay for the child's care in the future. Initially, we did not see it as our responsibility to comment on compensation issues, but the problem was raised so often by families and clinicians alike that we came to feel that we must consider them.

- 21.52 We have seen that children injured in heart operations are a tiny minority of the children who suffer from cerebral palsy and other neurological conditions every year. Any arrangement we propose for the heart children would have to make sense from that perspective. The court system (relying mostly on the tort of negligence) has been much criticised. Recent reforms of court procedure following Lord Woolf's report on Civil Justice (37) should result in more cases being resolved without proceedings, and more speedy and economical litigation. But still there is the requirement to prove negligence and that the damage results from that negligence, and this none of the families we interviewed have yet been able to do.
- 21.53 Negligence claims, whether successful or not, cannot compensate for the neurological damage and loss that the child and family experience, probably for the rest of the child's life. We believe that improving State provision for people with disabilities is the key to this situation.
- 21.54 Doctors commonly express feelings of frustration that their patients who do not have a negligence claim get such inadequate provision, whereas those who can maintain a claim get almost everything they need. It is indeed grossly unfair that a successful claim can result in the ability to purchase all the physical comforts and adaptations that help to alleviate some of the burden of care, whereas those that are not successful or do not claim have to compete for scarce social services (which are variable from one locality to another) on top of everything else.
- 21.55 A number of clinicians and families suggested to the Panel that there should be a no fault system. We define no fault as a system for providing compensation of some sort following an adverse outcome that is not a normal result of a medical procedure a 'mishap' of some sort. It is not payable for the results of disease.
- 21.56 No fault compensation has the immediate attraction that it distances clinicians from fault, thereby making audit easier. It may not entirely solve this problem. The event itself and its consequences for the child would still arouse emotional reactions and cause problems for those involved. But there seems little doubt that a fault free culture would improve on the present situation to some extent.

- 21.57 One of the great problems of the legal system at present is the high cost in legal and experts' fees of recovering damages, which probably varies from about 5% of the damages for the largest cases to almost 100% in the smallest. No system of establishing facts in relation to medical accidents (to prove that some mishap has occurred) is likely to work without a considerable amount of expense of this sort but the less the claimant has to prove the cheaper it is likely to be.
- 21.58 No fault could provide compensation in a situation where there are risks that cannot be foreseen in relation to a particular individual. We know that a tiny proportion of children who are operated on will suffer and that a child is more likely to be at risk if the particular procedure they have to undergo is long and complex, or novel, but we do not know which of these children will suffer this result. On the face of it this makes the children good subjects for no fault compensation. But we are aware that there are serious problems with no fault, which may make it impracticable.
- 21.59 The first is affordability. If the scheme were to cover all accidents in every context (road traffic, employment, home) the cost would be huge. Even if it were restricted to medical accidents the cost could be very high. Recent unpublished research, quoted in the Chief Medical Officer's recent report *An Organisation with a Memory* (8), estimates that there are about 850,000 adverse outcomes a year in the hospital sector of the NHS alone. Of these about half are regarded as avoidable. These range from quite minor injuries to very serious ones. But at present only a tiny fraction of these injured people take proceedings for negligence. This seems to indicate that the cost of compensating everyone who has a bad outcome and wants to claim could be very high. There does not seem to be any reliable way of estimating what proportion of people would claim if they could do so without cost but there is no doubt that cost is one very important factor which stops most people injured by negligence from claiming.
- 21.60 Looking specifically at the children whose problems concern us most, only a tiny proportion of the children who suffer cerebral palsy in particular do so as a result of cardiac operations. The vast majority sustains their injuries prenatally, usually as a result of circumstances quite unconnected with medical care. These children would suffer all the same problems as children injured as a result of a 'mishap'. Any scheme would have to compensate only people who had suffered some sort of 'mishap'. As a result the state would be 'compensating' people who had suffered a disability in some circumstances and

not compensating others with a similar disability, and not because of any allegation of fault. The tort system of compensation for negligence as it exists at present and is operated through the courts at least has the justification that it constitutes a disincentive to be careless with other people's lives; the proposed system would involve spending a lot of time trying to establish something which serves no useful purpose and this would seem both wasteful and unjust. To make such a scheme effective claimants would have to have access to legal and medical advice.

21.61 For all these reasons we suspect no fault is not likely to be a practicable solution generally even though it might benefit some of the families we have heard from.

CONCLUSIONS

21.62 Consideration should be given to a transitional expenses scheme for children who suffer serious injury in the course of operations, with ring-fenced funding which could be drawn on to meet the costs of dealing with the injury. Parents of such children find themselves unprepared for the problem of coping with a child for whose care equipment and therapy they cannot pay. They may lose their jobs and injure themselves before help arrives via social services or the local health services (if indeed, in some areas, it ever does). We believe that the introduction of a government grant, to be disbursed through an intermediary agency along similar lines to the scheme established to deal with the victims of vaccine damage would be a fairer and more equitable way to direct support to families to compensate for the costs of this type of neurological injury. In establishing the criteria for accessing the fund, care should be taken to ensure that cases of children who have already suffered severe neurological injuries are reviewed to establish and respond to their current needs for support.

RECOMMENDATIONS

The Panel recommends that:

72. The Department of Health introduces a national system of reporting serious injury arising from paediatric heart surgery. This should provide that every such event must be reported to a central agency, which maintains a comprehensive dataset permitting the comparison of one event with another.

- 73. The Department of Health establishes a transitional expenses fund available nationally on which families could draw to cover care, equipment and other expenses arising suddenly in a situation where they cannot easily adapt to caring for an injured child without such help. This should be retrospective.
- 74. The Department of Health ensures that families of children who are neurologically damaged in the course of medical treatment have the benefit of dedicated liaison services allowing them to access support services easily when the need arises.
- 75. The Trust ensures that cardiac liaison nurses or other designated staff be available on the ward and PICU on a daily basis to help families deal with the fear of and the development of neurological injury.
- 76. The Trust ensures that staff are trained to recognise that acknowledgement that a neurological injury may have or has occurred is vitally important to parents; frank communication of hopes as well as fears is the best policy.
- 77. The Trust ensures that paediatric neurologists be actively involved in the management of children who may have acquired neurological injury, with such management to include accurate advice and diagnosis to families.
- 78. The Trust ensures that physiotherapists trained in rehabilitation and others who are specialists in this field be available on the ward and in PICU to provide baseline assessment, intensive therapy and demonstrate to parents the type of specialised physio support that they need to access on a local basis.
- 79. The Trust develops a protocol requiring notification of every instance of neurological injury following operation, a full investigation including recorded interviews with relevant staff, a morbidity meeting which is properly minuted and recorded, and a meeting with the parents to report on the results of the investigation and the meeting. This meeting should be minuted and the minute circulated to parents and clinicians.
- 80. The Trust's audit arrangements monitor these outcomes closely and develop links with other databases that are attempting to do the same.

81. The Trust locates a specially designated and trained social worker in the PICU, part of whose duties are to work alongside families and liaise directly with local social services departments, to ensure that plans are made to support the child and the family on their return home.
22. CARDIAC LIAISON NURSES

INTRODUCTION

- 22.1 Poor communication is a recurring theme running through the Inquiry's evidence. Parents were often left feeling that their concerns were not adequately acknowledged by the clinical team, or that they were given insufficient information about their child's care and treatment. Several parents complained that they were left on their own to cope as best they could with any medical or psychological problems, especially following their child's discharge from hospital. One parent said: 'He never fed properly until the day he died With hindsight, we should have gone home from the Brompton with a [naso-gastric] tube so that he could feed that way We had no support nothing from the Brompton not even a number to say 'ring this person' I would never allow it to happen now I would stamp my feet and demand to be seen'.
- 22.2 Cardiac liaison nurse (CLN) posts fulfil an invaluable role in giving support and counselling, providing an on-call service to families, and ensuring effective communications between the family and the clinical team. They are able also to act as a link between the various elements of the clinical team, such as community- and hospital-based staff. Many other centres have had CLNs in post for several years, but the RBH has not regarded such posts as a priority until now.
- 22.3 In October 2000 the Trust informed the Panel that two CLN posts were advertised in the early summer. This resulted in one appointment; the remaining vacancy was being readvertised. The post now filled is full time, with flexible hours to allow for evening and weekend work, and the contract is on a permanent basis. It is based at Harefield, covering families from both hospitals and working in the hospital and in the community.
- 22.4 These two posts are funded by the Trust, although a bid has been made for funding for one or two posts from a research foundation because of the *'research possibilities of this work'*. A bid is also being made, under the Government's initiative *Access and Enhanced Services in Primary Care*, for two nursing liaison posts in paediatrics.

- 22.5 In order to learn more about the role of CLNs, we invited two cardiac nurse specialists from Southampton, a paediatric nurse specialist from Birmingham Children's Hospital and the Lead Nurse, Children's Critical Care Service, Guy's and St Thomas' Hospital, to share their experience with us. We also obtained written information from other centres about how their CLN, or equivalent, service operated.
- 22.6 We were told that most CLN posts have been created within the past five years. They are held at the paediatric cardiac units in Birmingham, Bristol, Cardiff, Edinburgh, Glasgow, Leeds, Leicester, Liverpool, Manchester, Newcastle and Southampton, and at Guy's Hospital and Great Ormond Street Hospital in London. In Oxford there is a ward-based nurse carrying out part of the role. At the majority of centres, the CLNs are on nursing grade G because they are expected to work independently of other services, often on their own in the community, which requires in-depth knowledge of paediatric cardiac care and good interpersonal skills.

THE ROLE OF THE CARDIAC LIAISON NURSE

- 22.7 Birmingham Children's Hospital has summarised the current role of their CLNs as being to:
 - Provide counselling and support for mothers whose babies are diagnosed *in utero*.
 - Support parents/families and patients from birth to adulthood.
 - Educate staff/carers about congenital heart defects, promoting early identification of problems, often resulting in an outpatient appointment rather than admission and allowing children to remain in mainstream education.
 - Provide support to ward and PICU staff, especially during distressing circumstances.
 - Provide on-call service to support families during a crisis, such as deterioration or death of a child.
 - Hold a clinic where patients are seen following discharge (as arranged by staff or parents of the child).
 - Provide information and advice to various charities.
 - Share the same caseload and act autonomously.
- 22.8 The family's first contact with the paediatric cardiac centre is normally at an outpatient cardiology clinic, either at the centre or at a peripheral clinic. Wherever possible the CLN

attends the consultation, although this depends on the number of CLNs in post, and the number and distribution of clinics. Even if they can be there, a clinic with up to 30 patients and a maximum of only 30 minutes for a new patient affords little time for providing reassurance or checking the parents' understanding of what they have been told. A close working relationship with the clinical team, and particularly the consultant paediatric cardiologist, is vital. If the CLN is unable to attend the consultation, she aims to speak to the consultant before going to see the family. At the clinic, the paediatric nurse gives parents a cardiac liaison card with details of how to contact the CLN. Very often the parents and child will not have taken in what was said at the clinic, especially if they were unprepared for the diagnosis and its implications. Part of the CLN's task when meeting the family is to go over the information again to ensure that parents have a better understanding of their child's condition.

- 22.9 We were told by the Southampton CLNs that they do not wear uniforms, referring to themselves as family support nurses. Whereas the focus of ward staff is on the child, theirs is on the family as a whole, both at home and when they come to the hospital. They also act as a bridge between the various elements of the service and provide a resource to other professionals in order to enhance the totality of care. After the initial assessment and consultation, and having spoken to the consultant and met the family face-to-face, the CLN contacts the health visitors and others in the primary or community care service to ensure that they have all the relevant information.
- 22.10 In some cases, the child needs admission for cardiac catheterisation, and will need to be prepared for that. In others, the next contact after the cardiologist is with the cardiac surgeon. The CLN always tries to attend that consultation, as the consent process starts from that point. Surgeons sometimes need to be encouraged to communicate with parents in a way that facilitates a better understanding of the available options and risks. The CLN also plays a critical role in ensuring that the needs and wishes of the parents are properly explored and evaluated. Adolescent children are also encouraged to participate in decisions about their care. We believe that children younger than adolescents can and should be involved in discussions and exploration of care options (see Chapter 8). All families have different needs, as do the individuals within it. The CLN works around these. With regard to children, for example, we were told by the paediatric nurse specialist from Birmingham that communications were: 'very much a two-way process. We were receiving information from them as well Everybody has different needs, and we are very

up front about that, because children very easily think that we are talking about them, but we are not in the power game of not telling children in an appropriate manner So we provide the child with the opportunity to increase their knowledge, to make some sense of what is happening to them The development of appropriate tools to help children understand is very important'. She told the Panel that computers were a popular aid to communication and, for younger age groups, the child was encouraged to use drawings, and the nurse worked in partnership with a play specialist.

- 22.11 Before admission, the CLN can make an invaluable contribution to easing the anxiety of the child and parents. At the Royal Manchester Children's Hospital, from where children are referred to Liverpool or Birmingham for surgery, the role of the CLN is especially important in providing a bridge between the cardiology and surgical services. The post was originally funded, in 1993, by the DSA for research into the service delivered to children with Down's Syndrome. It was subsequently developed: 'to support all families with a child with congenital heart disease and this role plays a major part in supporting and helping these families understand the difficult and complex issues surrounding open heart surgery'. At the Bristol Hospital for Sick Children, the CLN writes to the parents and child introducing herself and enclosing a copy of a video funded by the Bristol and South West Children's Heart Circle (a volunteer family organisation). She also invites them to attend a pre-admission clinic, where they will meet her and the play specialist and visit the area of the hospital that they will be attending.
- 22.12 At the time of admission, the CLN can introduce the family to the ward and the hospital, if that has not already been done. This enhances trust and confidence and reduces anxiety. Because of her knowledge of the family, she is able to pick up on stresses and worries that ward staff do not have the time or understanding to observe or discern. The CLN tries to see each family on the ward every day, although this is dependent on workload. In the PICU the CLN complements the role of nurses by focusing on communications with the family, to ensure that the family does not feel ignored or marginalised.
- 22.13 After discharge from hospital, the CLN plays a pivotal role in ensuring that the family have been told all they need to know about follow-up care, whom to contact for advice and support and what will happen next. This prevents the sort of problems described to the Panel by RBH and Harefield parents, some of whom felt that they had been abandoned by the hospital and left to cope on their own. The Southampton CLNs told us that the greatest

problems tend to be with the growing child, and those who are dying or have suffered neurological damage. Where the child survives treatment, the supportive relationship with the family can last a long time. Even where the child dies during or after treatment, the CLN has a continuing role with the family and plays a major part in establishing appropriate bereavement support.

22.14 Language can often be a barrier to understanding for those whose first language is not English. Some centres provide specialist services for children from minority communities and are recruiting CLNs with the relevant language skills or using interpreters.

EFFECTIVENESS OF THE CARDIAC LIAISON NURSE

- 22.15 An article in the British Medical Journal in 1999 (38) pointed out that: 'few randomised trials have looked specifically at the value of clinical nurse specialists in terms of clinical and cost effectiveness, although evaluative surveys have revealed high levels of satisfaction with the care received'. In that respect, we noted that the cost of the CLN posts in at least one of the centres was met from 'pump-priming' funds rather than from the core budget. This was because the costs would otherwise be reflected in the pricing of the service and could affect the negotiations with the relevant purchaser authorities. It was important to be able to demonstrate the value of such posts, and the contribution that they made to service quality and standards, before including them in the pricing structure.
- 22.16 An internal review conducted in Birmingham showed that 95% of those replying to a questionnaire sent to parents of children treated in the cardiac unit felt supported by their CLN, 79% rated the CLN role as excellent, and 20% as good. The Panel understands that the response to the service in general was that it was of invaluable use to both parents and staff. Nearly 25% of those who responded would have liked greater contact time with their CLN, but 62% felt that no improvement was needed. The RBH Director of Nursing provided us with a copy of a proposal for a research trial on *Children's Cardiac Liaison Nursing* (December 1999). This shows that 44.4% of RBH families expressed a need for more information about disorder/treatments/prognosis and forms of help, and 89.4% had seen their GP in the last year but contact with other statutory professionals was minimal.

EVIDENCE FROM CLINICIANS

- 22.17 We raised with clinical staff at the RBH and Harefield the fact that no CLNs had been recruited by the Trust until 2000, and asked how they viewed the role of such posts. One of the RBH doctors told us: 'It is imperative in a hospital such as the [RBH], which depends on a number of outreach relationships for its patient workload, to have a very good system of communication and of dissemination of information in both directions We would probably need a minimum of maybe four or five [cardiac liaison] nurses'. He added that a CLN service was: 'one of my major personal areas of interest and one of the stipulations that I made before accepting the post'.
- 22.18 There was some confusion about the CLN's role with regard to PICU. One Harefield doctor told us that: 'The appointment of the liaison nurses would help a lot. It would improve the care for the families'. He also remarked that: 'I am not sure that liaison nurses, as the job description goes at the moment, will have much involvement in the intensive care unit management. I think the design is more for the care in community ...I would hope that they would spend some time in the hospital. Because I think it is crucial that they meet the parents at a time when the parents who are going through a hard time of their child being in the intensive care unit and not being well, so they can establish a communication link and personal link with the family, if they have not met them before the operation'.
- 22.19 Looking to the future, when the Harefield service is transferred to the RBH site, the hope was expressed to us that: *'there will be enough provision for liaison nurses at the [RBH]* and some form of liaison nursing maintained at the Harefield site even on an outpatient basis to provide care for the community there'.
- 22.20 At our hearing with the nurses, the Director of Nursing made a similar point about the CLNs' involvement in the PICU. 'The [CLN] will have a big role in the pre-hospital and the post-hospital, but certainly I had not envisaged the [CLN] having a major role in PICU'. She envisaged that: 'our long term aim would be something like a team of eight [They] would be drawn into represent particular areas, to go out to the peripheral clinics as well go out to homes and work out from the hospital with the families'. Another of the nurses commented that the CLNs would attend 'discharge meetings and things like that for the family to make sure that they have appropriate support'.

EVIDENCE FROM THE TRUST

- 22.21 The Chief Executive assured the Panel in July 2000 that 'the commitment to [recruiting two CLNs] is absolutely there and the process is actually under way'. With regard to any future expansion of the CLN service, he said there were many competing claims on resources, such as for additional intensivists. We expressed concern that, if nurses from the PICU applied for and were appointed to CLN posts, this would create additional problems for intensive care and surgical throughput. This point was acknowledged by another senior manager from the Trust, who said: 'It will be filling their vacancy with [a PICU] nurse that is going to be the problem'. However, the Board's Chairman commented: 'I don't think that can impair or torpedo the idea, and we will have to find a solution for it'.
- 22.22 The Panel asked management how round-the-clock cover could be provided with just two cardiac liaison nurses. We were told that they would operate a liaison service, available on a planned basis and that 'hopefully the majority of [the] need can be timed in for the day the same with hospital admissions, processes like that'. If there was a greater demand, the Trust would have to 'build that into the equation it's a fact of life that when you create a new service, you create an increased demand for that service, and [the] exponential sort of vertical graph might get worse'.

CONCLUSIONS

- 22.23 We are pleased to note that the Trust has fulfilled its commitment to start a cardiac liaison nursing service. Many of the concerns brought to us by parents were about events that occurred before CLNs had been established in any paediatric cardiac centres. The Panel is in little doubt that, had CLNs been in post from the mid 1990s, some of the anxieties suffered by parents could have been avoided.
- 22.24 The role of the CLN is wide ranging: supporting families from initial diagnosis, through treatment and discharge to follow-up care, and, where the child has died, giving bereavement support. They can also provide support and information to the clinical team in the hospital. It is critical that all members of the team recognise that CLNs are there to complement, not substitute for, the service that they provide. We would be extremely

concerned if clinicians and nurses viewed CLNs as a resource to relieve them of their responsibility to communicate with families.

22.25 The Trust's management is concerned about the prospect of exponential growth in the demand for the service that CLNs are able to provide. There is little doubt that the Trust's concerns will prove to be well founded, as our Inquiry has provided compelling evidence of the extent of parents' need for advice and support. Although the Trust has met the cost of the initial posts from its revenue budget, it is pursuing other possible avenues for funding, including research grants. We hope that this does not reflect a view on the part of management that a CLN service is an optional extra, rather than a core service. We believe that the support provided by CLNs is central to providing a high quality, family-centred service. There needs to be a gradual and sustained programme of expansion of the CLN service, and the merger of the Harefield service onto the RBH site should provide the opportunity for a major step forward in this direction. The 'cost' of not doing so will be continuing distress to parents, and intolerable workload pressures on the single CLN currently in post. However, we are concerned that if PICU nurses are recruited to fill any of the CLN posts, this will exacerbate existing staff shortages in intensive care. We are reassured that the Trust Chairman acknowledges the dilemma and the need to address this, although we recognise that the shortage of PICU nurses is a national, rather than a local, issue.

RECOMMENDATIONS

The Panel recommends that:

- 82. The Department of Health embarks on a programme designed to secure a marked increase in the availability and retention of nurses trained in paediatric intensive care by reviewing grading and remuneration for specialist nurse posts.
- 83. The Trust commits itself to increasing the number of CLNs progressively over the next three years, including a significant expansion in the CLN service with the transfer of the Harefield paediatric cardiac service to the RBH site in 2001.

84. The Trust seeks advice from other paediatric cardiac centres in the UK to clarify the role of their CLNs prior to, during and after hospital treatment and care, particularly in respect of the provision of support for families.

23. COMPLAINTS AND RELATED ISSUES

INTRODUCTION

- 23.1 Families not just parents but siblings, grandparents and other carers find different ways of trying to deal with death or serious impairment of a child after treatment. Their experiences, whether positive or negative, can be of great help to others who will encounter similar situations in the future. Many of the parents involved in the Inquiry found it harrowing to recount events going back over a number of years. Neither the NHS complaints procedures nor, indeed, the courts are able to take up long-standing concerns, except in special circumstances. That is because, as time passes, it becomes increasingly difficult to obtain sufficiently firm evidence to reach firm and fair conclusions.
- 23.2 Very few of the parents involved in our Inquiry had used the complaints procedure to resolve their concerns. Those who did so either found it unsatisfactory, were unaware that they could pursue the matter to a further stage, or gave up as they regarded it as a pointless exercise. There seemed little value in reviewing the complaints procedures in operation at the RBH and Harefield throughout the period covered by our Inquiry, as they have been changed both nationally and locally during this period. Instead we examined the current arrangements in order to highlight any areas for improvement, in the hope that our recommendations would help resolve the concerns of parents and future complainants without the need for an Inquiry. Complaints are best dealt with locally and as soon as possible after the events in question. NHS users are entitled to expect that a sound complaints procedure, which provides answers and puts right the cause of the complaint, is in place, well publicised and accessible.
- 23.3 We therefore commissioned a review of the Trust's current complaints procedures. Our analysis and conclusions in this Chapter are based on the report of that review. The Executive Summary is reproduced at Appendix 13, and a copy of the full report has been made available to the Trust. We understand that much of it has already been implemented.
- 23.4 The arrangements for dealing with NHS complaints have changed considerably over the past 30 years. Until the NHS Reorganisation Act 1973 introduced the Office of Health

Service Commissioner, or Ombudsman, aggrieved complainants had nowhere to take their concerns if local attempts at resolution failed. However, the Ombudsman was precluded by Statute from dealing with clinical or primary care complaints. The same Act brought Community Health Councils into being, and they provided a valuable advisory and advocacy service for users of the NHS. Then, in the early 1980s, the DoH and representatives of the medical profession agreed a new procedure designed to resolve patients' concerns about clinical care. Under this procedure, an aggrieved person could request an independent professional review by two consultants, who were nominated by the Joint Consultants' Committee of the British Medical Association from the relevant specialty practising elsewhere in the NHS. In 1988 all NHS authorities introduced new procedures, which included the designation of a senior officer to be responsible for complaints handling and a requirement for regular reports to be provided to the authority or board.

- 23.5 In 1996 the procedure now in force across the NHS was implemented (39). This comprises two stages:
 - Local Resolution, which should be open, fair, flexible and conciliatory and should aim to provide a comprehensive response that satisfies the complainant. Many complaints should be capable of resolution orally but any complaint, even those made formally, should be answered within 20 working days.
 - Independent Review Panel, whereby the NHS authority's complaints convenor (a non-Executive member of the Board) has the discretion to ask for review by a panel chaired by a lay person and advised by at least two independent clinical assessors.
- 23.6 The key objectives for the new arrangements include ease of access and an approach that is honest and thorough, with the primary aim of resolving the problems and satisfying the concerns of the complainant. Also, in 1996, the remit of the Ombudsman was extended to cover all complaints about NHS care, subject to certain conditions.

CONCERNS EXPRESSED BY PARENTS

23.7 In the questionnaire (Appendix 4) sent to families before they met us, we asked whether they had used the complaints procedure and with what effect. Only 14 of the 42 RBH parents whose questionnaires were examined by our reviewer had tried to raise a complaint at the time. Those who did not complain gave a variety of reasons. One said: 'I wrote many letters but never posted them because I felt a lone voice'. Another said: 'The other sad thing is that this Inquiry has to take place at all. It is a waste of NHS money and it should not be required. But it only comes about when parents and patients band together in a group as an individual you are completely powerless are disregarded'. Another parent had not wanted to trouble busy staff: 'When you lose a child, it is difficult to raise questions You also do not want to drag them away from intensive care where there are still children who need their care'. Four did not know about the complaints procedure. One parent said: 'We were not aware of the complaints system'. Another said that an Independent Review Panel had not been requested 'because no one told us'.

- 23.8 Five of those who did make a complaint said that they had received no answer when they had complained orally to a member of staff. When one parent saw a consultant about her complaint 'he seemed very shocked that we were complaining. His attitude was that we should have been pleased with [our son's] care and treatment at the Brompton. We did not get answers to our main concern'. The parents in one case said: 'We did not go through [the complaints] route. We consider it to be a complete waste of time, effort and resources'. Others who made no complaint told us that they had not wanted to do so while their child was still in hospital.
- 23.9 The parents in three cases obtained an Independent Review Panel, but they did not find the process satisfactory. One told us: 'I wrote to the Director of Clinical Services and the Chief Executive re my complaints [and] was offered a clinical complaints review I did not find this review particularly helpful and I was told "you do not appear to be demonstrating much emotion"'. Another said: 'I believe that the way I have been dealt with by the hospital and the [independent review] panel has been appalling. It took nearly 18 months to get some information as to why my daughter died. There are many questions which have not been answered The complaints system did not deal with my concerns or work to answer my questions The system operates to cover up problems'. A parent in the remaining case told us: 'The primary fault is that the dialogue becomes adversarial and consequently traumatic for the parents [who] do not have access to the relevant medical knowledge So they are always going to be at a severe disadvantage'.
- 23.10 At the hearings we discovered that few families whose children have died were, or had been, interested in pursuing litigation. As a parent whose child died said: '*After all*,

throughout this process – maybe people have been guarded in one way or another – but throughout the process litigation had never entered our minds at all. All we ever wanted to find out was the truth'. They simply wished to have their concerns acknowledged and acted upon and, in some cases, to receive an apology for what they perceived as poor care or communication. For those whose children have died, they want the truth and to understand why their child died. We heard that for some families, even after years of investigation with several expert opinions, the medical knowledge was not available to deliver certain answers. That, and the desire to see changes for the benefit of future users of the service, is the motivation for most complainants. As one parent, who had met a consultant to discuss her concerns, said to us: 'What we were looking for [was] some acceptance that things went wrong and we were looking for things to be put in place to prevent these things happening again. That would give us some satisfaction that [our daughter] had not died in vain'.

23.11 In some cases parents are seeking much more than an apology. Sometimes, particularly if the child has suffered neurological impairment following surgical treatment, they are looking for financial help to provide for the child's needs and for the physical and other demands on the family as a whole. Neither the complaints system nor the NHS Ombudsman is able to provide that sort of remedy, which can be obtained only through the courts and negligence must be proven. We made clear to parents that we did not have the powers of the courts so could not adjudicate on whether treatment was at fault. However, we discuss in Chapter 21 how practical help might be considered for families coping with the tragedy of severe brain damage in their child.

THE CLINICIANS' RESPONSE

- 23.12 Doctors raised the dilemma that the openness and honesty expected of them in their dealings with parents and patients could be prejudicial where there had been a mistake. That was because disclosure could result in either the practitioner or the hospital being sued. As one doctor said: 'One would be naïve after a child has died not to be aware of the fact that you may be sued. So I think there has to be a balance between what it's appropriate to say and what isn't and it's very difficult'.
- 23.13 One doctor said: 'When things go well, there is never a complaint about communication. It is when things go badly that there are complaints, but presenting information to the family

as early as possible doesn't mitigate the anguish that is involved'. We were also told that it was not always possible to say precisely why something had gone wrong. One of the doctors told us that: 'more latterly I have taken the view and said, "No one knows why these things happen. There is no obvious evidence of negligence but something must have gone wrong, something must have happened for this to happen which was avoidable", but that is all we can say. I think people feel unhappy because we cannot say, "This is why it happened", but they think something is being covered up; but it is genuine thing, we do not know why it happened'. The inability to provide a definitive explanation might be perceived by the complainant as a cover-up. Another doctor said: 'A lot of the troubles can be avoided if the communications are as effective as they can be throughout I would personally prefer to say the mistake has happened, even if that means there is a litigation issue that has to be handled. It is an honest approach'. The Panel understands that the medical defence organisations now advocate much more openness in responding to complaints. This is both right in principle and very much to be welcomed.

THE TRUST'S RESPONSE

23.14 In discussions with the Trust Board we were told that monitoring of complaints was a key priority in the Trust's corporate governance and accountability arrangements. The Trust Chief Executive told us: 'Specifically the Board monitors complaints and compliments. Compliment measurement is always a very tricky thing. I think the review of complaints is more meaningful. [The Board] actually gets information on every individual complaint and discusses them on a selected basis'. The Board receives at alternate meetings a detailed report on complaints from the Director of Nursing and Quality. The Trust Chairman said: 'They're very carefully kept records and the difficult ones are discussed at Board level. So we do have a means of dissemination to the Board. That means a very sophisticated and well-observed specific item on every other Board agenda about *complaints*'. One of the non-Executive Board members informed us that she was working with the Director: 'with the aim of actually improving something that was already very good into making it even more clearer and precise in being able to highlight problems and in particular to see trends. So that it wasn't just a mass of numbers coming at us which had no meaning or context, but to actually be able to say there is something happening here over a period of time I think that is quite important that the Executive and non-Executive are working to achieve a better understanding of what patients are facing'.

23.15 The number of complaints received by the RBH was described to us as 'astonishingly small' by the Trust Chairman. Users of the Trust's services are asked in the patient satisfaction surveys 'whether we're making it easy for them to express an opinion to the hospital, and probably those mechanisms have improved and were not very patient friendly in 1987 if you go back. So we are in the middle of a process of improvement'. Disappointment was expressed to us that: 'the parents, even after the whistle blew, or at any other stage, did not make any inquiries as to whether there was any formal complaints procedure to which they could resort'.

REVIEW OF THE TRUST'S COMPLAINTS PROCEDURES

- 23.16 Since the autumn of 1999 the regular reports to the Trust Board have shown what action was taken as a result of complaints, as well as categorising the issues arising from them. As a result of this change, Board members can follow the progress of individual complaints, remedies and trends more easily than before. In the second quarter of 1999, a total of 41 complaints was received for the Trust's two hospitals. Only two of these were categorised as being about communication, yet at least five of them seemed to involve a failure to give an adequate explanation. Experience across the NHS suggests that a substantial proportion of complaints involve poor communication. The Panel believes that communication should be recorded as a secondary issue in such cases, even if the primary concern falls into another category.
- 23.17 The Trust produces a range of information leaflets for patients and relatives about services and facilities, but these do not provide clear, consistent advice about making a complaint. All leaflets should include basic information about how to complain and where to get advice. They should also refer to the more detailed complaints leaflet, which has a sympathetic tone but is not issued routinely to patients and is not consistently available at reception or outpatients. Similarly, posters are not well or widely displayed. We were told that this would be remedied, and that a new poster was being prepared. Hospital users should be involved in the drafting of new leaflets and posters.
- 23.18 Complaints to the Trust can be made either orally or in writing. The former are normally resolved informally at ward or department level, but more serious complaints are referred to senior management and ultimately to the Chief Executive. In accordance with NHS procedures, an acknowledgement has to be sent within two working days and a definitive

response within 20 working days. None of the present material makes clear, either to staff or to patients, that others can complain on the patient's behalf, subject where necessary to the patient's consent.

- 23.19 A complaint is more likely to be resolved in a satisfactory way if complainants are asked at the outset what they hope to achieve, and who they think might be able to provide relevant information, otherwise time and effort could be wasted by the hospital dealing with a complaint in a way that is never going to satisfy the complainant. The Director of Nursing and Quality has told us that this is now being done. At present, staff involved in the investigation are not routinely identified. Given the current, and growing, trend towards openness in public services, this is likely to become increasingly untenable. The Trust has said that it is balancing the interests of complaints and staff, and that 'naming and shaming' might lead to a less constructive climate for dealing with complaints. The Director of Nursing and Quality commented: 'As we develop [a] more co-operative approach, then it may become more natural to [name staff in responses to complaints]'. While we understand that the staff feel strongly about this, it seems to us that NHS Trusts should be encouraged by the DoH to move towards a presumption of disclosure, other than in exceptional circumstances.
- 23.20 Complainants are normally asked if they would like to come in and talk about their complaint, but the Director of Nursing and Quality has acknowledged that this is not always done as early as it could be. While there must also be a formal written response, a meeting can help to achieve better understanding and resolution of the complaint. Leaflets should clearly state that complainants themselves may request a meeting and can be helped with writing or presenting their complaint. The anonymised written responses examined as part of the review that we commissioned were thorough in their explanations, offered apologies and proposed remedial action. However, no time-scale for remedial action was given, and only one letter said that it was open to the complainant to request an Independent Review Panel, which appears to contravene NHS guidance. However, the overall impression was of a Trust that was not defensive but committed to dealing thoroughly with complaints.
- 23.21 It would help complainants, and those carrying out the investigation, if there were guidance on how to frame a complaint, and what can and cannot be achieved through the complaints process. The responses to our questionnaire showed that patients and

relatives might be deterred from complaining because they believe that it might affect future care or relationships. It is crucial that guidance, for both patients and staff, makes clear that recrimination against complainants will not be tolerated. The Director of Nursing and Quality has assured us that she will consider how this should be done.

- 23.22 While the introduction to the staff guidance booklet talks about working in partnership with patients, both the guidance and the complaints procedure could do more to enable that to happen. There needs to be a shared understanding of why patients complain and what they are trying to achieve. The guidance, which is expressed in the language of rights and entitlements rather than of partnership, also needs to convey an understanding of what the experience of a complaint is like for the complainant and those complained against. The importance of a co-operative approach to resolution should be stressed, particularly in an essential service that relies on long term relationships of trust. There is also little guidance about how to prevent requests or minor irritations from ending up as complaints, or how to ensure that oral complaints are treated properly.
- 23.23 All staff who deal with patients, with the exception of doctors, have periodic training on complaints handling. The Panel firmly believes that listening and responding to patients' concerns should be viewed by medical staff and others as an integral component of total care, not as an irritating diversion. We speculate that, had there been a more open approach to parents' criticisms during the period under review, many of the concerns brought to us could have been resolved at the time.
- 23.24 Staff who are the subject of a complaint may find the experience stressful and need emotional support. Line managers can provide a degree of support, but this may conflict with their duty to the patient to be rigorous and objective in investigating the complaint. Some staff may choose to turn to their trade union for assistance. What neither of these options can address is the need for staff to have the option of discussing their emotional needs in a confidential setting. We believe that this support should be part of the provision that the Trust makes for stress counselling more generally for its staff.
- 23.25 The Trust treats complaints seriously and tries to learn from them. The anonymised reports to the Board are discussed fully in the open part of the meeting. A Review Group, drawn from staff at all levels and from many departments, was set up about 18 months ago to look at trends or systemic problems revealed by complaints at both the RBH and

Harefield Hospital. This is a commendable initiative, and the Director of Nursing and Quality has indicated that she will consider strengthening the Group by including user representation. The Trust could use this process as a way of learning more about the experience of those trying to use the complaints procedure, and the barriers they encounter in using it. Feedback should be given to individual complainants by means of a follow-up letter saying how, and with what effect, changes have been implemented as a result of their complaint.

- 23.26 Regular surveys of patients' opinions have been undertaken at the RBH since at least 1993. The wording has changed over the years to make the questionnaire more user friendly, although there is still scope for making the language less formal and some of the questions more straightforward. The emphasis should be on the contribution that the outcome of such surveys can make to enabling the Trust to provide a better service. Focus groups of patients have been introduced and, in this respect, we note that at the Bristol Royal Hospital for Sick Children, there is a Parent User Group, which undertakes surveys and works with the hospital to improve services. This is an imaginative and welcome expression of partnership in service delivery. The Trust could use both avenues for learning more about the experience of those trying to use the complaints procedure, and the barriers to using it.
- With regard to the quality of complaints handling, the right under the Patient's Charter (40) to a response within 20 working days was met during 1998-1999 in 84% of cases at the RBH and 92% at Harefield. The overall figure in the first three quarters of 2000 was 80%. This is an area that needs attention by senior management. We understand that the Thames Audit Consortium has recently carried out an audit of clinical negligence and complaints procedures at the Trust, and this may provide useful material from which lessons could be learned and action taken.
- 23.28 Information about oral complaints dealt with informally at ward or department level is not captured systematically, partly because an experiment at Harefield from 1996 to 1998 showed that the information obtained was of limited value. If a way could be found of collecting and analysing such information, this would help to disseminate good practice, give positive feedback to staff and contribute to promoting a responsive, 'customer care' culture.

23.29 The handling of complaints at the RBH is part of the remit of the Head of Administration, whereas at Harefield there is a Complaints Manager. Clinical complaints, and the requirements of the post-1996 procedures, will have increased the scale and complexity of the task considerably. While we do not advocate merging quality, complaints handling, clinical governance and risk management within a single department, as suggested by the NHS Executive, we do see great merit in including the Complaints Manager in a group or committee charged with overseeing risk management and the quality of service delivery.

CONCLUSIONS

23.30 From the experiences of the families we met we have identified a number of areas where changes would improve the way in which complaints are handled within the Trust. By the time our Inquiry had been established, the Board had already put in train some important changes in the way that complaints are handled and reported. A change in culture, from defensiveness to openness, is the key to user satisfaction and, if handled sensitively, should command the support of staff who are committed to a high quality service. Whatever shortcomings there were in the past, the Trust has made good progress in improving the way in which complaints are dealt with. Some of the further improvements that we have suggested are already being pursued by the Director of Nursing and Quality. We believe that our recommendations should contribute to making the Trust more open and accessible to those who have concerns about the care which they, or their child, have received at the RBH or Harefield. In addition, we believe that the Trust could benefit from developing a close partnership with groups such as Heartline, the DSA and the DHG to ensure that they are aware on an ongoing basis of parents' concerns about services provided at the RBH.

RECOMMENDATIONS

The Panel recommends that:

85. The Department of Health considers with all relevant interests our proposal that staff involved in a complaint or its investigation be identified in the response to the complainant unless, exceptionally, that might expose the member of staff to serious personal risk.

- 86. The Trust ensures that analysis of any complaint, for the purpose of the report to the Trust Board and for action, establishes whether poor communications were a contributory factor.
- 87. The Trust improves the content and display of complaints leaflets and posters to make them more accessible and welcoming to patients and relatives, and in doing so involves representatives of users of the service.
- 88. The Trust reviews the wording of the patient satisfaction survey questionnaires with a view to making them easier to follow.
- 89. The Trust considers sending a follow-up letter after six months, informing the complainant about changes that have been made as a result of the complaint and with what effect.
- 90. The Trust explores how to encourage medical staff to participate in complaints training, and to view complaints handling as an integral part of total patient care.
- 91. The Trust provides support systems including stress counselling for any staff involved in a complaint procedure.
- 92. The Trust develops a partnership with parents' organisations such as Heartline, the DSA and the DHG to ensure parents' views are at the heart of service development.

24. MEDICAL RECORDS

INTRODUCTION

- 24.1 The making and management of proper records should be viewed not as a burden but as a crucial factor in high quality patient care. It provides a contemporaneous record of facts, results, observations, discussions and decisions. This is important both for charting the way in which the patient's condition has progressed and responded to treatment, and for ensuring effective continuity of care. Many individuals from a number of different professions will be attending the patient, and each needs to be informed about the clinical history in order to be able to deliver or prescribe future treatment. Good teamwork must therefore be underpinned by full and legible records that can be followed by all those who need to refer to them.
- 24.2 It is axiomatic not only that the records must be properly maintained, but also that the documents are present in the case folder and easy to locate within that folder. It is intensely frustrating to the clinician, and potentially damaging for the patient, if crucial information cannot be found when decisions are being made.
- 24.3 Both the keeping of adequate records and the maintenance of case folders in good order are issues that parents have raised with us. The panel also had concerns, in particular we encountered serious problems in obtaining records and with the quality and extent of the copy documentation. Sound protocols and good discipline in record keeping are vital not just for current treatment but for subsequent review whether for examining and learning from treatment and outcomes, audit and research, legal proceedings or an Inquiry such as ours. An individual's recollections have some value as circumstantial and subjective evidence, but the contemporaneous record is much more reliable as a basis for determining what happened and why.
- 24.4 Record keeping is a major and specialised area that has been the subject of policy guidance, audit scrutiny and special study both locally and nationally. The report from one of the audits, written by the London Postgraduate Audit Consortium, recognised that the efficient management of medical records was a formidable task. The responsibility for the

Trust's records library lies with the Patient Services Manager, who is responsible to a Directorate manager who is in turn responsible to the Operations Director. The Patient Services Manager's position is therefore two levels below the Board in terms of the chain of accountability. As part of her duties she has overall responsibility for medical records at both the RBH and Harefield. Her staff comprises an assistant manager, library team leader, optical disc supervisor and clerks.

24.5 We have not seen it as part of our remit to duplicate, or substitute for, work by others on this area of activity; instead, we have concentrated on the particular issues encountered during our Inquiry. To help us in reaching conclusions, we commissioned a small-scale review of the Trust's management of medical records. This review was based on site visits, meetings with relevant staff including the Chief Executive, examining procedure documents and management arrangements, and studying audit and other reports on medical records. Our analysis and conclusions are based on the review, and a copy of the full report of the review has been submitted to the Trust for information and action.

FINDINGS OF THE REVIEW

The making of records

- 24.6 We have referred in earlier chapters to concerns by parents that their observations or anxieties appeared to have been neither heeded nor recorded by staff. We also found that in many cases there was no, or at best very scant, reference to discussions about treatment options or risk factors as part of the process of obtaining informed consent. In six cases we found no record of a key decision or episode. In one, we could find no entry by any doctor in the medical records for an entire week shortly before the child died as the parents in this case said: *'nothing for the whole week when I was staying that was the one week when [she] was ever really ill'*. In another case, nothing was recorded about who made a decision to undertake a procedure, which was followed shortly afterwards by the child's death. The parents said: *'We're looking for who made the decision, what made them take the decision on that day to [undertake the procedure], and why didn't they ring us?'*. We came across one case where the PICU charts were timed but not dated.
- 24.7 The Panel came across a few examples of inappropriate entries. The parents of a child aged one drew our attention to a letter from one clinician to another which read: *'refrain*

from competitive sports and strenuous activity' which the parents thought was bizarre in view of the age of the child. One parent found that '*things are not dated and they are not timed*', and another that the child's hospital number was incorrectly quoted on several documents. Although these are likely to have had no, or very little, significance in clinical terms, we recognise how they serve to undermine the confidence and trust of parents in the decisions made about their child's treatment. The patient, or parent in the case of a child, now has the right of access to the medical records, and this should have a salutary and beneficial effect on record keeping by clinicians.

- 24.8 In April 1999 the Trust published its latest policy document on medical records. This incorporated the recommendations from the reports of two audits carried out for the years 1996 and 1997. There were two reasons why these were undertaken. First, the appointment of a Clinical Risk Manager responsible for investigating adverse clinical events led to greater awareness of the legal implications of documentation. Second, and more importantly from our point of view, the medical records staff had expressed concern that the standard of record keeping was deteriorating, and that they were unable to influence clinical staff to adhere to the Trust's policies. The Clinical Records Committee, which has some power to influence clinicians, was reconstituted in August 2000. Another initiative to promote higher standards in record keeping is that a pocket-size medical record code of practice is now issued to all clinical staff, giving essential information and contact names.
- 24.9 As for the structure of the folder itself, we understand that this is being reviewed by the Trust. There are some good examples of structures that have clear divisions between different types of documentation, and clear instructions for clinicians and medical library staff on how these need to be organised.

Missing documents or records

24.10 In a significant minority of cases at the RBH, important documents appeared to be missing. In four cases the anaesthetic report relating to an operation was missing, and in another the surgeon's typed operation note turned up only after a search. As the parents commented: 'If we dealt like that we would be sacked immediately in our job But these guys who are looking after people's lives are allowed to bin it'. We are aware that tracking records is a common problem throughout the NHS; nevertheless missing documents can sometimes lead the parents to wonder whether there was a cover-up. In one case, there were a number of important records which were missing (the patient's last complete set of records, including a 24 hour tape). In this case, where there was no letter after a consultation and nothing documented about the findings of an echocardiogram or chest x-ray, the parent commented to us: '*My feeling is why are the records missing, but we don't know what was in them, but there should have been records*'. In eight cases, either the anaesthetic records or PICU charts were absent from the records sent to the Panel, preventing our doctor from reaching a clear view and advising the parents with any certainty about a critical episode in their child's care and treatment. In at least two cases it seemed possible that flow-chart information was computer-generated but not captured in hard copy format. Post-mortem reports, mortality meeting reports and other key documentation relating to a child's death and subsequent post mortem or inquest were not always in the medical records. There was no fluid balance chart for one child during the period leading up to the child's death, despite there having been problems with fluid intake.

- 24.11 In one case the nursing records were said to have been lost, along with others, when an underground storage room was flooded in 1991. Both the nursing records and the charts were missing for another child who died five days after an operation, having needed major support in the PICU. In another, the records were mislaid for some time and eventually tracked down by the parents to the consultant's office: *'They admitted that they had lost them, and I told them where they were'*. They knew that the consultant had had the records when they saw him about the post-mortem results some eight months before they were found there. The parents of one child, who had been involved in a clinical research trial, told us that the records had been missing *'literally one month after she died. They should not have got lost in a month'*.
- 24.12 The records library, which at the RBH is located in the basement, retrieves over 100,000 case notes and over 50,000 x-rays each year for patients attending outpatients and for admission almost 1,000 case notes and x-rays each working day. A major part of the work in the library is concerned with pulling and preparing notes in readiness for an outpatient clinic. The library also receives a steady stream of individual documents test results and other material which have to be inserted in the correct place within the folder. After a clinic, or when the patient has died or been discharged, and the relevant clinician has taken follow-up action such as writing a letter or preparing a summary, the folder is returned to the library. One of the audits recommended that the case notes should be

checked before being filed away. This was rejected by the Patient Services Manager because the limited budget meant that staff had to give priority to the essential task of preparing notes for wards and outpatients.

- 24.13 Many of the problems we and parents encountered centred on the records of children who had died. We accept that the primary purpose of medical records is clinical care, but it is distressing to parents when key documents are missing after the death of a child. Our review established that the reason for this was often that documents were worked on, and in some instances removed, for mortality meetings, audit and research and put back with insufficient care. Folders returned after research can be in complete disarray, as researchers take copies of papers and often leave extra copies and papers in the file. The folders relating to patients who have died are stored separately from other records. They do not seem to be checked for content, completeness or chronological order.
- 24.14 Although in none of the cases involved in our Inquiry did the entire case-note folder fail to turn up, considerable delays were experienced by some of the parents in receiving copy records. We therefore looked at the system for tracking folders issued by the records library. Although they are supposed to be tracked, this does not always happen if they are used by, and passed between, a number of different people. This appears, again, to be a particular problem where the folder is required for research purposes. The library only records the name of the initial borrower. This might account, at least in part, for the vague responses and explanations given by staff at the RBH when notes were requested by parents and could not be located. The role of medical secretaries is pivotal in tracking the movement of case notes, and also in ensuring that they are kept in good order.
- 24.15 There is at present a dual system for the tracking of folders. Computerised tracking has been introduced, and there appears to be general agreement that computerisation provides considerable benefits, particularly as the Trust's services operate on more than one site. However, a manual system is still in operation and continues to be invaluable, not least in tracing folders when the computer system goes down or cannot be accessed. The manual system takes the form of a tracer card incorporating a pocket for loose documents awaiting the return of the folder. This card stays in the hanging file when the folder is removed, and the identity of the initial recipient is recorded. With the further development of electronic tracking, and indeed of electronic record keeping, the manual system will no doubt in due course become redundant.

24.16 A 'missing medical records' poster is displayed in all clinical areas concerning the importance of tracking notes and the adverse effect on patient care when they are not available at the right time. The nursing documentation, and that of other disciplines, should be regarded as an integral part of the total patient record. In some of our cases the nursing records were missing, and the review found that they often stayed on the ward after the patient died or was discharged. The Trust's policy is that since the mid 1990s all RBH clinical documents are stored together in an individual record folder and nursing notes are no longer kept separately, but the folders are not checked for completeness on return to the records library. The fact that some nursing records were destroyed by a flood in the early 1990s suggests that they used to be stored separately in unsuitable accommodation.

Provision of copy records

- 24.17 The parents in four cases experienced unacceptable delays in receiving copy records. In one case, the records arrived more than four months after being requested and only a week before the hearing – too late for them to use when completing our questionnaire – 'We did that without access to [her] notes, just from memory and all our notes'. The parents of another child who died in hospital were still waiting, over three years after their original request for the records, when they came to see us. The mother, herself a hospital consultant, said: 'I have been asking for those [notes] since the month after she died [three years ago]. I subsequently contacted [the consultant's] secretary about five times in the many months and they were never available. My initial request was not because I had any queries about her care, because initially I did not have any. I think they acted in her best interests and did the best they could It was purely that I wanted everything to do with her'. Another parent said: 'It took us from July to December to receive these medical records and I spoke to [the hospital] repeatedly and was fobbed off on every single occasion and then they admitted they had lost them and I told them where they were, which was in [the consultant's] office when we discussed the post mortem'. In another case the parents were asked to pay a fee of £10 before a copy of their child's records would be released. We understand that the Trust now refunds the copying charge to parents.
- 24.18 The poor quality of the records sent to the Panel in the early part of the Inquiries was such that we met senior staff from the Trust in January 2000 to discuss this. Many of the records were in an appalling state, with papers jumbled together randomly, pages and page

numbers duplicated or illegible, and key documents missing. As one of our Panel members commented, it was 'just as if someone had thrown them down a flight of stairs or shuffled them'. This made the task of our doctors, in producing a clinical analysis and summary for the Panel and the parents, unnecessarily frustrating and difficult. Some parents encountered similar problems. As one said to us: 'It has been dreadful. It has taken five people in my family to try and sort these notes out, trying to put them where they are supposed to go'. Another remarked: 'The state of them was a problem. It did take an awful lot of piecing together. I think for some that will be a lot to cope with'. The poor state of records suggested to parents a lack of respect for their plight. Following our discussion with senior Trust staff, the quality of the copy records improved significantly during the course of our work.

- 24.19 The Patient Services Manager, who is responsible for the medical records function, was not apparently aware of the extent of the problems encountered by parents and the Panel until the meeting with senior management in January 2000. She accepted the criticisms and, as a result of the meeting, the medical records were checked at the hospital before being forwarded to the Panel. This was at least half way through our cases. We were told that the unsatisfactory response to parents' requests, and the varied standard of the notes, had arisen because many individuals at different levels of seniority were dealing with them. No one was designated with the responsibility of ensuring that requests were responded to promptly and efficiently, nor were case notes checked by senior personnel to ensure that they were in good order.
- 24.20 We understand that the Trust's policy is to scan records four years after the patient has died, or after the last attendance. Initially a commercial bureau was employed to do this, but an in-house unit was subsequently established. When files are scanned to make copy records they are not always put into order beforehand, although the in-house unit endeavours to do so. The staff do not have the knowledge or experience to be able to check whether all the documents that should be in the folder are in fact there. After being scanned, the original records are destroyed. Our reviewer carried out a check to see whether the copy records that we received were representative of the general standard of folders in the library. An audit of five randomly selected 'active' case notes of patients still under the Trust's care found that these were generally in good order. This would seem to suggest that those sent to us in the early days of the Inquiry were not typical of the general standard of case note management.

- 24.21 Thirty nine sets of case notes provided for the Inquiries related to children who had died. In the end only 28 of these cases were reviewed by the Panel as the remaining 11 cases were deemed to be ineligible or the parents decided not to be involved in the Inquiries. Of the 39 sets of case notes, eight had already been scanned, and the remaining 31 were scanned before being copied for us. They were scanned in the condition in which they were received from the library, and this would probably explain why some of the files were in a reasonable state, and others were not in order or were incomplete. Even where copies were made from original documents, they were not always of good quality. We understand that although scanning can sometimes enhance an image, it is not always possible to obtain clear copies where the original document has been severely damaged. Because of the conditions under which records were stored, some documents had water stains and damp patches and images were almost indecipherable. In addition, some of the paper used for ECG recordings does not hold the image and fades quickly over time.
- 24.22 A total of 56,854 pages were scanned for us within a very short period. Preparing case notes for the Inquiries was an additional burden and cost to the library, which was not given additional funding for the task. Given the volume of scanning that needed to be done within a short time-scale, there was insufficient time to take stock of the situation, nor was there an allocation of senior staff time to focus on meeting the needs of parents and the Panel. It was reasonable for the staff who scanned and copied the records to infer, in the absence of guidance or funds from the Trust's management, that the Inquiries' requirements did not need to be given priority.

THE CLINICIANS' RESPONSE

- 24.23 We raised with the doctors our concerns about the state and quality of records supplied to the Panel and to parents. One said that: 'from my experience of having looked through a lot of hospital notes from other hospitals over the last two or three years, my impression is we are no better or worse than most other places'.
- 24.24 The Panel also drew attention to the fact that rarely was there any record of what was said to parents, what concerns they expressed, and what were the views of the clinician concerned. We wondered whether this was an area that would merit the development of protocols. One commented that: *'it's something that we have to take on board and do*

something about'. Another clinician accepted that: 'this aspect of record keeping needs to be improved. I think that it has already improved in the last few years. The protocol should be that proper records of all such consultations and advice should be recorded'.

24.25 We also discussed various aspects of record keeping with a group of nurses. One of them, responding to a question about the quality of notes, expressed the opinion that: 'they have improved now we are recording the documentation on Careview [a computerised record-keeping system] that automatically dates and times when events take place But I think we can always improve on our communication'. Another, commenting on making full records of conversations about treatment options, said that: 'from a time perspective we could not do it'.

THE TRUST'S RESPONSE

- 24.26 A non-Executive Board member told the Panel: '*The auditors [recently] gave a very positive review of the medical records department, and in their experience ours was outstandingly good*'. Regarding the poor state of copy records, another noted that: '*the problem having been identified has been addressed*'. Nevertheless, the Chairman acknowledged: '*that shouldn't have happened and I will accept responsibility for that on behalf of the hospital*'.
- 24.27 As for the future, when the paediatric cardiac service at Harefield transfers to the RBH site, we noted from the Implementation Plan that 'the Trust will review its communications policy to ensure fuller involvement of parents/children in the medical record system including parent/child held records and, when required, copies'.

CONCLUSIONS

24.28 The shortcomings we identified in record keeping are not unique to the RBH and Harefield. The most probable cause is not disinclination on the part of clinical staff to adhere to good record-keeping practice, but workload pressures which mean that, understandably, records take second place to attending to the patients. That said, all clinical staff need to be reminded of the importance of the records both for good patient care and teamwork, and for subsequent audit and review of treatment. The pocket guide to good practice is a step in the right direction, but it needs to be backed up by training and

supervision. Regular awareness and training sessions on the practical and legal aspects of record keeping should be viewed as an essential component of effective health care and risk management. This needs to be taken forward as an important component of the clinical governance agenda. The re-constituted Clinical Records Committee could play a lead role, provided that it has the membership and authority needed to promote and secure compliance with agreed procedures and standards. The Committee should be prepared to provide a voice for the medical records staff when they challenge poor practice.

- 24.29 Instances quoted by the parents in particular, and also encountered by the Panel, illustrate the problems, distress and, in some cases, suspicion that can arise when key documents are missing. It was worrying that important documents such as anaesthetic records and PICU charts were missing from some files provided. Although this problem may not be unique to the Trust, the impression given is of a cavalier approach to the removal of documents. The most likely explanation is that they were removed for some reason in the period following the child's death or discharge. We cannot over-estimate the importance of maintaining a complete record, not least because the absence of key documents could attract severe criticism in the event of legal proceedings – or of Inquiries such as ours. If a particular document needs to be retained by a researcher or clinician, it should be photocopied and the original put back immediately in the correct place within the folder. Nursing records also should be regarded, and stored, in a manner that reflects their critical importance as a record of the patient's condition, progress and treatment. They should not be housed in a room where the conditions – such as flooding – are liable to lead to damage or loss.
- 24.30 Delays in providing copy records to parents were attributable, at least in one case, to the fact that the originals could not be traced for several months. The tracer card system is of limited value if movements of the folder after the initial issue are not reported to the library. Equally, a computerised system will fare better only if staff throughout the hospital are diligent in recording the transfer of folders. This is a matter that requires early attention by the Medical Records Committee.
- 24.31 Although many of the case-note folders supplied to the Panel were inadequate, the standard improved considerably after we complained to senior management and the Patient Services Manager became involved and took personal responsibility for the task. What is clear, however, is that the lack of additional resources for the considerable task of copying over

50,000 documents, and the lack of management guidance, meant that staff were not aware of the importance of the Inquiries' work. So far as parents were concerned, delays of several months, and in one case over three years, in meeting requests for copy records is unacceptable. All such requests should be logged, and action monitored regularly by the Patient Services Manager. As for the £10 fee that was charged to one of the families, we understand that the Trust now refunds the copying charge, a development we welcome.

24.32 We believe that initiatives to secure compliance with the Trust's policy, to change systems or to improve record keeping require the support of senior management. In addition, the Board as a whole should receive periodic reports on the development of policies and procedures and on their implementation.

RECOMMENDATIONS

The Panel recommends that:

- 93. The Department of Health ensures that, for any Inquiry established within the NHS, sufficient additional resources are allocated to enable copy records to be provided without detriment to the continuing responsibility to meet the day-to-day needs of the clinical service.
- 94. The Trust ensures that all clinical staff be reminded of the importance of recording key decisions, events and discussions affecting a patient's care and management.
- 95. The Trust underlines the importance of not removing documents from case-note folders, of keeping documents in proper sequence, and of notifying the records library immediately of any movement of records, to all NHS, academic and research staff working in the Trust's hospitals.
- 96. The Trust Medical Records Committee reviews arrangements for the training of clinical and other staff in record keeping.
- 97. The Trust includes monitoring of compliance with good record-keeping practice within its arrangements for clinical audit and performance.

- 98. The Trust ensures that any requests from patients or parents for copy records are logged and their handling monitored by the Patient Services Manager.
- 99. The Trust Board receives periodic reports on policies and performance in record keeping and maintenance.

25. CLINICAL AUDIT

INTRODUCTION

- 25.1 In this Chapter we examine the effectiveness of the clinical audit arrangements at the RB&HT in advancing the quality of care and treatment delivered to patients. Shaw (41) has described clinical audit as: 'a three-part cycle. The first stage is to define expectations, the second is to compare these with reality and the third to bring about appropriate change in clinical practice'. The process of audit, as described in a paper published by the BRI Inquiry (42), involves:
 - Defining standards, criteria, targets or protocols for good practice against which performance can be compared; gathering systematic and objective evidence about performance.
 - Comparing results against standards and/or among peers.
 - Identifying deficiencies and taking action to remedy them.
 - Monitoring the effects of this action, i.e. 'closing the audit loop'.
- 25.2 Data can be pooled and analysed at many different levels, from within individual centres comparing the results of individual clinicians right through to evaluating the outcomes of different procedures on an international basis. Treatments or outcomes can be measured, problems identified, and changes in practice brought about. However, the value of audit findings is critically dependent on the accurate collection onto a searchable database of all relevant data submitted in accordance with standardised classifications and definitions. Clinical audit must also be seen as an educative process, which in turn depends on effective clinical leadership and promotion of an organisational learning culture.
- 25.3 Clinical audit not only underpins quality management and helps to extend scientific knowledge but it also, and most importantly for patients or parents, provides the basis for realistic discussion of risk. Without such systems, it is virtually impossible in the rarer operations to have honest input into the discussions leading to informed consent for operations a subject that we discuss further in Chapters 8 and 15. Indeed, figures for

paediatric cardiac surgery that have not been properly validated or adjusted for the presence of additional risk factors (risk-stratified) can have harmful consequences such as:

- Avoidable loss of public confidence in a centre that has a valid reason for apparently poorer outcomes, such as being a national referral service with a high proportion of the very ill patients with more complex conditions.
- Loss of confidence on the part of a purchasing authority, which might decide to refer cases to a centre with apparently better results.
- Loss of confidence in, and unwarranted criticism of, an individual surgeon.
- Loss of confidence among trainee cardiac surgeons, and a damaging effect on recruitment to a small specialty which is in the media spotlight and within which many of its pioneers are reaching retirement age. In December 2000 there were only 27 consultant surgeons in the UK involved in children's heart surgery, and of these only nine worked exclusively in paediatric heart surgery.
- 25.4 Many of the accounts we heard made clear that the parents either did not take on board, or were not given, a realistic assessment of the possible outcomes of surgery. Because there are so many different operations in children's heart surgery, some very rare, often the only way that the average risk of a procedure can be assessed is by looking at aggregated data from a large number of centres.
- 25.5 In the United States, a programme known as the Paediatric Care Consortium at the University of Minnesota, has been in place for 18 years (43), to pool the experience of several institutions (currently 27 paediatric cardiac centres in the USA and Canada). The performance of a single centre is compared with the performance of the entire group. A specific data set is collected, validated for accuracy and completeness, and any problems resolved before the data are analysed. The Consortium provides each participating centre with a summary, which highlights its own performance and identifies significant variations from the results aggregated for the group as a whole. A second report shows the operative mortality for specific surgical procedures, and a third provides the trend analysis over the time.
- 25.6 How far has clinical audit been developed nationally in the UK, and even across international borders, in this specialty? And to what extent has the RBH, which is regarded as a centre at the forefront of developments in clinical practice, been involved in
that development? The Panel considered it important to look at these questions in order to address the concerns of parents whose cases we were asked to examine.

NATIONAL CONTEXT

- 25.7 Cardiac surgery, both adult and paediatric, was one of the very first UK specialties to record and share data. In 1977 the UK Cardiac Surgical Register was established by the Society of Cardiothoracic Surgeons of Great Britain and Ireland to collect activity and outcome data, one of the agreed treatment outcomes being death in hospital and within 30 days of surgery. The data are collected retrospectively on manually-completed returns, for the year ending each 31 March, by all of the UK units providing the service, so it has the virtue of being comprehensive. However, information was until two years ago unit, rather than surgeon, specific. It is now both unit and surgeon specific but still lacks stratification of risk. This limits the value of the Register for making statistically valid outcome comparisons between centres.
- 25.8 In the early 1990s the same Society recognised the need to collect more comprehensive patient-specific data for patients undergoing cardiac surgery. Surgeons in the USA had also voiced concern about publication of raw mortality data without reference to patient-specific risk factors or other consequences of cardiac surgery such as neurological damage. What is more, the creation of the NHS 'internal market' meant that both purchasers and providers of health care needed some means of measuring and assessing options and outcomes for cardiac treatment. Since 1994 a group of adult cardiac surgeons have worked on the development of a 'real-time' information system to meet these requirements. It was initially piloted in six sites, and it uses the PATS software system provided by Dendrite Solutions, which also provides the data analysis service and report production.
- 25.9 The resulting data-set and coding definitions now in use for adult cardiac surgery in the UK were implemented in 1997 and are compatible with most international data-sets, including those of the Society of Thoracic Surgeons (USA) and the developing European Cardiac Surgery Registry (ECSUR). The 1997-1998 results, for the 70% of UK adult cardiac surgery units contributing their results, represent the end of the first stage in a process that will continue to evolve. They show the benefit of a nationally agreed data-set for adult cardiac procedures and demonstrate the trends in the volume and complexity of

the adult cardiac surgery workload, as well as risk-stratified outcomes. As the introduction to the first report remarked, realisation of this data-set for adult cardiac surgery as a fully comprehensive record and analysis for all such work in the UK depends upon the enthusiastic support of all cardiac surgeons and the meticulous – and contemporaneous – recording of data by each local unit.

- 25.10 There has therefore been steady, if slow, progress in developing a national system for auditing the results of cardiac surgery in adults in the UK. This is a high volume and potentially high-risk service, having the advantage of a limited number of procedures whose classification and risk stratification had been published in the medical literature and widely adopted.
- 25.11 The position regarding cardiac surgery for children with congenital heart disease is much more disappointing. This is not least because there are only 3,500-4,000 operations each year, spread across some 60 different procedures, in 15 units across the UK and Ireland. There are no national or international agreed systems for collecting data on the process and outcomes of children's heart surgery, and only in Germany are there national mortality data on congenital heart disease. The main stumbling block appears to be that the accepted descriptions of the various forms of congenital heart disease have been too imprecise to be useful for case-mix or risk stratification. For many years cardiac surgeons, anatomists and cardiologists were unable to agree a nomenclature that allowed for definition of the degrees of complexity of congenital heart malformations.
- 25.12 The great strides forward that have been made in treating congenital heart disease, despite the absence of comparative data, have depended on the pioneering skills of surgeons. They have devised innovative surgical approaches to give the chance of life to children formerly condemned either to die in infancy, or perhaps to survive to childhood or early adulthood after a life with severely restricted activity and a final period of increasing dependency, struggling with heart failure. They worked in partnership with the paediatric cardiologists, whose skill in developing the use and interpretation of new diagnostic tools, from cardiac catheterisation to echocardiography, enabled accurate anatomical diagnosis to be made. This meant that any proposed surgical treatment could be meticulously planned preoperatively. The work of these interdependent teams of paediatric surgeons and cardiologists, supported by improved anaesthesia and the development of paediatric intensive care and specialist nursing, has resulted in dramatically improved outcomes for

children. Media attention and public perception over the years has tended to focus on the success stories resulting from pioneering surgery. This has led to expectations that all outcomes will be good and even an assumption that death or major life-spoiling complications must be the result of incompetence or negligence.

- 25.13 In the absence of a national system, many paediatric cardiac units devised their own databases and now have some 20 years of local follow-up outcome data. However, because of the persistent problems resulting from the lack of an agreed universal classification system, these could not be aggregated into national statistics allowing comparative audit. The fact that only small numbers of the less common procedures are undertaken at each unit has also meant that each individual unit has an insufficient cohort of cases to produce statistically valid risk analysis or discern trends. This in turn diminishes the accuracy and value of risk information given to parents. Particularly in the early days, units could share results and attempt to increase knowledge about the management of rare conditions only through clinical meetings and published papers, as there was no means by which they could access comparative data.
- 25.14 Over the past decade an informal group of British cardiologists and cardiac surgeons, concerned about this absence of a national framework for effective audit, has made extensive efforts to address the deficiencies in the current descriptions of congenital heart disease, which is one of the key obstacles. At the international level, a group of paediatric cardiac surgeons from across Europe formed the European Congenital Heart Surgery Foundation in the early 1990s and committed themselves to devising an effective way to share their personal results. These initiatives led eventually to the development of the European Congenital Heart Disease Database (ECHDD), which is managed from Warsaw. All ECHDD work is done on laptops, as the hospital computer systems are in general not able to cope with the data, and the software seems not to be compatible with many current UK hospital systems. Individual surgeons, rather than units, contribute their own data to ECHDD and, in addition to purchasing their own laptops and originally the relevant software (now available free on the internet), they also pay personally for the database manager.
- 25.15 This work in Europe, and attention in the UK and USA to the intractable problem of coding, has led to the production of a hierarchical system of coding and classification. Two paediatric versions have recently been agreed across Europe and North America, one for

surgeons and one for cardiologists. These will be cross-mapped, and it is expected that the resulting system will be adopted during 2001 as the international standard. This will be the culmination of years of detailed work by clinicians committed to the extension of knowledge and sharing of best practice to the benefit of their patients. Professor Robert Anderson (formerly of the RBH, now Professor of Paediatric Cardiac Morphology at Great Ormond Street Hospital), Mr Martin Elliott (consultant paediatric cardiac surgeon at Great Ormond Street Hospital), and Dr Rodney Franklin (consultant paediatric cardiologist at Harefield Hospital) have led this development in the UK.

- 25.16 The DoH has also had a central role in developing audit in all clinical disciplines, though at least a decade behind practice in the USA, where the medical insurance companies demanded objective evidence of outcomes of care (mortality within a specific period being the most clear cut). In 1989 a market model for the NHS was described in Working for Patients (44), launched by the Secretary of State for Health in a nation-wide live television link-up. All board level managers, including Medical Directors, were required to attend. This document said: 'The Government will encourage all the Royal Colleges to make participation in medical audit a condition of being allowed to train junior doctors'. It added that: 'every consultant should participate in a form of medical audit agreed between management and the profession locally. Management should be responsible for ensuring that an effective system of medical audit is in place and also that the work of each medical team is reviewed at whatever regular frequent intervals are agreed locally'. It concluded: 'The Government recognises that medical audit needs a significant investment of time by doctors themselves, and adequate support to ensure that the necessary information is available'. Although these audit requirements were officially welcomed by the medical profession as a tool for education not for discipline, progress on implementation was variable.
- 25.17 Nearly a decade later, in 1997, the current Government published *The New NHS Modern* and Dependable (45), introducing the concept of clinical governance: 'Professional and statutory bodies have a vital role in setting and promoting standards but shifting the focus towards quality will also require practitioners to accept responsibility for developing and maintaining standards within their local NHS organisations. For this reason the Government will require every NHS Trust to embrace the concept of "clinical governance" so that quality is at the core, both of their responsibilities as organisations and of each of their staff as individual professionals'. This was followed, in June 1998, by

the publication of A First Class Service – Quality in the NHS (46), which spelt out the components of clinical governance for NHS trusts, including: 'full participation by all hospital doctors in audit programmes including specialty and subspecialty national external programmes endorsed by the Commission for Health Improvement'.

- 25.18 Clinical audit is clearly seen by the DoH as being at the heart of managing clinical services in an individual unit and as a basic tool of quality improvement and clinical governance. The lack of an agreed coding and classification system was not seen as an insuperable barrier to many Trusts who, presumably seeing their potential at least in local quality management, set up paediatric surgery and cardiology databases in their units.
- 25.19 In 1997 the DoH contributed central audit funding to set up the UK Central Cardiac Audit Database (UKCCAD), a pilot cardiac disease audit system combining five other cardiological databases including the European Congenital Heart Disease Database (ECHDD). A steering group led by Professor Ken Taylor, an adult cardiologist from Hammersmith Hospital, worked to establish a data collection system that produces a few simple easily identifiable outcomes, such as mortality and freedom from re-intervention. UKCCAD data were contemporaneous, validated and sent electronically, but use a very limited data set by comparison with the ECHDD, one which does not allow risk stratification. It was piloted at six cardiac centres, of which only Leeds and Southampton had paediatric cardiology on site. Although central funding was originally planned to end in June 2000, it has now been committed by the DoH for a further three year period.
- 25.20 The DoH has recently signed a contract to run the Central Cardiac Database (CCAD) with the group of doctors who developed the software, (based on Lotus notes – not an obvious choice for a searchable database). The CCAD is now charged with extending the congenital paediatric cardiac surgery database from the original two to all 14 sites in the UK. We understand that it will be implemented using the agreed international paediatric cardiological (not surgical) classification system for congenital heart conditions, to be officially cross-mapped during the next year. This team is also providing the same software management system to run the MINAP (Myocardial Infarction National Audit Project) working with the Effectiveness Unit of the Royal College of Physicians, and accountable for the whole CCAD project to the National Information Agency. The MINAP project will monitor the treatment of acute myocardial infarction (AMI) in every DGH against the published National Service Frameworks. It appears that the DoH, after a

slow start in focussing support on the audit of children's heart services, has now coupled this with a nation-wide project setting up an unpiloted database on the management of acquired cardiac disease in adults, to be 'rolled out' in every DGH. The Panel hopes that this latter project will not shift the focus from the development of audit of children's heart services.

25.21 The Government's NHS Plan (5), published in 2000, also re-emphasised the importance now attached to data collection and clinical audit: 'All doctors employed in or under contract to the NHS will, as a condition of contract, be required to participate in annual appraisal and clinical audit, from 2001'.

CLINICAL AUDIT AT THE ROYAL BROMPTON HOSPITAL

- 25.22 The important test for a clinical audit system (in a unit or nationally) is whether it is structured to provide reliable information about the quality of clinical care. Audit of paediatric cardiac surgery at the RBH, as elsewhere in the UK, has been hampered by the lack of an agreed national classification and risk stratification for paediatric cardiac surgery. In the absence of this, audit of paediatric cardiac surgery at the hospital has been based on the aggregate information provided by returns to the annual Surgical Register, a database of all post-operative deaths of children since 1990, and on the monthly analysis of all deaths of children following cardiac surgery.
- 25.23 The clinical audit office at RBH was set up in 1992. Its first part-time Director, who is still in post, was previously the medically qualified head of the physiology and lung function laboratories at the RBH and is an expert in quantitative and statistical analysis. He is supported by a full-time Clinical Audit Manager who, in turn, manages two graduate audit staff. In addition to completing the mandatory returns to the various national databases (CEPOD, SCTS, UK Cardiac Registry and UK Thoracic Registry), the office maintains the in-house databases, advises the directorates on audits and responds to *ad hoc* requests from the Board and the Medical Director, who is the Board member with responsibility for clinical audit. The directorates of cardiac surgery and thoracic surgery each employ a graduate audit assistant. They are accountable to the relevant clinical director for their directorate's audit function and relate professionally to the Clinical Audit Manager.

- 25.24 The initial focus, when the audit office was established, was on the outcome of adult cardiac surgery which, as we have described, had the advantage of a limited number of procedures whose classification and risk stratification had been published in the medical literature. This allowed mortality and morbidity data to be reported annually in the RBH clinical audit report. As an early UK leader in the development of a risk-stratification approach to adult cardiac surgery outcomes, the RBH was only able to compare the results with those of another UK hospital for one year. For all other years, in the absence of comparative published UK hospital data, their results were compared with outcomes published in the United States. Similar analysis of the outcome of paediatric cardiac surgery has been more difficult because of the considerable number of different types of congenital heart disease, many of which are of low volume, and the lack of a nationally agreed classification and risk stratification for congenital heart disease.
- 25.25 The clinical audit office at the RBH has a database of every post-operative child death since 1990. Each death is the subject of a monthly audit undertaken by the surgeons, cardiologists and pathologists, who provide a written report with their recommendations and conclusions. In addition, since 1995 the clinical audit office has been responsible for the returns made to the UK Surgical Register, which include congenital and acquired heart disease in both adults and children. The office has therefore had both aggregated data of the outcomes of paediatric cardiac surgery on a year by year basis and reports of the investigation of each death from the monthly mortality meetings.
- 25.26 The low volume of the majority of paediatric cardiac surgery procedures means that regular review of each death by all of those involved in the care of paediatric cases in these circumstances was considered by the Trust to be a more rapid alerting system to developing problems than statistical analysis of aggregated data. For example, in April 1996 the regular monthly review of paediatric cardiac mortality identified an increase in the mortality from Switch operations in the hospital. These were investigated by comparing the results of the relevant period with those going back to 1990. This showed that during a six-month period, mortality had increased from less than 10% to 17%. The surgeon concerned recognised the problem, took remedial action and mortality from these operations rapidly returned to its previous rate.
- 25.27 The clinical audit office has wanted to compare the results of paediatric cardiac surgery within the RBH with those at other centres. In two separate years approaches were made

to another centre in London to undertake a collaborative comparative audit project, but this did not prove possible. Subsequently, the clinical audit office acquired the database developed by Mr Jarda Stark (a retired children's heart surgeon) at Great Ormond Street Hospital. It was, however, found by the audit office to be inappropriate for the purpose of recording data to enable comparison with the results of other centres and it did not allow for inclusion of all necessary morbidity data.

- 25.28 In 1997 the RBH discussed with its host purchaser, KCWHA, the need for an audit of paediatric cardiac services within the hospital. The resulting audit allowed comparison of RBH results with published data from the UK Surgical Register.
- 25.29 As described earlier in this Chapter, the absence of a nationally agreed classification and risk stratification for congenital heart disease remains a barrier to undertaking comparative audit between UK centres. The ECHD database which had been developed at Great Ormond Street and Harefield Hospitals has not as yet been taken up nationally because many surgeons consider it to be too detailed and thus unwieldy. In 1998 the RBH decided to develop its own audit database, using the Toronto system as a basis. This allows contemporaneous entry of data, which the Trust hopes will provide the potential for proper comparison of results between centres in the near future.
- 25.30 The outcome of paediatric cardiac surgery at RBH was described by the Hunter Review (3) as: 'similar to, and in most cases better than, the results taken from the UK register run by the Society of Cardiothoracic Surgeons of Great Britain and Ireland'. However, Dr Hunter was critical of the audit arrangements at the RBH and expressed concern about the lack of a paediatric cardiac database. The Review states: 'each individual surgeon at the Brompton has collected his own data and submitted them separately to the Audit Office who have filled in the return for the UK figures over the years'. This meant that there was no routine and readily updated mechanism through which paediatric cardiac surgeons and cardiologists working at RBH could examine and evaluate the outcome of the whole unit. 'There are a few discrepancies between the surgical figures and the audited figures It is unfortunate that the three surgeons had not discussed the results with the audit department nor themselves'. The Review concluded: 'It seems inappropriate for a department of this size and reputation not to have a computerised database into which all operations are entered. Support by management with both personnel and finance to remedy this is essential'. The improvements sought by the Hunter Review have now been put in place.

Before this, it should be noted that the one occasion on which results from the RBH showed any important variation was rapidly identified and remedied through the audit system in place during the period analysed.

CONCERNS EXPRESSED BY PARENTS

- 25.31 The Hunter Review was unable to examine individual cases during the course of its work. It was not surprising that clinical audit, though not raised as such by parents, underpinned many of the concerns they expressed in relation to hospital performance. Many parents told us that they were very dissatisfied with the quality and accuracy of information given to them about the risks of death or serious complications especially brain damage when consenting to surgery for a congenital heart defect. It was not clear to some whether the risks quoted were those relating to the RBH, or to results aggregated from all UK centres undertaking the procedure in question. As one parent observed: '*All any of us can do is the best, and the best with the knowledge we have available at that time*'.
- 25.32 The parents of one child who died about one week after surgery from a rare condition double outlet right ventricle, subaortic ventricular septal defect (restrictive) posed the question: 'As we were informed that the operation was a technical success, has this operation been included in statistics relating to the successes of this operation which has been given to other parents?'. The clinical member of the Panel involved in our hearing of this case found nothing to criticise in the clinical management and, though it sounded inappropriate given the outcome, considered it correct to have described the operation as 'anatomically successful'. A technically satisfactory operation which resulted in death in hospital or within 30 days of surgery was recorded as a surgical death in the returns to the Society of Cardiothoracic Surgeons. The Panel member noted that there was unlikely to be sufficient data, even nationally, to allow precise mortality to be quoted for this particular child's condition, and that the best that could be achieved would be to examine the results from more prevalent, but similar, conditions.
- 25.33 In another case, the child was involved in a research trial. She died in the PICU about ten hours after returning from the operating theatre. Her parents wondered whether the outcome had been reported through the audit process and to the Research Ethics Committee. They told us: '*They have to do trials and as long as they learn from it that is fine All you want is if mistakes have been made, for people to learn from them, and that*

is all one can ask'. In fact, the Panel was informed that the outcome was indeed reported to the Trust's Research Ethics Committee.

THE CLINICIANS' RESPONSE

- 25.34 We did not question the clinicians at length about clinical audit, as we wanted to concentrate on issues of more direct concern to parents. However, one or two clinicians pointed out that inadequacies in the RBH's clinical audit arrangements were the result of insufficient funds. One said: '*Our lords and masters want us to do all these clever things but they do not want to supply the money to do it, and to get a really good audit system going, you need quite a lot of clerical staff. You probably need doctors, full-time doctors, to do it. Well, that is just not possible in the Health Service at the moment. So it is a nice idea but in practice it is pie in the sky really'. Another felt that not enough thought had been given to the subject: 'I think at the Brompton I would like to see a broader appreciation of how we develop outcomes. It is very difficult deciding exactly what to assess and how to present it without colouring it one way or the other'.*
- 25.35 However, another doctor commented that: 'the Brompton has audited the commoner conditions as a Department for the last five to ten years so we have always had reliable information to quote from'.

THE TRUST'S RESPONSE

25.36 The Medical Director wrote to us: 'The low volume of the majority of paediatric cardiac surgery means that the statistical analysis of outcomes of paediatric cardiac surgery is likely to indicate changes in outcomes less rapidly than the analysis of individual cases. Regular review of each death by all of those involved in the care of paediatric cases in these circumstances is a more rapid alerting system to developing problems than statistical analysis of aggregated data'. With regard to the concerns expressed in the Hunter Review, he commented that: 'there was actually quite a lot before [the Hunter Review]. What there wasn't was a systematic record of all mortality, morbidity, in relation to all the patients who were going through'. As a senior manager at the Trust said: 'It is true to say that the Stewart Hunter Inquiry, as it were, added a few hundred miles per hour to the speed in which the clinical audit department were recording and monitoring this [database]

[There is now] a new system to make sure all [information is] co-ordinated directly into the co-ordinator's office'.

25.37 The Chief Executive told us that management was 'wholehearted' in its support for the development of clinical audit. The allocation of £117,000 from the KCWHA had been supplemented, by the Trust, by additional funds totalling £275,000 in 1997-1998, £212,000 in 1998-1999, £242,000 in 1999-2000, and £297,000 in 2000-2001. The Medical Director had also: 'authorised funds within his budget to support the development of the paediatric database to ensure that, once we had decided which was suitable for our needs, the necessary support staff was available to ensure its rapid and proper utilisation in the hospital'. The Director of Clinical Audit endorsed this, saying that there was: 'a high and mutual respect between all levels of staff at the clinical audit office and all levels of management'. He said that the RBH's problems in respect of audit: 'lay in the understandable reservations of the paediatric heart surgeons to release detailed information to the clinical audit office until they were satisfied that it could not be misinterpreted'.

CONCLUSIONS

- 25.38 The implementation of clinical audit has for some years been a policy objective of the DoH and NHS management, and a goal of the professional bodies. In paediatric cardiac surgery the main obstacle, not only locally but nationally and internationally, to the development of a standardised basis for effective audit has been the difficulty in agreeing a satisfactory system of coding and classification. This is attributable to the large number of procedures and the relatively small numbers of each procedure performed in individual centres and to the persistent difficulty in developing a workable agreed coding and classification system acceptable to all the clinicians.
- 25.39 The RBH, which is justly proud of its research record and its contribution to international knowledge in the management of congenital heart disease, had the In-Hospital Deaths database as the only effective database of paediatric cardiac surgery for the entire period covered by our Inquiry. We have not examined the audit systems in operation at other centres in detail, but the lack of a national system meant that the children's heart surgeons at the RBH were unable readily or systematically to subject their own results to continuous review and to compare their results with those at other centres. Instead, with some success

they used the system of mortality meetings and analysis to identify any trends or results that might indicate a need to review practice. Nevertheless, we remain concerned that the continuing absence of an effective national framework for audit of paediatric cardiac procedures inhibits the presentation to parents of properly validated comparative information on risk, for the purpose of informed consent. We also observe that, had there been a database of all the children with congenital heart disease referred to the RBH, the Trust might have been able to identify the pattern of treatment of children with Down's Syndrome more readily and to address the accusations of discrimination.

25.40 The Panel is encouraged that the Trust has recognised the value of audit by allocating significant funding for its development, despite the lack of a national framework for classifying treatment of congenital heart disease. We have been impressed by the commitment of the Medical Director to this area of responsibility, and we expect that the Board will continue to press for, and monitor progress in achieving, a system for audit of paediatric heart surgery that enables results from all centres to be compared. The decision locally to adopt the Toronto-based system, rather than those developed by other centres, highlights the importance of devising a database that commands acceptance and support by those utilising the system within the hospital and will contribute cost-effectively to the extension of knowledge through international data collection systems. However, real advance in audit must depend on a greater sense of urgency and commitment at the DOH to promoting the identification and adoption of a common nomenclature and classification for congenital heart conditions. Progress should not have had to depend on a small group of self-funded individual clinicians getting together in their own time to find solutions.

RECOMMENDATIONS

The Panel recommends that:

100. The Department of Health should pursue vigorously and support financially the development of a national system of coding and classification for congenital heart disease, with a view to securing a database that enables meaningful comparisons and decisions to be made both within the UK and internationally. In addition the Department of Health should consider the staffing and pay structures for clinical audit staff to maintain their essential skills within the NHS.

- 101. The Department of Health should encourage the relevant Royal Colleges and specialist medical associations to define the timely and competent input of clinical data into audit databases as a core clinical responsibility, and regard evidence of such activity as a pre-requisite for individual professional accreditation and for a centre's accreditation for postgraduate specialist training.
- 102. The Trust's Clinical Audit Office should deliver support and services to the clinical directorates through annually reviewed service agreements, which require the directorates to provide the information required to support the audit process.
- 103. The Trust Board should receive regular progress reports on clinical audit arrangements and in particular on the development of, and results from, data relating to paediatric cardiac surgery.

26. POLICY ON SPEAKING UP

INTRODUCTION

- 26.1 As described in Chapter 1, the Trust's decision to commission the Hunter Review, which led in turn to our Inquiries, arose primarily from an anonymous letter sent to *Private Eye*. The arrangements whereby staff, or others working within the organisation, can raise concerns about the services with which they come into contact are commonly known as the 'whistleblower' procedure. In essence, this allows staff to raise concerns internally without fear of victimisation, with their identity remaining confidential in any subsequent investigation.
- 26.2 In this case, the allegations were made anonymously. We have strong reservations about the value of criticisms received on this basis, as they deny the institution the opportunity fully to understand the basis for the allegations and to investigate them thoroughly. While we believe that the Trust was right to commission an inquiry, the fact that anonymity made it impossible to discover and investigate what lay behind the original accusations may have impeded full resolution of all of the issues.
- 26.3 The anonymous allegations were also sent to the Down's Syndrome Association (DSA). They and their members have an interest in ensuring that any genuine concern about these children that staff may have will, in future, be raised in a constructive and proper way, so that the Trust can deal with them appropriately. We took the view that any lessons that could be learned on how to minimise the alarm and hurt caused to patients and staff by anonymous allegations directed at third parties were valid issues for the Panel to consider. That is not to say that speaking up should be discouraged, but if concerns are not raised directly with the Trust or the procedures for raising them are not 'user friendly' they may end up in the public arena and cause unnecessary harm or distress to the parties involved.
- 26.4 In the press release of 8 September 1999 (2), announcing the establishment of our Inquiry, the Trust's Chief Executive is quoted as saying: *'It remains a matter of considerable*

regret to us that the whistleblower who originally raised his concerns feels unable to come forward. Our 'Speaking Up' policy is quite clear'.

- 26.5 It was not part of the Panel's remit to discover, or speculate about, the identity of the author of the anonymous letter. However, given the terms of the above statement, and since the 'Speaking Up' policy was available only to staff, it seems reasonable to assume that the Trust believed the source of the anonymous allegation to be a present or former member of staff. The facts are that:
 - His or her allegations revealed some knowledge of the work of the Centre over a period of months, if not years.
 - He/she enclosed confidential draft audit data.
 - The Hunter Review referred to him/her as a concerned professional.

This led us to view the Trust's assumption as sound.

- 26.6 We have no information on which to assess the motives of the person who decided to write to *Private Eye* rather than raise concerns with the Trust. Since the person's identity is not known, we cannot say whether he/she was aware of the 'Speaking Up' policy, or whether a conscious decision was taken not to use it, and to go straight to Private Eye and the DSA. It is sometimes the case that anonymous disclosures are the preferred method of a malicious person, but it would be unsafe, on the information available to us, to reach any conclusion on this. Even so, the fact that the person chose to take their concerns outside the Trust was in a sense a breakdown in communication. We do not make, nor do we intend, any criticism of the Trust's handling of the matter. Indeed, we have commented earlier on the speed and openness of the Trust's response to this event. Nevertheless, we question why the Trust's 'Speaking Up' policy was not used in this instance and whether a well-publicised policy which provided a safe external route could have made a difference. In the context of the proposals in the report, An Organisation with a Memory (8) prepared by an expert group chaired by the Chief Medical Officer, we hope that any such lesson will be of value to the NHS generally.
- 26.7 As a general rule, even if a concern proves to be misconceived or cannot be substantiated, that does not mean that it should not have been raised. If that were the case, whistles would not be blown until it was too late, after further problems had arisen which might

otherwise have been preventable. Equally, if the automatic response to any anonymous allegations – however apparently specious – is to set up an independent inquiry, that would undermine the value of a 'Speaking Up' policy.

26.8 While the Hunter Review was not able to substantiate any of the allegations, it seems to us that it would have been unwise for the Trust to conclude that there was therefore no foundation to any of them. The fact that the Chief Executive, on seeing the anonymous allegations, and in the light of the recommendations of the Hunter Review, considered an independent inquiry to address the concerns of parents was the necessary and immediate response supports this view.

NHS POLICY GUIDANCE

- 26.9 On 27 August 1999, the NHS Executive issued a circular (47) on the Public Interest Disclosure Act 1998. In the Background section it states that: '*Ministers expect a climate of openness and dialogue in the NHS, a culture and environment which encourages staff to feel able to raise concerns about health care matters sensibly and responsibly without fear of victimisation*'.
- 26.10 The circular enclosed a resource pack produced by Public Concern at Work who also assisted our work on the Trust's arrangements for 'Speaking Up'. Every NHS Trust and Health Authority was required to have in place local policies and procedures, which comply with the 1998 Act and which should include:
 - 'The designation of a senior manager or non-Executive Director with specific responsibility for addressing concerns raised in confidence which need to be handled outside the usual line management chain.'
 - 'Guidance to help staff who have concerns about malpractice to do so reasonably and responsibly with the right people.'
 - 'A clear commitment that staff concerns will be taken seriously, and investigated.'
 - 'An unequivocal guarantee that staff who raise concerns responsibly and reasonably will be protected against victimisation.'
 - *(Prohibition of] confidentiality "gagging" clauses in contracts of employment, and compromise agreements which seek to prevent the disclosure of information in the public interest.*

THE TRUST'S POLICY

- 26. 11 The policy currently in operation at the Royal Brompton Hospital and Harefield Hospital was approved by the Trust Board in September 1998, predating the issue of NHS guidelines by approximately 11 months. The introduction outlined the recommendations of the Nolan Report (48) and stated that the Trust Board's aim was to: 'encourage those who work for the Trust to recognise that they have a responsibility to raise genuine concerns about wrongdoing in the organisation by speaking up. Confidentiality is of course essential If they are raised effectively at an early stage, confidence in the Trust which is vital to our success and our future can be preserved.'
- 26.12 As a Board member said: 'We truly did believe we were in the vanguard of having a written policy, and we made it as constructive and sympathetic as we could, I would suggest that, not in every hospital, but in many other areas too, thinking is only just catching up with current legislation in the policy which we had in place I would seriously hope that the way the Trust has accepted this letter to "Private Eye" would encourage people to feel that in future they don't have to go straight to "Private Eye", they can use the policy'. Another Board member also commented: 'I think I can remember that we all felt really disappointed at the time [of the anonymous letter in 1999]. We were very disappointed because, not to be self-congratulatory, but we thought that we had gone to a great length to try and make what's a very difficult situation, to sort of call out when we think that there is something wrong. We have gone to extreme lengths to try and make that a user-friendly methodology that people can adopt. I think it had been well communicated within the Trust as well. So it was really disappointing. I can remember us having this conversation at the Board meeting. We were really disappointed that the policy appeared to have been patently ignored rather than just not used'.
- 26.13 The policy states that: '.... in the first instance, if possible, a member of staff should speak to his or her head of department and can ask for anonymity'. As a Board member said: 'We put in place, two or three years ago, a whistleblowing policy which quite deliberately set out to encourage people if they had concerns, or were aware of concerns, to raise them, ... and that could be done in a wholly confidential fashion and would be taken very seriously, and they could bring those to any member of the staff whom they chose'.

- 26.14 There is provision for matters unresolved at head of department level to be referred to the Director of Nursing and Quality, who has the responsibility for ensuring that staff concerns about wrongdoing are investigated either through an internal inquiry or an external investigation. An appendix lists four individuals at each hospital who are *'alternative contacts for members of staff'*. There is also a flow chart which shows that concerns raised under the procedure culminate either in an 'Internal Inquiry', reporting to the Trust Chairman, or in referral to an 'External Authority' (regulatory body, police). Disclosure to the media is regarded as 'an action of last resort'. Except for a reference to the right of staff to make a complaint on behalf of a patient to the NHS Ombudsman, there is no reference to any mechanism whereby staff can take concerns to an external body. The policy is also silent on the matter of protection against victimisation.
- 26.15 We identified a number of weaknesses in the Trust's 'Speaking Up' policy:
 - It is too long. Staff require a clear and concise document telling them what they should do, and what safeguards exist for them.
 - It confuses anonymity (where no one knows the identity of the whistleblower), with confidentiality (where the identity is known by one or more trusted person).
 - The way in which the flow chart is constructed, with no 'break points', implies that any concern will proceed almost inevitably to a formal inquiry, either internal or external. In our view, whistleblowing concerns are best resolved at an earlier stage wherever possible, as the prospect of a formal top-level investigation may deter many staff from expressing their concerns.
 - There is no provision for access to any external body to whom a disclosure may safely be made.

CONCLUSIONS

- 26.16 We do not know why the whistleblower whose actions gave rise to our Inquiries chose not to use the Trust's procedure on 'Speaking Up', but we consider that changes could be made which would make it more likely that concerned staff will use it in future.
- 26.17 In the light of the alarming nature of the allegations made about the RBH, and the fact that they were made to the media, we recognise that the Trust had a difficult judgement to

make in establishing the Hunter Review and our Inquiries. We question, however, whether the weaknesses we have identified in the content and structure of the Trust's policy contributed to making an independent inquiry unavoidable.

- 26.18 A policy that is amended in line with paragraph 26.15, and is promoted effectively to staff, may in the future allow a Trust time to make initial enquiries before deciding whether an independent inquiry is necessary. The Trust would then be justified, where concerns are raised anonymously with the media, in asking why they were not raised internally or with an approved external body under the policy, such as the DoH. It could ask why, if the concerns appeared legitimate, these had not been raised at the time by other staff instead of being assembled by one person to raise anonymously long after the event. A Trust could approach staff who had recently left to assess whether they felt there was anything in the allegations. It could approach relevant staff, stressing the protection afforded by the policy, saying that serious allegations had been made; in the absence of reassurance that the allegations were misconceived or unfounded, an independent inquiry might need to be established.
- 26.19 We believe that the Trust, by modifying its policy and procedure in the light of our comments and of the provisions of the 1998 circular, will be better placed to manage the concerns of any responsible whistleblower and deal with any shortcomings in patient care thus identified.

RECOMMENDATIONS

The Panel recommends that:

- 104. The Trust revises its policy on 'Speaking Up' in the light of the Panel's comments and to reflect more closely the provisions of circular HSC 1999/19.
- 105. The Trust consults staff in preparing a revised policy, to ensure that the wording is clear and helpful.
- 106. The Trust Board ensures that adequate arrangements have been made for all RBH staff to be fully briefed on the policy and of their own responsibilities for raising genuine concerns in a responsible and timely manner.

Part Five

CHILDREN WITH DOWN'S SYNDROME

27. SETTING THE CONTEXT

INTRODUCTION

- 27.1 Our terms of reference required us to address allegations, made both by individual parents and through the family groups, DHG and DSA, that children with Down's Syndrome had been discriminated against by the RBH in the provision of care and treatment. The Hunter Review (3) could find no evidence of discrimination from analysis of the statistical evidence. In the Panel's view this was the most serious charge levelled against the Trust, not only for the families who believe that their child's treatment might have been fundamentally compromised, but also for the clinicians whose clinical and ethical responsibilities were being questioned. In view of this the Panel took a great deal of time over the subject, sifting the evidence, learning from experts and reading the literature of the period under review.
- 27.2 The concerns of patients and relatives about care or treatment provided under the NHS are, understandably, largely based on subjective value judgements. The Panel recognises that practices and attitudes within health care, as in society, have changed during the period under review. We have been mindful of the need to identify objective standards against which those concerns could be judged in order to answer questions about what patients have a right to expect and about the duties of health professionals towards their patients. To this end we took into account contemporaneous law, ethical and policy standards in order to arrive at conclusions judged against standards which applied at the time.
- 27.3 The available standards derive from:
 - International human rights law, which defines what rights the individual has against public bodies.
 - Statute law (Acts of Parliament) and Common law (case law established by judges in the context of our Inquiry the law of tort), which are subject to change, or new interpretations, with the passage of time. Such law defines, for example, what is discrimination and whether it is illegal, what is negligence, what is assault and

battery (treating someone without his or her consent) and what is in a child's best interests.

- Clinical standards, which define the health professional's duties to the patient.
- Policy standards, such as the Patient's Charter.

DISCRIMINATION

- 27.4 The Panel's definition of discrimination is when a person is treated less favourably than another on arbitrary grounds – for example because of their race, age, gender, area of residence or disability. Within the context of the NHS, decisions about treatment and care should, as in other public services, be founded on the principle of equity and be based on individual need. Put simply, people with equal needs should be treated equally.
- 27.5 Our concern has centred on whether there was discrimination against children with Down's Syndrome during the period under review. This does not mean differential care and treatment arising from the condition of Down's Syndrome, but unfavourable treatment where the child's Down's Syndrome rather than the child's heart condition governs advice on treatment and options.
- 27.6 However, it is the case that approximately 50% of children with Down's Syndrome are born with a heart defect. These children account for around 80% of all children born with CAVSD. Whether or not it is possible to disentangle these two conditions when making decisions is critical to considering a charge of discrimination.
- 27.7 Recent GMC guidance (49) states that, while discrimination on the grounds of disability is not acceptable, 'the clinical team in determining priorities and the utilisation of the resources made available to them by the NHS is entitled to take into account the likely success of the treatment proposed It would be appropriate in assessing priorities for transplantation to take into account co-morbidities'.
- 27.8 The European Convention on Human Rights (see paragraph 27.13) provides the benchmark for deciding whether a decision has been discriminatory (50). Sometimes value judgements for example related to factors such as limited lifespan, inability to get the most out of life, or not being a burden upon others or upon society may be introduced into what a doctor may genuinely believe to be an expression of clinical judgement.

- 27.9 Halper (51) has said in discussing adults with renal failure that the usual answer given by physicians to a question about how a decision is made on whether and how to treat is that it is 'a clinical judgement found by applying sound medical criteria to the individual patient's case'. He identifies several major problems with this approach. One physician's judgement may not accord with that of another, and different physicians apparently rely on different key indicators or criteria. More significantly, 'differences in medical judgements also flow from what one physician called the "inherent subjectivity" of the process'. Few patients are identical to others that the physician may have seen. Judgements are therefore in a sense the consequence of 'a subjective best estimate' and, in Halper's assessment, often become 'entangled with clearly non-medical considerations'.
- 27.10 It is the duty of the professional not to allow personal views to affect judgement, and to guard against moral judgements masquerading as clinical ones. There are in our view three safeguards to ensure that such value judgements do not determine treatment:
 - Clinicians should be open and transparent in providing full information on the considerations and options in a manner which the parents, as full partners in decision making, can fully understand.
 - The right to a second opinion should be explicitly given to the parents.
 - The best interests of the child, not the interests of the parents or society, must be paramount.
- 27.11 Discrimination, though inherently unfair and contrary to natural justice, does not necessarily lead directly to decisions or actions that are prejudicial to the child's best interests. From the allegations put to us by parents, we have identified four potential categories of alleged discrimination, and these are discussed in detail in Chapter 29:
 - (a) Allegations of discrimination in the treatment offered.
 - (b) Allegations of discrimination in the treatment delivered.
 - (c) Allegations of discrimination in the provision of advice.
 - (d) Allegations of discrimination in doctors' attitudes.
- 27.12 We have already said that, all other things being equal, children with Down's Syndrome should be treated on the same basis as other children. With regard to categories (a) and (c), there should be no denial of treatment or failure to put choices to parents. With regard to

category (b), some parents might have sought treatment elsewhere before giving the RBH clinician the opportunity to review the position at a subsequent consultation. It is important to distinguish clinical from other considerations as, if the clinical reasoning was sound, discrimination in the provision of treatment should not normally be an issue. We acknowledge that this is far from easy, and that the individual doctor may not recognise that the views or advice being given to parents are anything other than objective and evidence-based. In a House of Commons debate on 4 July 2000 (52), the training of health service staff in the care of people with learning difficulties was described as being of paramount importance. We agree that more attention needs to be devoted to the complex issues and dilemmas involved.

RIGHTS, STANDARDS AND POLICIES

Human rights law

- 27.13 The UK government has been a signatory to the European Convention on Human Rights since the 1950s (50). Until October 2000 the Convention was enforceable through the European Court of Justice. In October 2000 it was fully incorporated into British law and is now enforceable by individuals against public bodies under the provisions of the Human Rights Act 1998 (53). Relevant provisions of the Convention state that: 'Everyone's right to life shall be protected by law No one shall be deprived of his right to life intentionally save in the execution of a sentence of a court following his conviction for a crime for which this penalty is provided by law' and 'The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour or other status'.
- 27.14 It is reasonable to regard the European Convention as a statement of generally accepted human rights provisions. However, judges have quite recently upheld decisions on resource grounds which it seems could not be justified in law under the 1998 Act. It remains to be seen what view the courts in this country will take, now the Convention can be directly enforced through legal proceedings, of direct or *de facto* refusal on resource grounds to take action that would prolong life.
- 27.15 In 1989 the United Nations issued its Convention on the Rights of the Child (54). This was formally recognised in English Law under the Children Act 1989 (55), the relevant section

of which came into effect in 1991. In summary, the principal provisions under the Convention are that children have the right:

- To be protected from harm.
- To take an active part in society.
- To express their views, which should be given due weight in accordance with their age and maturity.
- To services which meet their needs.
- 27.16 The Panel identified three rights in relation to the delivery of health care to children against which to determine whether appropriate access had been offered:
 - Putting the interests of the child first and foremost (before those of the parents or of managerial priorities).
 - Everyone has the right to life (a well-established principle of international law).
 - No individual is to be treated less favourably than any other because of his or her disability.

Other Statute law

- 27.17 In addition to bringing the United Nations Convention within the ambit of English law, the Children Act 1989 includes the following principles for providing services to children:
 - The child's welfare is paramount.
 - Each child has a right to be treated as an individual.
 - The child's views should be taken into account where major decisions are to be made about his or her future.
- 27.18 With regard to the principle that individuals should not be treated less favourably than others because of their disability, the Disability Discrimination Act 1995 (56) applies to all service providers. Section 19 defines disability as being: 'a physical or mental impairment which has a substantial and long term effect on [a person's] ability to carry out normal day-to-day activities'. It also states that: 'it is unlawful for a provider of services to discriminate against a disabled person in refusing to provide, or deliberately not providing, to the disabled person any service which he provides, or is prepared to provide,

to members of the public' and 'a provider of services discriminates against a disabled person if for a reason which relates to the person's disability, he treats him less favourably than he treats or would treat others to whom that reason does not or would not apply'.

Common law

- 27.19 We have not thought it necessary to search for case law relevant to our work, given the administrative status of our Inquiry. Furthermore, the non-adversarial nature of our proceedings, the passage of time since many of the events at issue, and our lack of legal powers might also have made it unsafe for us to attempt to deploy quasi-legal arguments or precedent.
- 27.20 English case law defines what is negligent, the most significant case being *Bolam v Friern Barnet Hospital Management Committee 1957* (57). The 'Bolam' standard, or test, defines not what is best or even good practice, but whether there has been care of a standard which a reasonable body of similarly qualified people would consider acceptable. A patient cannot sue successfully for negligence if the court decides that the health professional concerned provided care that met that standard. This means that the care is of a reasonably good, but not necessarily optimal or excellent, standard. To illustrate the point, in respect of providing information for the purpose of consent to treatment, the 'Bolam' standard defines not what the best doctor would tell the patient, or what would the patient like to have been told, but what a reasonable body of similarly qualified doctors would tell a patient in the circumstances. It is therefore based on the standard of the profession in question.
- 27.21 While we might conclude that a particular action or practice at the RBH met that standard, that has not prevented the Panel from recommending a higher or different standard. After all, one of the main purposes of an Inquiry such as ours is to enable the NHS to learn from the experience or perception of users of the service.

Standards

27.22 It is a well-established and universally recognised ethical principle of clinical practice that the first duty of a doctor – indeed of any health professional – is to the patient. This is

enshrined in the Hippocratic Oath, which states that 'I will prescribe regime for the good of my patients according to my ability and judgement and never do harm to anyone'.

- 27.23 The clinician's principal duties of care have been defined by Chantler and Doyal (58) as being:
 - To protect the life and health of patients to an acceptable standard. *'Clinical practice must always be focused on the therapeutic benefits which it can potentially offer and any harm caused in the process must always be favourably balanced with such benefit.'*
 - To respect the autonomy of patients. 'It is they and not their clinician nor anyone else who have the right to make significant choices about their lives to the extent that this is physically and intellectually possible.'
- 27.24 Up to 1995 the GMC issued a series of pamphlets, known as the 'Blue Books', which governed the conduct, practice and discipline of the medical profession. Their new booklet *Good Medical Practice* (6) states that: '*Patients are entitled to good standards of practice and care from their doctors. Essential elements of this are professional competence, good relationships with patients and colleagues and observance of professional ethical obligations'.*
- 27.25 The new GMC booklet sets out the duties expected of a registered medical practitioner. They include:
 - Keeping clear, accurate and contemporaneous patient records which report clinical findings, decisions made and information given to patients.
 - Taking part in regular and systematic audit.
 - Establishing trust with patients by listening to and respecting their views, treating them politely and considerately, giving them the information they request or need in a way they can understand, and respecting their right to be fully involved in decisions about their care.
 - Not allowing the patient's social status or perceived economic worth to prejudice treatment.

- 27.26 In 1997 the Royal College of Paediatrics and Child Health issued *Withholding or Withdrawing Life Saving Treatment in Children: A Framework for Practice* (59), which it commended to paediatricians and which states that: '*fundamental to the issue has to be that the child's best interests are served*'. Five situations were described where withholding or withdrawal of curative medical treatment might be considered:
 - The brain dead child, where the criteria for this are agreed by two practitioners.
 - The permanent vegetative state, where the child is reliant on others for all care and does not react or relate with the outside world.
 - The 'no chance' situation, where life-sustaining treatment simply delays death without significant alleviation of suffering.
 - The 'no purpose' situation, where the degree of impairment following survival with treatment will be so great that it is unreasonable to expect the child to bear it.
 - The 'unbearable' situation, where the child and/or the family feel that in the face of progressive and irreversible illness further treatment is more than can be borne.
- 27.27 Clinical governance was introduced formally into all NHS authorities in April 1999. It is a process whereby high quality care is provided, standards continuously improve, excellence in clinical care is encouraged and clear accountability is observed. The standards that it demands relate to the management, organisation and performance of clinical care, communication with patients and avoidance of risk generally. Here again, while the formal framework is new, its provisions are a re-statement of well-established tenets of good practice.

Policies and charters

- 27.28 Delivery of care by the NHS has been governed over the years by policy and other guidance too extensive to describe here. *The Patient's Charter* (40) includes the following rights and standards of service that users of the NHS could expect to receive:
 - That users are entitled to receive health care on the basis of clinical need, not on any other factor.
 - That the NHS would make it easy for everyone to use its services.
 - That any proposed treatment, including any risks involved in that treatment and any alternatives, are clearly explained before deciding whether to agree to it.

- That any complaint will be investigated and a full written reply will be received within four weeks.
- 27.29 The Charter's provisions with regard to children were explained and amplified in 1996 in a companion booklet *Services for Children and Young People* (60). It states, among other things, that: 'You and your child can expect to take part in any discussions and decisions about your child's treatment and care' and 'If you and your child wish, you can expect to stay in the hospital with him or her and be encouraged to take part in the care' and 'Before your child is discharged from hospital, you can expect a decision to be made about how to meet any needs he or she may continue to have at home You and your child will be involved in making these decisions and will be kept up to date with information at all stages'.
- 27.30 The Panel also reviewed A Guide to the Development of Children's Palliative Care Services (61), produced by a Joint Working Party of the Association for Children with Life-threatening or Terminal Conditions and their Families (ACT) and the Royal College of Paediatrics and Child Health. This was concerned with the whole range of needs and services, both statutory and voluntary, relating to palliative care and support for children with life-limiting conditions. Many children with congenital heart disease potentially fall within this category. The standards particularly relevant to this Inquiry are: 'Each child and family should have a care plan, drawing together the provision of all components of care' and 'Every child and family should expect to be supported in the day-by-day management of their child's physical and emotional symptoms [and] receive help in meeting the needs of parents and siblings, both during the child's illness and during death and bereavement'. The Third Edition of the ACT Charter (62), published in 1998, also proposes a number of key principles. One of these calls for parents to be 'acknowledged as the primary carers and centrally involved as partners in all care and decisions involving their child'.
- 27.31 Although publication of these standards and rights occurred after many of the cases that we examined, they nevertheless reflect in clear, unambiguous terms what was good medical practice during the period under review. They also underpin many of our recommendations about how services at the RBH should be improved for the benefit of children and their families in future.

RATIONING

- 27.32 The rights and standards described above concern issues of access and quality in health care delivery. The nature and volume of care is, however, driven by the resources available to meet competing demands. These include financial resources, availability of specialised staff or, in the case of heart transplantation, the supply of donor organs. Once the nature and volume of service to be provided is determined, decisions have to be made about how and to whom the service should be delivered. Decision making in the allocation of resources between competing NHS services is a highly contentious and politically charged process.
- 27.33 A key issue raised by parents, and the DHG and the DSA, was alleged discrimination at the RBH both in clinical decisions and in attitudes regarding the treatment and care of children with Down's Syndrome. In order to be able to form views about these allegations and the responses from the staff concerned, which are discussed in Chapter 29, the Panel needed to understand the differences between rationing, priority setting and discrimination in the allocation of finite resources.
- 27.34 The starting point for treatment in the NHS, ever since it came into being in 1948, is that access to services should be based on need rather than the ability to pay or any other criteria. Need can be defined as the ability to benefit, whether the care or treatment in question is curative or palliative. Benefit usually takes the form either of an extension to life (or the avoidance of death) or of gains in the quality of life. A person for whom there is no effective treatment or intervention could be said, in relation to NHS provision, not to be 'in need'. Since the mid 1990s, it has increasingly been acknowledged, by politicians, managers and the professions, that the totality of need for health care cannot be met. That being so, choices have to be made, and some patients will be denied the treatment they require.
- 27.35 Rationing decisions are made at every level in the NHS. Nationally, decisions are made between services or programmes. For example, ministers may decide to divert or allocate resources for expanding heart services or, on the basis of expert advice, to restrict prescribing of a particular medication. Locally, commissioning authorities have to decide where and to what extent they purchase NHS care for the local population, for example whether and to whom *in vitro* fertilisation should be offered, although some of these

decisions are informed by priorities determined at national level. NHS providers are faced with the difficulty not only of deciding where to develop, or even reduce, services but how to control clinical activity. This is one of the reasons why we have been quite clear that the question of resources cannot be separated from that of the volume or standard of care delivered. Finally, at an individual level, there are decisions to be made about treatment options and priorities between patients.

- 27.36 We are not aware of any consensus on how to define rationing, which is concerned with the allocation of limited resources and making choices between service areas or patients. (However, as we discuss earlier in this Chapter, this must be done in a way that avoids arbitrary discrimination.) In addition, although charters and policies set out what users of the NHS are entitled to expect, they are not legally enforceable nor do they confer an absolute entitlement. How, then, should rationing decisions be made? We have noted work done in Sweden to establish an ethical platform for that country's health service (63), and which proposed the following principles upon which priorities should be based:
 - The principle of human dignity: all people are equal in dignity, regardless of personal characteristics and functions in society.
 - The principle of need and solidarity: resources should be committed to the person or activity most in need of them.
 - The principle of cost-efficiency: when choosing between different fields of activity or measures, a reasonable relation between cost and effect, measured in improved health and improved quality of life, should be aimed for.
- 27.37 Daniels and Sabin (64) have suggested, in the context of health care in the United States, that systems for making decisions about rationing should be characterised by or measured in terms of:
 - Openness and transparency.
 - Use of criteria or clear rules that are seen as fair and reasonable.
 - Provision for appeal.
 - Regulation of the process.
- 27.38 Those making decisions on treatment priorities should be expected to demonstrate accountability for reasonableness in their decisions. Decision making by individual

clinicians should be guided by protocols so that decisions are transparent and are seen to be rational, consistent and evidence-based. Without such safeguards, the risk remains that clinicians may be perceived to be unduly influenced by subjective views or value judgements. We recognise, however, that medicine is as much an art as well as it is a science. Doctors must be able to use their training and clinical judgement, interpret the clinical features, and be free to draw upon relevant literature or other evidence in deciding what course of treatment to recommend. Protocols that are too restrictive would not necessarily serve the best interests of the individual child.

RECOMMENDATIONS

The Panel recommends that:

- 107. The Department of Health ensures that the training of all health professionals should include the process and issues involved in taking decisions on rationing and priorities, and how to carry out their practice in a way that is non-discriminatory. Discrimination should be defined as the unfair or unreasonable introduction into the decision-making process of factors which differentiate on subjective or value-driven grounds between people with like needs and which do not serve the best interests of the individual concerned.
- 108. The Trust invites the Department of Health, with relevant professional and consumer bodies, to draw up guiding principles and protocols for taking decisions on priorities in allocating resources and delivering health care at each level of the service.

28. DEVELOPMENTS IN CLINICAL PRACTICE, COMMUNICATION AND ATTITUDES

INTRODUCTION

28.1 Before we consider in Chapter 29 whether there was any discrimination at the RBH against children with Down's Syndrome, we outline in this Chapter, with illustrative references from medical, legal and wider literature, changes in attitudes generally towards children with Down's Syndrome shortly before and during the period covered by our Inquiry and their implications for clinical practice generally. In the 1960s and 1970s negative attitudes towards people with disabilities of all kinds were common, and individuals with Down's Syndrome were often abandoned by their parents in the maternity hospital and often lived in institutions particularly in their later years. Since then there have been marked changes in attitude by both the general public and health professionals towards the care of individuals with learning disability, and towards Down's Syndrome in particular.

REVIEW OF THE LITERATURE

Attitudes and approaches

28.2 Writing about Down's Syndrome in 1977 in one of the standard American neonatal textbooks, Diseases of the Newborn (65), F Clarke Fraser said: 'Once the diagnosis [of Down's Syndrome] has been made with a fair degree of assurance, someone will almost surely suggest that the problem be solved by euthanasia. The suggestion may come from the obstetrician, from a nurse, from a member of the family who has been appraised of the situation, or it may occur to the paediatrician himself. Undeniably, euthanasia was resorted to, and not infrequently, in the past. It obviously presents an easy solution to what promises to be a long drawn-out, difficult situation. But the paediatrician must never allow himself to fall into this trap. Aside from the ethical considerations involved, euthanasia contravenes the laws of the state and makes the offending physician liable to severe penalties'.

- 28.3 There have been high profile legal cases in the United States, for example, the baby Doe case, and in the UK, for example, the Dr Leonard Arthur case (66) and the Hammersmith Hospital case, about withholding of treatment or allowing to die in children with Down's Syndrome. There have been significant changes in the Law on both sides of the Atlantic.
- 28.4 Even today the vast majority of women diagnosed in early pregnancy as having a foetus with Down's Syndrome opt for termination of pregnancy. Most hospitals offer screening programmes which may include blood tests, ultrasound examination, chorionic villous sampling or amniocentesis specifically in order to detect and allow the abortion of Down's Syndrome babies. In Southampton, for example, all pregnant women aged 35 years or more (who are at increased risk for having a baby with Down's Syndrome) are offered amniocentesis. Of those accepting the test in 1999, 35 proved positive for Trisomy 21. Only three women elected to continue the pregnancy and 32 chose to have an abortion.
- 28.5 In the United States a 1985 study (67) of 36 patients with complete atrio ventricular canal defect, 28 with Down's Syndrome, concluded that: *'in spite of the severity of CAVC some children with Down's Syndrome and this heart condition are being denied standard cardiac care by the process of late referral'.*
- 28.6 In 1990 in Ireland, a team from Dublin wrote that: 'A relatively conservative approach has been adopted with regard to surgery, based on the shorter natural expectation of life in Down's Syndrome, the complexity of many of the cardiac lesions involved and the recognition of the frequency of early intellectual deterioration in Down's [Syndrome] patients' (68).
- 28.7 This approach was not, however universal. For example, analysis of the infants registered in the Baltimore-Washington Infant Study (69), a regional case-control study of congenital cardiovascular malformations, which compared the age at cardiac diagnosis, the timing of cardiac surgery, and outcome after one year in 160 infants with Down's Syndrome and 540 infants with the same cardiac diagnoses but without chromosomal or other extra-cardiac anomalies, concluded: *'that for defects of comparable severity, the pattern of cardiac care in the Baltimore-Washington DC area for infants with Down's Syndrome is timely and comparable to care for infants with isolated cardiac malformations'.*
- 28.8 The standard British paediatric textbook (70) includes the following paragraph: 'Some physicians and surgeons have reservations about operating on cardiac defects in children with Down's Syndrome. Local facilities and circumstances must of course be considered, but if treatment is available it seems illogical to manage children with Down's Syndrome differently as they can look forward to many years of life. If they are physically incapacitated their quality of life will be diminished and the burden on those looking after them increased'.
- 28.9 More recently a review of changing attitudes was published in Sweden (71). This review describes the evaluation, decision making, and care of children with CAVSD by retrospective study of 136 consecutive cases from 1970 to 1996, of whom 115 (85%) had Down's Syndrome. Denial of surgery without obvious medical reasons, parental refusal of offered surgery, and institutional care of the children were all more common in the early years. Improved results in later years encouraged surgical treatment for all these patients, but more liberal attitudes towards patients with Down's Syndrome preceded the improved results. The use of echocardiography as a screening method for all newborns with Down's Syndrome made it possible to plan for correction within the first few months of life. The review concluded that changing attitudes in society and widespread use of echocardiography have significantly improved the management of children with a CAVSD and Down's Syndrome.

Surgical risk and survival

28.10 Deciding whether or not to attempt surgical correction of CAVSD in infants with Down's Syndrome at a time when surgical risk of early mortality was high was not straightforward. Before 1990, death rates within 30 days of operation or leaving hospital were universally high, averaging more than 20% (including the centres with the best outcomes that were publishing their results). A paper published in *The Lancet* in 1985 (72) by Bull and colleagues at the RBH drew attention to the fact that actuarial survival of the relatively asymptomatic child with CAVSD for the first 20 years of life was at least as good, if not better, with medical treatment rather than surgery. This paper, and subsequent papers authored by RBH clinicians, are discussed in more detail in Chapter 29. Even after Weintraub *et al* (73) reported results in 1990 showing that mortality had fallen to 6%, few centres were able to reproduce these results.

- 28.11 In addition to concerns about the early 30 day mortality there were also concerns about the longer-term outcomes of the operations. In 1992, an American team reported (74) that: 'From 1981 through June 1989, 59 children had surgery for a complete atrio ventricular (AV) canal defect at Oregon Health Sciences University. We compared the morbidity, mortality, and hemodynamic status of 47 children with and 12 without Down's Syndrome through review of operative, clinical, and cardiac catheterisation records. Overall, ten children with Down's Syndrome have died, nine from cardiac cause within 90 days of surgery. The two year survival of these children was $77 \pm 6\%$ as compared to 100% in children without Down's Syndrome (p = 0.08). Early age at surgery, the surgical anatomy of the AV canal, and gender had no significant effect on survival. Before surgery, the hemodynamic status of Down's Syndrome and non-Down's Syndrome children did not differ; in a small group of post-operative catheterisation, right heart pressures and pulmonary vascular resistance remained significantly higher in the Down's Syndrome as compared to non-Down's Syndrome children. These trends to higher mortality and poorer post-operative hemodynamics in children with Down's Syndrome may necessitate closer follow up if confirmed in other cohorts'. This statement in a textbook published in 1993 would have been based on information from the period when surgical mortality was high when there were also studies showing increased complication rates and poorer long term results for individuals with Down's Syndrome surviving cardiac surgery (75, 76).
- 28.12 Similar concerns about the longer term results following closure of ventricular septal defect were highlighted in a paper from Japan showing that post-operative patients with Down's Syndrome had higher pulmonary resistance and poorer left ventricular performance than a comparable non-Down's Syndrome group (77). They stressed the importance of early surgery.
- 28.13 Other factors influencing the decision-making process included evidence from the anaesthetic literature (78) that: 'Surgical correction of congenital heart disease in children with Trisomy 21 is associated with increased morbidity (post-operative atalectasis and pneumonia) and mortality, presumably due to increased susceptibility to recurrent infections, and an increased incidence of co-existing pulmonary hypertension'.

Quality added life years

- 28.14 From 1985 through to the early 1990s there were a number of articles documenting the association of Down's Syndrome and Alzheimer's disease based on pathological findings, on the location of the gene for beta amyloid protein precursor the protein found to be present in the Alzheimer plaques and vascular lesions found to lie on chromosome 21, and on clinical studies of dementia occurring earlier in individuals with Down's Syndrome.
- 28.15 These findings coincided with an intense drive in the NHS for doctors to make best use of scarce resources and the concentration by health managers and finance staff on 'QALYs' (quality added life years). It is perhaps not altogether surprising that all these complex issues became muddled. In the experience of one of the clinical members of the Panel, it was not at all unusual at that time for physicians, surgeons and administrators to be discussing the cost-effectiveness of treatment and to be questioning the use of resources in treating patients who would not derive as much benefit as others from treatment.
- 28.16 A 'snapshot' of the situation in the UK during the period under review is provided by the population study by Brookes and Alberman (79), which set out to assess the risk of early mortality and the quality of health of a cohort of 5-year-old children with Down's Syndrome and to provide information on prognosis. All 100 live born infants with a cytogenetic diagnosis of Trisomy 21 or related karyotype born in 1989 and diagnosed in the South East Thames and Oxford Regional Health Authorities were studied retrospectively in 1994.
- 28.17 Eighteen of the sample of 100 had died in the first three years, and seven were reported as adopted. Fifty six mothers were interviewed, including five mothers of children who had died. High rates of associated congenital defects were reported. The most common were congenital heart defects, which were reported for 29 of the 69 children for whom health information was available, and which were certified as the underlying cause of death of 12 and required surgery in 11. At least five children had had gastrointestinal atresia or other gut blockage, most presenting at birth but one case occurring at three years of age, and these had necessitated a colostomy in two cases. Leukaemia had occurred in two children, both of whom had died. As expected, mothers also reported high rates of defects of hearing (often treated with grommets) and of vision, and frequent severe infections. Information of this nature, as well as that regarding the more positive aspects of Down's

Syndrome, should be made available to those counselling parents considering the offer of diagnostic tests.

29. ALLEGED DISCRIMINATION AGAINST CHILDREN WITH DOWN'S SYNDROME

INTRODUCTION

- 29.1 We were asked to consider allegations that discriminatory attitudes by doctors to children with Down's Syndrome might have affected their treatment. Specifically, we were asked to look into concerns expressed by some families, to find out what caused these concerns, and to establish whether there are any common themes to the families' concerns. As stated in our terms of reference, this included addressing attitudes towards and communications with children with Down's Syndrome and their families.
- 29.2 We examined evidence from 14 families whose children had Down's Syndrome and cardiac abnormalities, who had attended the RBH during the period 1987-1999. As we explain in Chapter 1, this was a self-selected group of parents who had already been in contact either with the RBH or the Down's Heart Group (DHG) or the Down's Syndrome Association (DSA). They wanted to meet us to discuss their concerns in detail and to have their cases reviewed by our independent paediatric cardiologists on a confidential basis. There is therefore no evidence whether or not these concerns are representative of families with a child having Down's Syndrome who attended the RBH during that period.
- 29.3 There was also a group presentation organised by the DHG, and we met 13 families. Four families wanted to have their cases considered in detail, and these are included in the 14 referred to above that we were able to examine individually. We therefore heard evidence from a total of 23 families.
- 29.4 We found this aspect of our Inquiry the most taxing. We were conscious of the seriousness of these allegations and the need to consider carefully all the evidence given to us. This was not easy. We had to distil and sift evidence from many contradictory sources. First, there were the undocumented allegations of the parents which, in order to preserve the parents' confidentiality as complainants, could only be put to the doctors on an anonymous and general basis, and which the doctors rejected; second, the contemporaneous literature, bearing in mind that the views expressed in published papers did not necessarily translate

into practice; third, the RBH medical records of cases seen individually; and finally, the outcomes which, again, were not necessarily conclusive as some were the result of children being treated elsewhere.

CONTEXT

- 29.5 One of the main allegations considered by the Panel was by parents of children with Down's Syndrome who considered that their children were denied access to surgery to correct an atrio ventricular septal defect (AVSD) during the period under review. Statistics supplied by the Medical Director of the RBH show that throughout 1991-1999 approximately 40-60 children with Down's Syndrome attended the RBH each year, amounting to over 600 cases during the period under review. Thus, the cases heard by the Panel in respect of Down's Syndrome represented approximately 4% of cases of children with Down's Syndrome and less than 0.2% of all cases treated at the RBH and Harefield Hospitals during this period. The majority of the allegations relate to decisions made prior to 1996, not all of which were considered by the Panel on an individual basis.
- 29.6 At the beginning of the 1980s the risks of the operation for repair of complete atrio ventricular septal defect (CAVSD) were high and many children across the UK were not operated on at all. However, by the middle of the decade the risks fell to levels that were considered reasonable in some centres which were offering surgery to children with CAVSD (most of whom would have had Down's Syndrome), as Table 2 shows. It is also clear from the Table that the total number of operations rose steadily in the UK between 1985 and 1990 and more dramatically between 1990 and 1992. A similar pattern is demonstrated by the RBH figures from 1990 onwards.
- 29.7 Between 1991 and 1998/99 the average number of children with Down's Syndrome who had heart operations at RBH was 22 (as compared to an 'expected value' of 18, based on the RBH undertaking some 10% of paediatric cardiac surgery nationally). In only one year, 1996/97, when 15 operations on Down's Syndrome children were undertaken, were fewer than 18 operations undertaken. The data from the Hunter Review indicate that the number of operations on children with CAVSD varied during this period from 8 in 1991 and in 1992, to 18 in 1997/98, with 4 in 1996/97. 75% of the children with CAVSD operated on at the RBH during this period had Down's Syndrome.

- 29.8 Comparison of these data with the number of operations for CAVSD and their mortality rates reported to the UK National Cardiac Surgery Registry (UKNCSR) is difficult because of the lack of a clear case definition of CAVSD and of indices of case severity other than age.
- 29.9 Atrio ventricular septal defects comprise about 5-7% of all cases of congenital heart disease. They are also termed AVSDs and endocardial Kushings defect. They comprise a hole in the top part of the heart (an atrial septal defect ASD) a hole in the bottom part of the heart (a ventricular septal defect VSD) and have a common valve between the top and bottom parts of the heart. There is considerable variation in the structure of the heart in this condition. Any of the features outlined above can be absent or present. For example there may only be an ASD without a VSD (ostium primum ASD). There may be a VSD without an ASD. The atrio ventricular valve may be severely malformed with a severe amount of leak. Various of the leaflets may be absent or rudimentary and in some cases there may even be two orifices on the left side. In some cases, in particular where the condition occurs in children without Down's Syndrome, one or other of the ventricles may be very small (unbalanced ventricles). Lastly, AVSDs can occur in conjunction with other conditions such as Fallot's Tetralogy.
- 29.10 Atrio ventricular septal defect is therefore an umbrella term, which includes a wide range of heart defects of variable severity. These variations are often highly important for surgery and may be risk factors for adverse outcome. To allow a valid comparison of different centres, it is therefore essential that like is compared with like. This is usually not the case and inclusion criteria often vary widely. For sensible comparison of surgical results the complexity of the lesions must also be taken in account.
- 29.11 The UKNCSR return forms contain only two sections to enter AVSD lesions: these are partial AV canal (which equates to ostium primum ASD) and complete AV canal (which is CAVSD). The definition of AVSD used by the Hunter Review used recently published 'benchmark' criteria, which were applied retrospectively to cases operated on at the RBH. The clinical audit office at the hospital has independently sought and identified all cases of AVSD operated on at the hospital during this period. In addition, Drs Al Hay and Shinebourne undertook a retrospective review of surgery on cases of AVSD operated on at the RBH between January 1986 and December 1998 (as yet unpublished).

- 29.12 Each of these have used different criteria for inclusion and therefore case numbers and severity have varied. Drs Al Hay and Shinebourne, for instance, included all children in whom AVSD was part of the diagnosis, from the most simple to the most complex, some of which would not have been included as AVSD in the annual returns because of other associated lesions such as Fallot's tetralogy such cases with AVSD and Fallot's would instead have been coded as the latter.
- 29.13 The total number of cases of AVSD operated on at the RBH between 1987 and 1998/99 varies according to the criteria of inclusion from 139 in the Al Hay and Shinebourne report to 118 in the Hunter report and 114 in the Clinical Audit Office Review.
- 29.14 To be informative, comparisons of outcome between institutions and over time, must be based on comparing 'like with like'. The difficulties created by a lack of a clear case definition for AVSD during this period highlight the important need for agreed definitions of case and complexity in the future.

Table 2: The annual number of operations for repair of complete atrio ventricular septal defect and the early mortality in the UK as reported to the Society of Thoracic and Cardiovascular Surgeons

		Infants under 1 year				Over 1 year		
		No	(Deaths)	Mortality*	No	(Deaths)	Mortality	
				%			%	
	1985	17	(8)	47.1%	39	(9)	23%	
	1986	36	(9)	25%	74	(14)	18.9%	
	1987	39	(11)	28%	39	(3)	7.7%	
	1988	56	(11)	19%	43	(8)	18.6%	
	1989	64	(16)	25%	40	(8)	20%	
	1990	61	(9)	14.8%	52	(3)	5.8%	
	1991	120	(20)	16.7%	81	(8)	9.9%	
	1992	123	(16)	13%	61	(5)	8.2%	
	1993	92	(12)	13%	58	(1)	1.7%	
	1994	92	(11)	12%	32	(3)	9.4%	
	1995	105	(15)	14.3%	24	(0)		
	1996	93	(5)	5.4%	30	(0)		
	1997	78	(5)	6.4%	29	(1)	3.4%	
*	Mortality	Mortality rate is death in hospital and within 30 days of operation (i.e. it does not include later death).						

OUR APPROACH

- 29.15 We followed the procedures described in Chapter 2 to examine the concerns and allegations. Our approach can be summarised as follows:
 - Interviews with 14 individual families. Clinical and non-clinical issues arising from the questionnaire that the family had completed were summarised and discussed at the Panel hearing.
 - Review of the medical records of these patients.
 - Presentation by 13 families from the DHG (four of whom were also included in the 14 families seen individually).
 - Interviews with representatives of the DHG, the DSA and Heartline.
 - Meetings with doctors, including paediatric cardiologists, paediatric cardiac surgeons, intensivists, nurses and a paediatrician.
 - Interviews with non-clinical experts including two ethicists, a social researcher, a Disability Rights Commissioner, and an assistant director of a health advisory body specialising in services for people with learning disabilities.
 - Review of contemporaneous literature both from textbooks and original articles in peer-reviewed medical, surgical and ethical journals.
 - Analysis by the Panel and Secretariat, bringing to bear our own experience from medical, legal, ethics, managerial, and disability sectors.
- 29.16 Much of the information obtained by us related to attitudes and communications what was allegedly said and how it was perceived rather than to statistics or other 'hard' information. It was therefore largely qualitative in substance. While patients' records provided valuable information about medical decisions and the context of treatment plans, they are incomplete for our purposes. They do not, for example, record in sufficient detail the discussions with parents or any feelings or attitudes that might have been felt or expressed at the time. Such information would have helped us to make a more informed assessment of the allegations of discriminatory communication. Most doctors did not recollect the alleged statements or even the context in which they might have been made. While we recognised and respected the parents' strength of feeling and were impressed by the intensity with which they expressed their recollections, fairness to the doctors meant that such recollections had to be approached with a degree of caution, given the

considerable lapse of time; and we were also aware that, for the doctors, a particular conversation would have been one of hundreds.

- 29.17 Words have many meanings, and what one person intended them to convey can be construed quite differently by another party. This is especially the case when a person is in crisis or shock and, because of that, might be unable to retain all that is being said or understand the complexity of the situation being described. We heard a great deal of oral evidence from parents, particularly in relation to allegations of negative attitudes and comments made to them about their child's care, which conveyed a quite different impression from that given to us by doctors. This led us to conclude that failure sufficiently to record what was said, particularly where there was concern or anxiety regarding the progress or direction of care, is a serious weakness. We doubt that the RBH doctors were unique in this respect.
- 29.18 The subject matter that we dealt with was contentious and we were conscious of the need to be fair to all parties. It was important that, in reaching conclusions about serious allegations, we did not damage the trust of people with Down's Syndrome, their families and future patients who are referred to health professionals at RBH and elsewhere, but we were also conscious of the need to be fair to the doctors.
- 29.19 Among the nine families who did not want to have their cases examined on an individual basis, some were concerned to maintain anonymity lest disclosure might in some way impact on the quality of care offered to their children in the future. We should make it clear that we have seen no evidence to suggest that this concern is justified. As a result, the medical records of these children could not be scrutinised, although some of the families supplied us with selected extracts, and we could not put the allegations to doctors, except as generalised concerns. This meant that it was impossible for us even to attempt to reach a view on whether discrimination occurred in these particular cases.
- 29.20 We explained earlier the benefits and limitations of adopting a non-adversarial approach in our investigations. The promise of confidentiality given to parents and doctors, the informality with which both parties were encouraged to express their concerns to us, the lapse of time and the fact that allegations could only be put to doctors as generalised concerns, has made it impossible for us to test fairly, or to reach firm conclusions about the specific allegations of discriminatory remarks or attitudes made by some doctors in

relation to children with Down's Syndrome. What we are able to conclude, however, is that there were occasions on which a serious breakdown in communication and trust occurred between parents of children with Down's Syndrome and doctors. We are not able to set out in our report the specific details of what has been alleged to us because the allegations have not been subjected to cross examination. In order to do this, a fact finding inquiry would need to be established in which confidentiality of all parties would be waived.

THE ALLEGATIONS IN OUTLINE

- 29.21 Some of the parents alleged that their child was not offered the option to have corrective surgery for CAVSD and other heart abnormalities, or that they were '*steered away*' from requesting it. These parents alleged that, when they were seen with their child by consultants at the RBH, they were given strong clinical reasons for not opting for surgery. They alleged that such advice was often supported by other reasons, usually concerning the child's poor quality of life in the future even if the surgery itself was successful, which suggested strongly that medical management was the best way forward for these children. Some of the parents also contend that the doctors' attitude and approach was insensitive or discriminatory.
- 29.22 The DHG and the DSA also made more general allegations, supported in their view by information which they had assembled, that doctors at RBH had discriminated against children with Down's Syndrome between 1987 and 1999.
- 29.23 Some of the parents believe that their child might have benefited from corrective surgery at the RBH but did not receive it because of discrimination. Six of the parents of children whose cases were individually reviewed by the Panel went elsewhere for an operation, generally because they had heard allegations of discrimination about RBH either from other parents, or from the DSA or DHG, or through the media. The debate was opened up following the publication of the 1985 *Lancet* paper (see paragraph 28.10), co-authored by three doctors from the Department of Paediatric Cardiology at the RBH (72), which suggested that the parents of a child with Down's Syndrome should be counselled differently from those with a chromosomally normal child with an atrioventricular canal defect. This paper caused the parents' groups and later some_parents themselves to feel anxious about possible discrimination against Down's Syndrome children. We do not

know whether those children who went elsewhere would have been operated on had they remained with the RBH. For two of the three children initially seen in the 1980s who were treated medically, surgery was no longer possible in the 1990s when risks fell because they had by then developed pulmonary vascular disease.

29.24 The allegations can be divided broadly into four categories. Our findings in respect of each of them are set out later in this Chapter.

a) Allegations of discrimination in the treatment offered

Half of the 14 families we saw individually and almost all of the families in the group presentation felt that the treatment they had been offered was discriminatory.

b) Allegations of discrimination in the treatment delivered

Fewer families felt that the treatment delivered was discriminatory.

c) Allegations of discrimination in the provision of advice

Almost all believed that misleading or inappropriate advice had been given in their child's case, which affected the delivery of treatment. Within this category, the groups' representatives felt that the risks of operation had sometimes been overstated to deter parents from consenting to surgery and, further, they alleged that the prognoses for children being medically managed were not accurate. For example, they felt that the gradual deterioration of these children as they get older and suffer from the increasing effects of pulmonary vascular disease had been minimised. Two families said they remembered being told that their child might develop Alzheimer's disease prematurely if he or she did survive but not that the alternative of death from heart failure could be slow and distressing.

d) Allegations of discrimination in doctors' attitudes

Most also felt that communication in their child's case had been either inappropriate or insensitive. The remarks attributed to some hospital staff were seen by their parents as implying that children with Down's Syndrome are of less value to society than other children and were less suitable recipients of scant NHS resources.

THE CLINICIANS' RESPONSE

- 29.25 When we put the allegations to the RBH doctors, which we could only do in generalised form, all of them denied that they had ever made the remarks complained of or had in any way discriminated against children with Down's Syndrome. Indeed, they pointed out that, until the late 1980s, very high mortality rates from surgery for correction of AVSD were being reported. It would, in their opinion, have been irresponsible to recommend high-risk surgery, carrying a mortality risk possibly in excess of 30%, for a child who was relatively symptom-free and feeling well. They argued that, if a child could live reasonably well until their twenties without surgery, this was surely what most parents would have wanted. At most, but not all, centres such as the RBH, medical management rather than surgery was commonly recommended for asymptomatic children with Down's Syndrome as the preferred option.
- 29.26 The recollection of the RBH paediatric cardiologists was that, by the late 1980s, they were discussing and offering both the surgical and the medical management options to parents, with a stated preference for surgical intervention. One cardiologist described how from 1990 onwards he had instituted a policy of joint care with a fellow consultant paediatric cardiologist, which meant they held two combined outpatient clinics each week and saw each other's patients. The advantage of this approach was that they would both usually be in attendance but there would always be one cardiologist at the outpatient clinic when the other was on holiday or unavailable for any other reason.
- 29.27 Both cardiologists had agreed that, in keeping with what they viewed as best practice, all patients with Down's Syndrome and congenital heart disease should be managed independently of their Down's Syndrome. In fact, on the whole, consultations with families with children with Down's Syndrome were considerably longer than for those without Down's Syndrome.

DISCUSSION OF THE LITERATURE

29.28 In addition to a review of the relevant literature on developments in clinical practice, communication and attitudes regarding children with Down's Syndrome (see Chapter 28), the Panel was fortunate in being able to derive much understanding of the influence of Down's Syndrome on the management and treatment of CAVSD from the published

writings of some of the RBH paediatric cardiologists over the past 15 years. One of these, Dr Elliot Shinebourne, is author or co-author of all these papers. He is clearly keenly interested in, and has written and spoken widely on, ethical issues; he has been a leader in instigating debate about these issues as they relate to the treatment of children with Down's Syndrome. We have, therefore, quoted liberally from these published papers, giving the Panel's comments on each in turn.

The 1985 paper

- 29.29 As noted earlier (see paragraphs 28.10 and 29.16) the seminal paper on the subject was published in the Lancet in 1985, co-authored by three Brompton clinicians, Dr Bull, Dr Rigby and Dr Shinebourne. Entitled Should Management of Complete Atrioventricular Canal Defect be Influenced by Coexistent Down Syndrome? (72), the paper reviews the situation as it was then. CAVSD was: 'the most severe of congenital cardiac conditions currently regarded as correctable. Repair carries a substantial mortality as well as the possibility of residual haemodynamic effects (e.g. "mitral" regurgitation). Despite these risks, early operation offers the only possibility of averting pulmonary vascular disease which often becomes irreversible by the time the child is two years old. Most affected children also have Down syndrome. This association compounds the dilemmas of decision making, both for cardiac units, which have widely varying general policies, and for the parents of the individual child. Faced with the possibility of a major cardiac operation for their doubly handicapped child, parents may defend their baby's right to be considered no differently from a normal child or may feel that "nature should take its course"'. The Panel has explored the proposition that children with Down's Syndrome should be treated differently from normal children with a complete atrioventricular canal defect by reviewing the outcome of these anomalies after surgical or medical treatment.
- 29.30 The paper reviews the treatment of 75 patients with Down's Syndrome and CAVSD seen at the RBH since 1970. These patients were referred at different ages and 25 of them already had irreversible pulmonary vascular disease when first seen. The remaining 50 were considered suitable for operation; eight were operated on, but not all were corrected; some underwent pulmonary artery banding, a palliative procedure. The others, like the 25 already inoperable, were treated medically with drugs. 'A consensus was reached between the referring paediatrician, the family and ourselves not to undertake surgical treatment.' Of the RBH contingent of unoperated children, eight died in early childhood, but actuarial

survival among unoperated children was 80% at ten and 15 years. 'Deaths again became more common amongst patients who had been followed up for longer than this, with the death of a 22-year-old man from terminal pulmonary vascular disease. The oldest surviving patient is 28 years old.'

- 29.31 The paper reviews surgical outcome and produces a table of outcomes from various centres over the previous five years. It points out that success depends to some extent on age at operation; children in whom some pulmonary vascular resistance has built up are less likely to survive, so it is important to operate as early as possible. Results from various centres may depend on the age at which children are referred or operated. The paper concludes that for children operated at 14 months of age, for example, 73% are likely to achieve a cure, with 27% dying or surviving with considerable haemodynamic instability leading to late death or re-operation for mitral valve problems. But 50% of survivors had raised pulmonary vascular resistance.
- 29.32 The paper goes on to examine the likely survival of a child with Down's Syndrome without cardiac abnormality, to establish what expectation of life such children have if they survive corrective surgery. It concludes that other disorders associated with the condition affect mortality, so survival for the first ten years, based on one large study, is only about 76%. After that there seem to be no reliable figures for the survival of children with Down's Syndrome and no cardiac abnormality. The paper comments that: *'all individuals with Down's Syndrome have a shorter life expectancy than normal, although survival into the fifth and sixth decades is increasingly reported. Survival to 71 has been reported...'.* It comments that, even after successful surgery, long-term heart problems may develop. Without surgery, death is inevitable, but *'many patients survive into their twenties. Death most commonly occurs in the fourth decade'.*
- 29.33 The paper goes on to set out how the authors believe parents of children with CAVSD (whether or not they have Down's Syndrome) should be counselled, and recommends: 'For the occasional child with life-threatening heart failure in infancy, surgery may be the only way to restrict the torrential pulmonary blood flow. For most who are acceptably controlled on medical therapy, elective surgical repair of the cardiac defect should be discussed with the parents who should be given the following information:

- Unless a unit can offer very exceptional surgical results, survival through childhood is better on medical treatment.
- Without surgery there will be an inevitable deterioration in exercise tolerance dating from the late teens and twenties with the probability of premature death from pulmonary vascular disease (or other complication of Down syndrome) in the twenties or thirties.
- Early surgery offers the only chance of avoiding pulmonary vascular disease. Chromosomally normal patients who have a surgical cure may revert, at least theoretically to normal life expectancy while those with Down syndrome revert to that of others with Down syndrome and a normal heart. This chance is at the early cost of around 30%.
- Some survivors will have residual cardiovascular abnormalities that may shorten their lives'.
- 29.34 The paper concludes: 'Although the suggestion that parents of a child with Down syndrome should be counselled differently from those with a chromosomally normal child with an atrioventricular canal defect apparently contravenes the law in some states in the USA, we believe that many of the parents of our patients may have different priorities. The choice is between the probability of survival through childhood with death in early adult life and a high risk of early mortality but a prospect, albeit small, of long adult life without major cardiac disability. In our experience, many parents of children with Down syndrome chose medical treatment while those with chromosomally normal children chose surgery'.

Reactions to the 1985 paper

29.35 Some doctors, at the time, disagreed with the paper's conclusions. Two had letters published in the *Lancet* (80) stating that surgery should be offered to all children with CAVSD irrespective of any association with Down's Syndrome, providing that there are no surgical contraindications. Many of the parents whom we saw have taken the paper as an indication that their own children were discriminated against at the RBH. However, the paper was widely regarded as an authoritative work by many cardiologists at that time and was used to support a similar approach in other centres.

29.36 In another assessment of the subject in a paper published in 1994 (81): 'When we pointed out in 1985 that an argument could be made that the 15-year actuarial survival for a patient with Down's Syndrome and complete AVSD was greater with medical than with surgical treatment unless the surgical results were outstanding, a reviewer for the New England Journal of Medicine commented "there are laws in this country that required that they (patients with Down's Syndrome) should not be discriminated against". At the time we wondered if not submitting for surgery constituted positive rather than negative discrimination given the relative mortality rates'.

The Panel's comments on the 1985 paper

- 29.37 The Panel entirely agree that, at a time when one in three children undergoing this operation would not survive it, even at the best centres, it was reasonable not to advise it for a child who was reasonably well and likely to remain so, let alone compel an unwilling parent to agree to the operation.
- 29.38 We wondered, however, how much parents understood about the reality of reduced exercise function in the late teens. A parent with a young baby will find it difficult to envisage what this can mean, but the Panel has seen, for example, a teenager dependent on oxygen therapy to get through the night, crawling upstairs and otherwise wheelchair dependent. This is not to suggest that the authors are unaware of or indifferent to these problems in these patients. On the contrary, for example, at the time the 1985 paper was written, Dr Shinebourne was researching means of ameliorating the problems of this condition and co-authored a paper published in 1986, which recommends the nocturnal use of oxygen concentrators at home to relieve breathlessness (82).
- 29.39 We now look at the 1985 paper for information on the then current attitudes to operating on children with Down's Syndrome, in order to understand why some young adults were not operated on and are now consequently in terminal right heart failure. At the time, this paper was concerned to counter the view that such individuals would necessarily die in early childhood if not operated on. It was also concerned, no doubt, to emphasise that if surgery were to be carried out, it needed to be early. In this it was a valuable piece of academic work with far-reaching consequences for patients, and we do not doubt that the lives of children who would otherwise have been referred for surgery too late, and the lives of other children who would otherwise have died as a result of surgery, were saved.

Conversely, we accept that the surviving young adults now suffering from pulmonary vascular disease or heart failure are unlikely to survive long into adulthood and will die because they were not operated on during this period.

- 29.40 However, there are aspects of the reasoning in this paper that we do not accept.
- 29.41 The authors report parents of children who have Down's Syndrome as feeling that 'nature should take its course'. This suggests that they feel that this can be an acceptable approach for the child's doctor to adopt in dealing with his or her treatment. Can it be that doctors are accepting that it can be right for nature to take its course in the case of a child with Down's Syndrome when it would not be right for a chromosomally normal child? In that case it is hard to escape the inference that considerations which are completely non-cardiac, and which are likely to be at least partly social (rather than clinical), are being brought to bear, presumably relating to assumptions about the child's likely quality of life as an adult.
- 29.42 Further, we go on to ask, in whose interests is it that 'nature should take its course'? Is it even the child's interests (which are, after all, the only considerations his or her doctors are entitled to consider in advising on his or her treatment) that are primarily in question here?
- 29.43 If, as the paper describes, most parents of chromosomally normal children choose an operation, this suggests that it was a reasonable choice, though a very hard one to impose on an unwilling parent. A disabled child has a right to life equal to that of a non-disabled one and should be no more dependent on the wishes of its parents. So this difference in the treatment of children should not in our view have prevailed.
- 29.44 This was an agonising dilemma, for doctor and parent alike. We do not pretend that it was easy for either. But, although it was reasonable not to recommend such a high-risk operation, and certainly reasonable for parents to be unable to face such high risks for their children, we do not accept the authors' reasoning that a different approach was appropriate for the parents of chromosomally normal children as against those whose children had Down's Syndrome.

The 1989 chapter

- 29.45 In 1989, in a book called *Doctors' Decisions* (83), Dr Shinebourne, one of the authors of the 1985 paper, described the basis of his decisions in a chapter entitled *Management of a child with a heart defect: ethical dilemmas.* This reviewed a number of ethical dilemmas around different cardiac anomalies.
- 29.46 The chapter begins by asking: 'Are there circumstances when a heart operation is possible, but it is preferable or justifiable not to operate? The paediatric cardiologist has to treat (or not) the child, not only the cardiac abnormality. The child does not exist in isolation. Neither the child's heart nor the child can be considered independently of other persons concerned with the care of the child. For the newborn this is first the mother and then the father. Additional factors affecting management include associated abnormalities, the range of possibilities indicated by the family's social circumstances, the availability of expertise within a given hospital, and the extent to which society elects or can afford to allocate scarce resources to a particular child. Should co-existent abnormalities in the child influence treatment? If a child has two medical conditions it may be wrong to treat one without taking account of the other'.
- 29.47 There follows the example of a child with spinal muscular atrophy combined with a cardiac abnormality, then Dr Shinebourne continues: 'Now, if the child did not have weak muscles but rather a chromosomal abnormality such as Down's Syndrome, should this child have an operation? Again, the answer is clear cut. Surgery should be carried out because the risk is low and the child's life expectancy will be increased. Though intellectually impaired, a child with Down's Syndrome can form warm relationships with his family and others. Should then all children with Down's Syndrome and a congenital heart abnormality be treated like children chromosomally normal? I would argue that there are circumstances where co-existent Down's Syndrome does influence the decision'. Here Dr Shinebourne references the 1985 paper and summarises current mortality (in 1989) from CAVSD correction as: 'an optimistic estimate of 10-year survival would be 70%. While some patients will have a technically perfect result others will not'.
- 29.48 He then reviews and repeats the reasoning in the 1985 paper and, after recounting the lower than normal life expectation of people with Down's Syndrome goes on: *'Furthermore, over the age of 35 years an increasing proportion of patients with Down's*

Syndrome develop presenile dementia, particularly Alzheimer's disease. I would suggest that the frequent association of Alzheimer's disease in adults with Down's Syndrome may be a reason for considering the early decades of life to be more important than a possibly longer life after surgery. Acknowledging that the way in which information is presented may influence the decisions made, our experience has been that many parents of children with Down's Syndrome and an atrioventricular septal defect elect for medical, not surgical treatment. Conversely, the majority of parents with chromosomally normal children and the same defect choose surgery. An interpretation of Federal Law in the USA may consider it unlawful not to operate in these circumstances. In our opinion, however, the decision not to operate because of co-existent Down's Syndrome may at times be equitable and not unethical. If the parents wish for surgery, especially if the child presents in the first three months of life, then operation should not be refused'.

The Panel's comments on the 1989 chapter

- 29.49 In this chapter Dr Shinebourne again suggests that there may be good reasons for a different approach to counselling parents (which, as he acknowledges, means in effect making the decision with them) in relation to a child with Down's Syndrome as opposed to a chromosomally normal child. We have set out in paragraphs 29.34 to 29.37 above our reasons for disagreeing with his justification for advancing this proposition.
- 29.50 Further, he suggests that the ability to demonstrate '*a potential for human relationships*' should be a factor in deciding whether a child should have surgery. Children with Down's Syndrome, as he says, do have this potential. However, we cannot accept that people need a qualification of this sort in order to access treatment on equal terms with others.
- 29.51 Dr Shinebourne contends that because some children with Down's Syndrome may develop Alzheimer's disease this may be '*a reason for considering the earlier decades of life to be more important than a possibly longer life after surgery*'. He appears to mean by this that this risk is a reason for not operating on a child with Down's Syndrome in case he or she turns out to be one of these unlucky ones in their thirties who develops Alzheimer's.
- 29.52 We could not accept that this was a valid reason for adopting a course of treatment that would result in the probability of heart failure as a teenager and the virtual certainty of death as a young adult. It could not be right to make any treatment decision on the basis of

a possibility that a disabling disease may affect the patient thirty or forty years hence if he or she survives the current condition long enough to develop it. In fact, as Dr Shinebourne and his co-author acknowledge in the 1994 paper discussed below, the evidence for early development of Alzheimer's was pathological evidence from post-mortem examination of people with Down's Syndrome (see paragraph 29.50) rather than significant clinical evidence in living patients. This makes it all the more unacceptable as a factor in decisions about the treatment of young babies.

29.53 Parents who ask about the future of a child with Down's Syndrome may want to know the whole medical picture of the Syndrome, and may want information of this sort. However, we do not think that either parents or doctor ought to take this into account in making a decision as to whether or not the child should have a corrective operation. Dr Shinebourne is effectively inviting the parents of children with Down's Syndrome to take account of matters other than the nature of the cardiac anomaly itself, deciding on their child's behalf whether treatment should be given that will ultimately provide them with a possibility of life beyond early adulthood.

The 1994 paper

- 29.54 The 1994 paper (81) by Dr Shinebourne and Dr Carvalho reviewed the question of what advice should be given to parents of children with Down's Syndrome and CAVSD. They say: 'In the light of improved surgical results it seems reasonable to reconsider this question being aware also of the duration and quality of life of a patient with Down's Syndrome and a normal heart born in the 1990s'.
- 29.55 The paper reviews the hospital records of 75 patients with Down's Syndrome and CAVSD aged between a few months and 40 years who had not been operated on, to determine the survival data associated with them and degree of disability the survivors suffered. Because the number of patients in the sample aged above 20 years was small, the study is of limited value for survival beyond that age. In terms of survival below the age of 20 years, the study showed that, after five deaths in the first three years of life, there were no more deaths up to 20 years of age.
- 29.56 The authors looked at cyanosis caused by pulmonary vascular disease. This was not common in the first decade of life. It increased with age but only about half of patients

aged between 11 and 20 years suffered from it. No patients were confined to bed or were totally wheelchair dependent.

- 29.57 The authors acknowledge the improvements in life expectancy of individuals with Down's Syndrome without congenital heart disease (61% survival to age 50 and 14% to age 68). They then go on to discuss the association of Alzheimer's disease and Down's Syndrome, and acknowledge that the pathological findings on post mortem do not equate to clinical evidence. However, they say: 'Even though neuropathological evidence of Alzheimer's is not closely related with clinical dementia, the majority of older patients with Down's Syndrome do show increasing impairment of intellectual function with a decreasing ability to sustain human relationships'.
- 29.58 The paper then recounts the great improvement of success rates in operating on CAVSD, down to peri-operative mortality of 6% in some reported series (although 16% required re-operation within two years). These improved results were associated with a much younger median age of correction, 4.3 months of age.
- 29.59 The discussion which follows the recounting of these research findings deals with three groups of patients.
- 29.60 First, the authors say that for the symptomatic baby with heart failure, resulting in breathlessness, poor feeding and failure to thrive, surgery is indicated. 'Some would argue that total correction should be carried out irrespectively of the parents' views, but this may not be everyone's view.'
- 29.61 The second group considered is that of children presenting after the first year of life, where risks are much higher: 'because acute pulmonary hypertensive crises may occur post-operatively which are resistant to therapy. In our view older patients (that is, over one year of age) with Down's Syndrome and a complete AVSD treated medically and not subjected to surgery are still likely to have a better 15-year actuarial survival than patients having surgical correction, but clearly individual family wishes may result in surgery being requested. (Whether these wishes should be acceded to will depend on the precise level of pulmonary resistance measured and hence the risk)'. Dr Shinebourne and his co-author are here suggesting that these children should not be operated on because they have a high risk at operation, such that they are more likely to survive through childhood if they

are not operated on, just as all children with Down's Syndrome and CAVSD who were not affected by heart failure were in this situation in 1985.

- 29.62 The third group considered is the one with which we are most concerned. The authors say: 'The major ethical dilemma is in the group of infants who are relatively well because the pulmonary vascular resistance has not fallen normally after birth and who therefore do not have grossly excessive pulmonary blood flow and so are not unduly breathless. Without surgery we know they have an excellent (approximately 90%) chance of living for 20 years with some but not necessarily severe symptoms or gross reduction in exercise ability. There will be limitation however and life expectancy will not be the same as for other individuals with Down's Syndrome'.
- 29.63 They go on to say that the risk of death from surgery for such individuals in their own unit (RBH) is now below 10%. They then state: 'Our view remains that even for the asymptomatic infant with Down's Syndrome and a complete AVSD, the parents or those who will care for the child should decide if they wish for the risk of surgery, on the basis of the above information together with the concerns of further intellectual deterioration in later life from Alzheimer's disease. The latter may be a reason for giving the early decades of life priority over the later years in Down's Syndrome in contrast perhaps to chromosomally normal individuals. Parents will make their decisions not only on relative risk factors but will be influenced to some extent by the way the information is presented. If told there is a more than 90% chance that their child will have a successful operation and lead a normal life, surgery is likely to be requested. If told the full picture, together with an understanding of possible late complications both of surgery and Down's Syndrome per se, not all parents will choose surgery'.
- 29.64 The 1994 paper concludes: 'Even if the surgical results in the unit concerned are outstanding, we do not believe there is an overriding ethical obligation to undertake surgery if the family elect for medical rather than surgical management. Earlier age of operation with improving surgical results, however, do make a stronger case for surgical intervention than existed ten years ago'.

The Panel's comments on the 1994 paper

- 29.65 The authors are here suggesting that it may not be appropriate to force surgery on children whose parents do not want it. The legal position is that, if a doctor considers that surgery is in the best interests of the child and parents refuse their consent, the doctor has either the option or the duty, depending on the circumstances, to apply to the court for authority to perform it. In this paper, Drs Shinebourne and Carvalho express the view that this duty does not exist in cases of children with Down's Syndrome and CAVSD, even though the risk of mortality has fallen to 10% or thereabouts, because of the factors they recount. We cannot agree. We have heard from other doctors that in 1994 it would not be usual to discuss the medical option as a true alternative; parents would be advised that it was in the best interests of their child to have the operation. It is easy to understand, from reading this paper, why parents being counselled in this way may have felt that they were being 'steered' towards medical treatment of their children at this point in time, when the risks of the operation had fallen to a level considered acceptable elsewhere.
- 29.66 In making these recommendations, are the authors thinking primarily of the parents' interests or those of the children? In responding to our criticisms of this chapter, Dr Shinebourne insists that the paper is concerned only with the interests of the child, not those of the parents. But we think that, for example, the passage beginning 'the parents or those who will care for the child should decide if they wish for the risk of surgery', suggests a concern for 'the parents or those who will care for the child. Although this is not explicitly stated, the suggestion is that doctors should not force parents who cannot face looking after a disabled adult (as opposed to a disabled child) to take a step which would result in the child surviving into adulthood.
- 29.67 It is easy to understand why a doctor should feel concern and anxiety on behalf of parents whom they see trying to come to terms with this prospect. But in our opinion this approach, though commendably open and honest, is not currently tenable. It focuses, by implication, on the wishes and interests of parents rather than those of the child and, if expressed nowadays, would probably contravene the Disability Discrimination Act 1995 and the Human Rights Act 1998. These embody the propositions that every child has a right to life, which does not depend on their family's wishes and that every child has a right to medical treatment without discrimination on grounds of disability.

The 2000 paper

29.68 Dr Shinebourne is also co-author with Drs Al Hay, MacNeill and Yacoub of a study, as yet unpublished, of risk factors and management of patients with Down's Syndrome and CAVSD. This reviews 147 children with CAVSD between January 1986 and December 1998, 106 of them with Down's Syndrome. The total peri-operative mortality (within 30 days of the operation) of babies with a simple CAVSD was 11%. The paper recounts that previously the medical option was sometimes chosen but that now surgery is routinely performed in infancy, at an average age of about 4 months. Thus it appears that views have evolved such that surgery is now considered clearly the preferred option. It is also noteworthy that the number of cases of CAVSD repaired at RBH is in keeping with the figure that would be anticipated on the proportion of total UK paediatric open heart operations performed at RBH as discussed in paragraphs 29.6 and 29.7.

The effect of the publications

29.69 We observe that the published views of the RBH clinicians on the clinical management of children with CAVSD and Down's Syndrome seem to have been highly influential, both in defining the position of the clinical team – at least until the early 1990s – at the RBH and in stimulating debate in the field of paediatric cardiology nationally and internationally. Indeed, not only families but also some doctors, including some from RBH, have referred to it as 'policy'. We understand from the Trust's Medical Director that no such written or formal policy or protocol was ever adopted by it or its predecessors. It would be better perhaps to regard the publications as expressing the 'agreed practice' adopted by the cardiologists. It is clear that these attitudes towards counselling parents and recommending treatment for children with CAVSD in association with Down's Syndrome became widely known to the representative groups. Some members of these groups began to think that discrimination was occurring at RBH and urged caution upon other parent members whose children were in treatment there.

THE CONTROVERSY

29.70 The perception, arising out of the 1985 *Lancet* paper, that there was an RBH 'policy' of medical management, led some parents to take their child elsewhere for a second opinion

and treatment. Where surgery was offered elsewhere, they felt it was presented as a more positive option compared with the RBH, where the only alternative outcome had seemed to be one of slow but certain deterioration. The RBH doctors argued that unnecessarily high risks were often taken for those children who had a successful operation at other centres. In others an operation might have been unnecessary since, if the lesion was a ventricular septal defect, it might have closed of its own accord, obviating the need for surgery.

- 29.71 The doctors concerned have pointed out that recommending medical management was entirely justifiable at a time when mortality rates for surgical repair of CAVSD were so high. They believed that they had taken their duty of care seriously by pointing out the high risks of surgery and the likely prognosis for children with Down's Syndrome, if they were to survive surgery into adulthood. They refuted the allegation that they had portrayed the surgical risks in unnecessarily pessimistic terms and they point to the concluding part of the 1985 paper, repeated in the 1994 publication, as giving the emphasis they intended to convey.
- 29.72 The parents of three children who were treated in the early 1990s allege that the doctors sought to steer them away from the surgical option (although eventually all in fact did_have surgery either at the RBH or elsewhere), in some cases referring to evidence that people with Down's Syndrome would suffer early onset of Alzheimer's disease.
- 29.73 One doctor admitted that his own feelings were bound to affect his conversations with parents and subsequent advice to them. Another doctor accepted that you can persuade people to come around to your point of view, especially when parents are ambivalent and more open to suggestions or advice. Thus medical staff were well aware of the sensitive and difficult task they faced in dealing with these issues with parents at a vulnerable time.
- 29.74 It was clear to us that there was a considerable difference between the attitude of parents and that of some doctors about how these matters should be dealt with, and who should take responsibility for decisions in these situations. Many of the parents felt that the doctors at the RBH had been prejudiced in their dealings with children with Down's Syndrome, while the doctors considered that they had been acting with caution and care.

INTERVIEWS WITH INDIVIDUAL PARENTS

- 29.75 We heard from the parents of 14 children with Down's Syndrome who wanted their child's treatment reviewed because of their concerns about discrimination. This does not include the complaints of a further three families with children with Down's Syndrome about their child's general treatment at the RBH, which did not include allegations of discrimination.
- 29.76 The parents of three of the 14 children had not thought at the time that there was any discrimination in their child's treatment, but now wanted the case reviewed for discrimination in the light of the establishment of our Inquiry. Having reviewed these cases, we were able to reassure these parents that their child's clinical treatment had been entirely appropriate.
- 29.77 A further three families felt that their children had been discriminated against, but there was no specific evidence to connect the child's treatment with discrimination. These parents firmly believed that they had been subjected to insensitive and inappropriate communication as a result of their child's Down's Syndrome. The complaints they made were either similar to those of other parents whose children did not have Down's Syndrome or were of inappropriate clinical management. Our doctors found no evidence in the medical records of incorrect or inappropriate management and we could not identify objective evidence of discrimination as the cause for the poor communication complained of by these families.
- 29.78 The other families felt that their children had been discriminated against; parents reported their recollections in clear and often graphic terms. We were, however, unable to test these recollections, which related back a number of years, not only because considerations of confidentiality prevented sufficient details being put to the doctors but also because no reference was made in the medical records. This does not mean that we did not take the parents' concerns extremely seriously. Below we have categorised and analysed parents' allegations within two distinct periods of time.

1981-1987

29.79 Of the 14 individual cases, four of the children were born and diagnosed during this period. At the time the risk of death as a result of surgery for CAVSD in infancy was very high with a UK average of above 30%, so a child with Down's Syndrome who seemed well on presentation at the clinic would usually be offered only medical management. Many other cardiac centres adopted similar attitudes towards surgery for this condition at this time. Two of these families did not accept that their children were inoperable and sought second opinions elsewhere. Both these children were operated on at older ages and with high risks attached to surgery, which would have been considered 'heroic' at the time. They are, however, doing well. The other two are now young adults whose health is steadily deteriorating. Their parents felt strongly that they had not been given sufficient information by doctors at the early stages as to how distressing many of the symptoms of advanced pulmonary vascular disease could be for both the sufferer and the carer. Furthermore, they said that they had been given insufficient guidance on appropriate treatment or how to cope as their children's cardiac condition deteriorated.

- 29.80 A study in the USA undertaken in 1990 (84) documented the consequences of deciding to adopt the medical management model, saying: 'Patients who survive with complete atrioventricular canal and pulmonary vascular obstructive disease are significantly worse off than their peers who have received treatment in their early 20s these children often must use a wheelchair, are persistently short of breath, cyanotic [blue colouration of skin and lips owing to a lower amount of oxygen in the capillaries], and polycythemic [increased number of red blood cells]. They may develop right cardiac failure. Clinical manifestations of their chronic hypoxemia [a condition where the blood contains too little oxygen] include visual disturbances, severe headaches, dyspnea [breathlessness] on any exertion, chest pain, syncope [loss of consciousness related to lack of blood flow to the brain], cardiac dysrhythmias [disturbance of rhythm], and, in some cases associated bleeding tendency. There is no doubt that the quality of life in the unoperated patient who develops pulmonary vascular obstructive disease is poor'.
- 29.81 Of these latter two children, one mother described the condition of her 19-year-old son now: 'As his health declined, he started to bleed from nose, mouth, spots etc. He was like a zombie in the mornings. From other parents, newsletters etc. I found out about oxygen therapy I shouldn't have had to ask'. In fact most of this boy's treatment was provided by paediatricians at the local hospital and we wondered why this child was not seen by a cardiologist from the RBH between 1991 and 1998. We were left wondering if more could have been done by visiting RBH doctors to support and advise these parents.

- 29.82 The two children who had been managed medically were later referred to the GUCH clinic, which was established in 1990. The parents told us that the dignity and respect with which they and their children were received at the GUCH clinic contrasted favourably with what they perceived to be the insensitive treatment they had received at the hands of the paediatric cardiology service. We noted that some of the paediatric cardiologists attended both clinics.
- 29.83 We were unable to establish, without investigating the position at the local hospitals, whether the overall treatment of two of these families was suboptimal and whether more could have been done to support and advise the parents of all the children who were not operated on.

1990-1998

- 29.84 The other ten children whose cases we considered individually had been born after 1990 and their parents' complaints related to a period ending in 1998. During the early 1990s the risk of death as a result of surgery for CAVSD in infancy fell from around 30% to 12-15%, as discussed in Chapter 28. Some of these ten children suffered from rare and complex conditions, not simply an isolated CAVSD. Eight received surgical repair, five at the RBH and three elsewhere. One of the remaining two children received a palliative operation only, pending further operation, which turned out later not to be feasible, and the other suffered from a very rare condition and to date no operation has been possible (although this is still under review at another hospital where the child is now being treated).
- 29.85 In two cases, although the parents believed that unsatisfactory aspects of their children's treatment were due to discrimination, we found no evidence to connect their treatment with discriminatory attitudes or behaviour, when the parents' accounts and the medical records were considered together.
- 29.86 In one case, the only evidence of a discriminatory approach was a remark in the doctor's letter of referral to a colleague at a different hospital, where he cited the fact that he considered the high incidence of Alzheimer's in later life a factor in the decision of whether to advise surgery. We did not feel this was an appropriate factor to take into account in giving advice to parents about a child's treatment and could therefore be construed as

discriminatory, although the remark was in a referral letter to a surgeon for a second opinion which was written after the first outpatient appointment with the cardiologist.

- 29.87 The parents of five of the remaining seven children treated during this period felt that their children had been discriminated against although it was not possible to substantiate their evidence.
- 29.88 Whilst we cannot say whether or not the concerns expressed by the majority of families reflected discriminatory behaviour, they suggested insensitivity in the attitudes of some clinical personnel. The practice of allowing junior doctors in specialist training to be part of the proceedings at the time of diagnosis was regarded as intrusive and unfeeling at a time of great distress. Parents recognised that junior doctors had to learn, but one family alleged that several junior doctors were encouraged by the consultant to check a heart murmur using a stethoscope on a distressed infant, while they were taking in the news that their baby had a serious heart abnormality as well as Down's Syndrome.
- 29.89 Whilst it is inevitable that junior doctors in training will be taught in the clinics, we discuss in Part Two of this report how this can be managed to make the experience less intrusive for parents. Many references were made to the high number of cancellations of surgery, sometimes when the child had been admitted and even pre-medicated. Chapter 9 shows that this is not an issue relating only to children with Down's Syndrome. As with so much about dealing with vulnerable parents, it is not just the event itself, but how it is handled and communicated, that can cause real distress. A well-meaning but inopportune remark can, in such circumstances, be interpreted as prejudiced and offensive.
- 29.90 Some of these families believed their children's treatment had been inappropriate, but our doctors felt it was appropriate. Some parents believed that attitudes were discriminatory, but in the absence of any documentary evidence, we were unable to test this. Some parents alleged that negative information was unsympathetically conveyed, and objected, for example, to being told that a child would not get a heart transplant because she or he had Down's Syndrome. We recognise that such advice would have been correct but we can see how a perception of discrimination could easily arise unless parents were given a clear evidence-based explanation as to why a child could not be placed on a transplant waiting list.

29.91 This left two cases in which, although the Panel felt that the treatment actually delivered was appropriate, the doctors were alleged to have made discriminatory remarks to parents on the basis of the child's Down's Syndrome. In both these cases the doctors disputed this and the child did have corrective surgery, one at RBH and one at another hospital. The parents felt that if they had not insisted this would not have happened but we were unable to test this.

Attitudes and remarks

- 29.92 Most of the concerns were about the way in which information had been given or how the parents felt (either at the time or in retrospect) about how their child had been regarded. In seven cases, there were allegations of discrimination regarding the treatment either offered or delivered.
- 29.93 In three cases we felt considerable concern about the offensive nature of remarks which were alleged to have been made in unacceptable terms in correspondence or to parents in conversation, suggesting that children with Down's Syndrome and CAVSD should be treated differently from or valued less than other children. One case concerned the referral letter mentioning Alzheimer's disease, which we have already criticised. The other two cases were alleged to have occurred in conversation. The doctors have strongly disputed that such remarks were made. We do not therefore consider it appropriate to repeat their substance here but the intensity with which these parents complained suggests at least that a serious breakdown in communication occurred.

REVIEW OF MEDICAL RECORDS

- 29.94 Our independent consultant paediatric cardiologists examined the records and summarised them for each of the 14 families whom we saw individually. These were then fully discussed with each set of parents.
- 29.95 We found no case after the risk of mortality fell substantially around 1990 in which a child did not receive surgical intervention, whether at RBH or elsewhere, where surgery would have been appropriate. However, we found a number of cases in which children were seen at the RBH and then transferred to another centre where they received surgery. We were unable to test some parents' contention that this was due to their insistence rather than to

what the doctors advised. We cannot say what would have happened if the child had remained under the care of the RBH but review of the medical records of the cases we examined individually showed that surgery was considered in each case and in many cases was indicated to be likely. In the other cases who remained at RBH the reasons for delaying decisions on surgery are clearly stated in the doctors' correspondence. We were also unable to find any case in which the doctors had quoted an incorrectly high risk for an operation. However, we do not know from the records whether discussions with parents included sufficient counselling as to the distressing nature of death from pulmonary vascular disease. The three published papers considered earlier suggest that insufficient emphasis may have been given to this aspect, but we have been unable to test whether this was the case in practice.

29.96 We had to view the decisions in the light of contemporaneous practice, so we needed to know whether paediatric cardiologists in other hospitals would have made similar decisions. Our cardiologists found that, in all these cases, the treatment given was generally in accordance with accepted clinical practice. In the six cases where parents sought a referral elsewhere, the clinical management at the RBH was felt to be within acceptable practice, although our doctors felt that more active management might have been expected in one of them.

PRESENTATION BY THE DOWN'S HEART GROUP AND DOWN'S SYNDROME ASSOCIATION

29.97 The Chief Executive of the DSA and the Chairman of the DHG were primarily concerned with strategic and policy issues rather than individual cases. The DSA had sent a questionnaire to its members in 1998 to examine the levels and areas of inequality in health care provision generally. They had a total of 1,509 responses, some of which were featured in their report, *He'll Never Join the Army*, published in March 1999 (85). Evidence from the DSA showed that 61 of those returning the questionnaires had complained specifically about cardiac care. Forty of these came from the South East and were concerned with RBH clinics operating in this region. Their written evidence stated: 'On talking to the families who did not want to pursue their complaints, we were alarmed to see a pattern taking shape. We were very concerned and in March 1999 sought advice on what action these families should take. The GMC was to be the next step but was pre-empted by the whistleblower's allegations and the subsequent Inquiry'.

- 29.98 In reviewing individual cases, the DSA and DHG wanted us to obtain the medical records or information from other hospitals at which RBH children had received advice or treatment. We explained that we had neither the authority nor the resources to extend the scope of our Inquiry in that way. We noted that a differing second opinion at another hospital did not in itself prove that the original decision was inappropriate or discriminatory. Not only could there be legitimate differences of view about diagnosis and treatment, but circumstances could change over time. The original decision at the RBH should be judged in relation to what was, or should have been, known at the time about the child's condition and the prevailing state of medical knowledge.
- 29.99 The 13 families from DHG, four of whom we also saw individually as part of the DSA families, gave evidence on a group basis. Five of the DHG group children who did not have their cases individually reviewed by the Panel were born and diagnosed in the 1980s (i.e. during the period when the mortality risk of surgery was still as high as 30%). All these families allege that cardiologists at the RBH had put pressure on them to opt for medical management rather than surgery. As a result they believed that their children could have been denied the opportunity for corrective surgery and left to face a premature death. One child received surgery at the RBH but the parents allege that they had to fight for it. The families of two children, who were not referred by RBH for surgery and who underwent successful surgery elsewhere, claim that without a second opinion and a chance encounter their child would have been much worse off. The remaining two children did not receive any corrective surgery.
- 29.100 The remaining four children in the DHG group were all born in the 1990s. Three were offered surgery at the RBH, although one had operations cancelled twice and, after seeking a second opinion, went elsewhere. The second child was operated on but died later. The third child was offered the choice of medical management or surgery. After seeking a second opinion elsewhere, which confirmed an urgent need for surgery, the child was returned to the RBH where an operation was successfully performed.
- 29.101 The fourth child in this group was referred elsewhere and operated on successfully. No child in this group failed to receive surgical help, although the DHG points out that 50% were operated on elsewhere. The parents allege that the advice given took the form of caution against the high risk of surgery and emphasised the positive aspects of medical

management. Some parents allege that remarks were made that devalued children with Down's Syndrome, which they considered to be discriminatory. As one mother said: 'What would have happened if we had been very different parents, believing that doctors know best, taking first advice and prognosis and not seeking a second opinion Can you imagine the burden of guilt that as parents we'd have to carry for the rest of our lives No person should ever be subjected to this'.

29.102 We did not see this group of families individually or have access to their medical records as they did not wish their cases to be heard individually by the Panel. We were unable to investigate or test their allegations with the doctors concerned so we cannot make findings as to what actually happened in these cases. This being the case, we have not been able to rely on this evidence in forming our conclusions. Nevertheless, it was invaluable for us to meet with the DHG group of families and hear their concerns, so movingly conveyed, about the dilemmas inherent in caring for a child with Down's Syndrome and congenital heart disease. We recommend that the views of this group are taken into account by the Trust in planning future services.

INTERVIEWS WITH REPRESENTATIVES OF THE DSA, THE DHG AND HEARTLINE

- 29.103 These groups play an important networking and support role in the lives of families of children diagnosed with congenital heart abnormalities and Down's Syndrome. Families had used the groups to learn of centres of excellence, and some had been warned by other members about doctors whom they believed not to be sympathetic to children with Down's Syndrome. The general consensus among the support groups was that, in their experience, the RBH doctors were not as empathetic with parents of children with Down's Syndrome as those in other centres, and that they were less likely to offer surgery.
- 29.104 Some newspaper articles and written evidence dating from the 1980s confirm that, whether fairly or not, other centres came to be viewed as more sympathetic and more likely to treat the children primarily on the basis of their heart condition rather than the fact that they had Down's Syndrome.
- 29.105 Given the impact and profound importance of support groups in the lives of families where there is a child with Down's Syndrome, it seemed to us most regrettable that there appeared to have been no attempt by the Trust to forge closer links between the Hospital

and these groups. Had they done so, the Trust could have both facilitated and demonstrated a fuller awareness by staff of the many needs and anxieties of such families, and ensured that appropriate counselling support, advice and guidance was provided for them. The Treasurer of Heartline wrote to us recommending that the RBH should: *'nominate one of its [non-Executive Directors] to be the lead on relations with patients, their families and support groups'*. We support such a proposal. We also welcome the recent appointment of the Chairman of the DHG to the project group set up by the Trust to plan for the implementation of the merger of paediatric cardiac services on the RBH site.

29.106 During our Inquiry we received a helpful submission from the DHG entitled *Towards Better Practice*, which suggests ways of improving services to children with Down's Syndrome. We drew heavily on this report in formulating the model guidance on the avoidance of discrimination against children with Down's Syndrome (Appendix 14).

EVIDENCE FROM CLINICIANS

- 29.107 In the view of the Inquiry's cardiologists, medical management of cases where children were presenting as asymptomatic with CAVSD was commonplace in the 1980s and was by no means unique to the RBH. Such management could nevertheless still have been discriminatory even though it fell within accepted practice at that time.
- 29.108 Meetings were arranged individually with cardiologists, intensivists, surgeons and nurses from the RBH who had treated the children involved in our Inquiry. We also met doctors, including a paediatrician, from other hospitals and centres. We had received much complex evidence from the families, and it was therefore important to put the issues and, in some cases, the allegations (in anonymised terms) to all concerned. We discussed the expectations and standards of service with past and present RBH doctors.

Evidence from RBH clinicians

29.109 When asked about attitudes to patients with Down's Syndrome, all the doctors concerned insisted that they had never held or expressed discriminatory views or heard them expressed by others. As one doctor said: 'I am very careful how to address families who have a child with Down's Syndrome. Because there is a lot of emotion around and a lot of projection and actually a lot of ambivalence. So that is not an easy interchange'.

- 29.110 The doctors told us that 40-60 new children with Down's Syndrome were seen each year by the Brompton cardiologists. Complaints had been received from only 14 out of the more than 600 families seen during this period. Moreover, only two families with children with Down's Syndrome had made a formal complaint since 1990. The doctors referred to the fact that some of the families had been persuaded that their children should undergo surgical treatment, when they had initially expressed a wish for such treatment not to be undertaken. Further, some families under their care and treatment were referred to the RBH from other cardiac units for a second opinion and underwent successful surgical treatment.
- 29.111 Surgery on children with CAVSD in the 1980s was acknowledged by the doctors to be very high risk. Accepted statistical evidence gave rates of mortality of 30% or more. A small number of Down's Syndrome children with AVSD defects were operated on at the RBH prior to 1985 (eight children in 15 years although not all were corrective), but at the time of the 1985 paper (72) it was not widely recommended. Most of the doctors to whom we spoke broadly agreed with this perspective.
- 29.112 All the RBH doctors agreed that pioneering surgery would lead to higher mortality rates in the initial phases as surgeons adopted and gained experience of the new techniques. A doctor from the RBH explained that in discussion with a colleague from Texas who had experience of 12 consecutive cases of children with Down's Syndrome and CAVSD who had died during the peri-operative period: *'I remember in 1987 saying at the moment our policy has been not to operate on those children with Down's Syndrome with complete AV canal defects unless the parents really, really feel they want surgery'.*
- 29.113 After 1990, surgical mortality started to fall due to improved techniques, intra-operative and post-operative care. It was already widely acknowledged that surgery should usually be recommended to those presenting early. When we took this up with the doctors at the RBH, they agreed with that view. One told us that, when surgical results were really beginning to improve at the RBH in around 1990, he remembered feeling that these children 'should be operated now because the results are getting relatively good'. However, the doctors disagreed about whether surgery was offered unequivocally.
- 29.114 We were told by one that: 'I would affirm that I have always offered families a choice between medical or surgical treatment. But that the emphasis in terms of positive advantages of surgery now clearly outweigh medical management'. A second RBH doctor said: 'It is very easy to have a policy when you have only got two cardiologists, because you have meetings every day and you talk every day. So when I arrived at the Brompton this was the way the department worked, that for children with Down's Syndrome and a complete AV canal defect, the majority did not undergo surgery.... there is no doubt that that situation of discussing the non-surgical option persisted into the early 90s and may have gone on beyond'. Another doctor said: '.... discussions about the non-surgical option persisted for too long'.
- 29.115 We also wanted to explore the negative comments that had allegedly been made by some doctors at the RBH with regard to children with Down's Syndrome. We had heard from a number of families that, in promoting the medical management option, consultants would use supporting statements regarding quality of life issues and use of NHS resources. We therefore asked many questions about this area of concern. One doctor explained: 'I would say, well, there is the possibility of 15 years plus of good quality life. The child will be with you during childhood, early adult life perhaps, but will inevitably develop pulmonary vascular disease and will die younger than if they have their heart fixed. If they go to have cardiac surgery, then there is a chance that they will not have that life. That was the sort of dilemma'. Another told us: 'If they wanted to discuss the option of no surgery, which was not unusual, then I would give them a balanced view'. However, one doctor responded: '.... very definitely, that the issues of quality of life, length of life support were discussed in the 1980s Now I think that there were at the time, perhaps mistakenly, issues of Down's Syndrome that were factored into that decision making, like life expectancy, like ability to lead an independent life'.
- 29.116 One doctor accepted that he had referred, on occasions, to the earlier onset of Alzheimer's disease in adults with Down's Syndrome. Indeed, he believed this to be justified by clinical evidence and referred us to a number of papers, including histopathological, on the subject. Another doctor had no doubt that he heard it said: *You need to think about how well Johnny is going to be in 30 years time and how well you will be and how you will be able to look after him, there is no doubt about that'*.

- 29.117 We asked whether reference was ever made to resource issues. Everyone whom we interviewed said that this would not have been an appropriate matter for a doctor to raise with parents, and that no such remarks would have been made.
- 29.118 With regard to the offer of a second opinion, the doctors at the RBH stated that they always did so in order that parents could consider all options fully. On the matter of choice, one doctor said: 'Those who now have a child with pulmonary vascular disease who is deteriorating clinically, feel very sad about it and may well feel that it is our fault [that] we did not give them the chance. I would dispute that. I do not think any patient was turned down'.
- 29.119 We tried to discover why the evidence presented by so many of the parents of children with Down's Syndrome seemed to be at such variance with the RBH doctors' accounts. One doctor responded: '*The parents' responses, emotional responses are going to play a very large part in how people are perceived. It is very difficult to get it right*'.

Evidence from doctors at other paediatric cardiac centres

- 29.120 We also discussed the expectations and standards of service with paediatric cardiologists from other centres, in order to be able to compare practice across the UK throughout the period in question. However, some doctors from other centres had not agreed with the views of the 1985 paper. One stated: 'I think that we already had a different point of view. If you look at our follow-on clinics there were very few children who came to us with the opportunity to have an operation and now have irreversible pulmonary vascular disease...'. Another told us: 'I do not believe there was ever a question that because somebody had Down's Syndrome they would be treated differently from somebody who did not have Down's Syndrome I was very upset when I read the Lancet paper and I was very pleased to see the letters of rebuttal'.
- 29.121 Whatever their view of the ethics of high-risk surgery, all doctors with whom we discussed this issue were in agreement that pioneering surgery would lead to higher mortality rates in the initial phases. A doctor from another hospital was not in favour of children with Down's Syndrome being given different medical treatment, saying: '*My argument was that if a child with AVSD had an operation and it was successful it would make it very much easier for the parents to be able to cope with that child afterwards. I thought that was a*

very good argument in favour of doing the operation. Today there is just no question about it'.

- 29.122 In referring to the 1985 paper (72), one doctor was concerned at the possibility of early onset of Alzheimer's disease being referred to as a ground for not choosing surgery because such an argument does not take sufficient account of the mode of death, saying: 'With somebody who does not have an operation you have this protracted cardio respiratory failure over a year or years, which is different from dying around the time of an operation when they are small. You cannot balance the equation, but you have to take account of that if you are not going to offer surgery'.
- 29.123 The doctors whom we saw referred to the impact of the publication of markedly improved results in 1990 (73) for surgery on children with CAVSD from the Melbourne Children's Hospital, which changed the position regarding operating on Down's Syndrome children with these abnormalities. However, these results were not reproduced on a wider scale for some years. It seems to us possible that, until the arrival of more surgeons who specialised in the newer techniques, some consultants sent these children to those centres where surgeons were already obtaining good results in this type of surgery, whereas others continued to recommend medical treatment within their own hospital. One cardiologist from another hospital explained: ' *if you have not got the technical ability to do something, I believe you should send patients to a place which has got the technical ability*'.

EVIDENCE FROM NON-CLINICAL EXPERTS

29.124 To achieve the widest possible perspective on issues related to the needs of people with Down's Syndrome and the allegations of discrimination, we invited several experts to submit evidence both orally and in writing. With regard to the position of parents in the decision-making process, we looked at papers (86) published in 1987 by David Silverman, then Reader in Sociology, Goldsmith's College, who was invited by Dr Shinebourne to become involved in this area of research. He wrote in 1987 about parents *'handing over the moral authority'* to the consultant at the initial consultation, when they were distressed and confused and unable to retain much of the information given to them. At that stage, they were trying to come to terms with their child's disabling condition. As the family

strengthened and learned to cope with the new child's condition, this was gradually regained.

- 29.125 One expert consulted by the Panel, Priscilla Alderson, a sociologist whose work had taken her into both the RBH and Great Ormond Street (GOS) Hospital in the late 1980s, told us that the emphasis and styles of the two hospitals differed. RBH had only two paediatric cardiologists at the time of her study, whereas GOS had six and these had as a result much more time to spend with patients. GOS was more 'heroic' in its approach to surgery. This meant that, while greater risks were taken, more children were offered the opportunity for surgery in the hope that it would 'do some good'. The RBH, on the other hand, advocated a more cautious approach of 'do no harm' and, in doing so, was more likely to consider medical management options in cases when surgical interventions carried extremely high risks. The majority of parents' responses during in-depth interviews and to a questionnaire survey expressed high confidence in the doctors' information giving and treatment recommendations. Dr Alderson accepted that an observer had a limited view of the complexities and subtleties that occurred in the interactions between doctors and patients She did, however, refer to the power of the doctor in such a regarding consent. relationship, as also acknowledged by Dr Shinebourne in his 1989 paper.
- 29.126 We met Philippa Russell, one of the newly appointed Disability Rights Commissioners, whose role will be to investigate cases and areas in which it is felt that people with disabilities are being disadvantaged or discriminated against because of their disability. She was specifically asked whether, as a member of the Disability Rights Taskforce which preceded the Disability Rights Commission, she had been aware of any allegations of the sort we were considering in our Inquiry. She said she was aware that parents of children with Down's Syndrome often felt that their children were discriminated against, particularly as Down's Syndrome was a condition that was so recognisable and diagnosed very early on in life. As such, she reiterated that generally, within the health field: *'parents of children with Down's Syndrome and a wider range of learning disabilities considered that they did not always get and might not be offered treatments that would be offered to other children. They were particularly concerned that assessments of their children's and the family's quality of life were often negative and failed to take account of their true potential'.*

- 29.127 Margaret Flynn, the assistant director of the National Development Team, a specialist organisation established many years ago to improve services in health-related services for people with learning disabilities, stated that poor quality service provision to this patient group continued to be a matter of national concern generally. She referred to the foreword written in a recent DoH practice document by a health minister, in which he stated that people with learning disabilities had not been fairly treated by the NHS. She told us that she was aware of the evidence that had been presented by the DSA and the DHG. She said that, if true, it was similar to the many examples of *'poor and weak practice'* that she had seen replicated throughout the country.
- 29.128 We also consulted Len Doyal, Professor of Medical Ethics at St Bartholomew's and the Royal London School of Medicine and Dentistry, and asked him to give an opinion on the treatment of children with Down's Syndrome at the RBH based on a review of the literature. In Professor Doyal's view, in the 1980s the clinicians at the Brompton were wrong when they recommended medical management rather than surgery because of the high mortality of the procedures to repair the relevant septal defects. He argues that this approach placed undue emphasis on the potential (but by no means guaranteed) well being during childhood of the person with Down's Syndrome rather than on the overall well being and length of life of the person with Down's Syndrome: 'Presumably, these clinicians must have believed that the value of the life of the Down's adult was not as great as that of a Down's child and that, therefore, priority should be placed on at least ensuring that as many of these young lives were preserved as possible, whatever the consequences for their mortality or quality of life as adults'. Doyal is equally unimpressed with the Alzheimer's disease argument, saying: 'Just as it would not have been possible to predict which children would be most symptomatic without surgery, it would equally have been impossible to predict which adults who had received surgery would have the poorest quality of life, including developing Alzheimer's'.
- 29.129 We asked Professor Chris Ham, Director, Health Services Management Centre, School of Public Policy, University of Birmingham, a health care academic who has written extensively on rationing, to describe how decisions were made about who would benefit from treatment. He described the complexity and tensions involved in making decisions when so many vested interests are at stake. The starting point for treatment in the NHS is that access to services should be based on need and that 'by implication, patients should not be discriminated against on arbitrary grounds'. He defined need as 'the ability to

benefit', which meant an extension to life or avoidance of death or gains in the quality of life. He stated: 'In the case of children awaiting heart surgery at the RBH, it would seem fairly clear that a need existed That is, an effective treatment was available which offered either an extension to life or improvements in the quality of life. There may have been some uncertainty about the benefits available to Down's Syndrome children compared with other children but the likelihood of benefit was not in question'.

- 29.130 Several experts referred to the differences in the exercise of clinical judgements by RBH doctors from their peers in other hospitals as lending substance to the argument that there was unfair discrimination against Down's Syndrome children at the RBH. In their view, evidence that cardiologists in other hospitals were reaching different decisions within three to six months of the original consultation at the RBH using their judgement and discretion, was significant. We felt there were other reasons which could account for this, such as centres taking different approaches and the tendency for doctors being appealed to for a second opinion to try to deliver what the patient (in this case the parent) wants. Further, it is not clear that, if parents had remained with the RBH, the doctors would have maintained their decision not to operate at a subsequent consultation. It is impossible to say. What is clear, however, is that a few of the parents we interviewed felt unable to remain with the RBH, believing this would not be in their child's best interests. In our view, their loss of trust in the RBH is regrettable.
- 29.131 In their report, the DHG referred to a BBC interview with one of the doctors in June 1998 (87) when he said that there had been a change of policy after the Melbourne Children's Hospital paper had shown improved mortality rates. This doctor reportedly said that, since that paper had been published, doctors had tried to operate on any child with that combination of abnormalities within the first 6 months. The DHG paper reviewed the new referrals for the period 1990-1999 and contended that: '.... there does not appear to be any noticeable increase in the surgical rate at Royal Brompton for children with Down's Syndrome and AVSD'. We have already discussed (see paragraphs 29.6 and 29.7) the fact that RBH appeared to be doing at least the expected number of repairs of CAVSD throughout the 1990s when compared to national figures. We recognise that there are many factors, as well as RBH doctors' decisions, that may have altered numbers of operations including pre-natal diagnosis and changing referral patterns.

CONCLUSIONS

29.132 We discuss our assessment of the evidence under the four categories of discrimination that we identified earlier in this Chapter at paragraph 29.17.

a) Was there discrimination in the treatment offered?

- 29.133 In our view there was an agreed practice throughout the 1980s to recommend medical management rather than surgical intervention for children with Down's Syndrome. We consider that during the 1980s this approach was in keeping with the practice of many other centres at that time and was based on a justified concern about the high risks of surgical correction. The views of some doctors at RBH were encapsulated in the *Lancet* paper published in 1985. Whatever the rights or wrongs of the paper's arguments and conclusions, we consider that the authors, in bringing such issues into open debate, made an important and courageous contribution to a subject of great clinical and ethical significance.
- 29.134 However, the importance which continued to be attached to discussion of non-surgical management into the mid 1990s, evidenced by the 1994 paper, was in our view too cautious by comparison with other centres, which by that time were offering surgical correction without the need for the same level of discussion as when the risks were higher. We are uncertain whether this approach was attributable to a paternalistic system of clinical care based on a policy of 'do no harm', or to an over-willingness to take account of the needs of the family in making judgements as to what was in the best interests of the child; but its effect was to give rise to a perception among some parents that the life of an adult with Down's Syndrome was seen as less worthwhile than either the life of a child with Down's Syndrome or of an adult without Down's Syndrome.
- 29.135 In contrast to the more aggressive and more risky approach towards surgical correction in children with Down's Syndrome taken by some other centres, some doctors at the RBH appeared to some families as reluctant to offer life-saving surgery to such children. We accept that these RBH doctors may not have been intentionally discriminatory in the way in which treatment was offered to some children, but that was, in our opinion, the effect of their approach as it appeared to the parents who made representations to us. It seems to us that, at what was for many the very early stage of parenthood, the parents acted on the

advice they were given, whilst trying to get to grips with complex information about their child's disabling condition. It is important for paediatric cardiologists to remember their power and their patients' vulnerability – never more pronounced than when dealing with parents whose baby has a heart defect. If a doctor advises against operating because of the high risk, it would be difficult for the parents to insist on surgery as they place their trust in him or her, as the expert, to guide them. However, as some families became more self-reliant and informed about their child's condition, they began to question some of the information they had been given. As they bonded with their new infant, they also felt strongly protective of his or her life and started to search for solutions and alternatives to those offered.

- 29.136 The doctor should always act in the best interests of the patient, in these cases the child. It appears to us that sometimes the assumed needs and interests of the parents and other family members may inappropriately have been taken into account by some doctors, in addition to those of the child. Although this was a commonly-held view within society at the time, it is not now considered good professional practice. By moving on occasions beyond an infant's heart condition and into non-cardiac concerns (such as whether the child would face a risk of Alzheimer's disease as an adult), it could be argued that some doctors strayed beyond the legitimate remit of paediatric cardiology into areas that could be better handled and dealt with by other disciplines.
- 29.137 We recognise that good doctors should be knowledgeable about the whole needs of a child with Down's Syndrome, not just the presenting problems, and will use consultations to provide parents with other clinical information that is relevant to the child's treatment. We are aware that many doctors dealing with children with Down's Syndrome who require life-saving surgery have had concerns for the families who are going to have to care for them. They are faced with parents who are often very distressed indeed to have learnt, often within the last few days or weeks, that their child has Down's Syndrome and who are struggling to adapt to it. In the face of this distress, doctors know that in offering a child surgical correction they are deciding not only his or her future but also the fate of his or her parents and perhaps other members of their family, possibly for the rest of their lives.
- 29.138 In our view, however, decisions affecting a child with Down's Syndrome should be based on judgements relating to the clinical management of the child's condition, not upon wider issues for the child (still less for his or her parents). While it is reasonable for a paediatric

cardiologist to inform parents of the risk of the early onset of Alzheimer's disease in adulthood, it is not, in our view, appropriate for treatment decisions to take account of this factor.

29.139 We conclude, therefore, that some doctors at the RBH, by taking into account non-cardiac concerns and the possible future demands on the family, did not focus sufficiently on what was in the best interests of the child as the patient. As a result the treatment offered was construed by parents as discriminatory.

b) Was there discrimination in the treatment delivered?

- 29.140 Some of the families alleged discrimination in the treatment that was delivered to their child. We found no child who presented from 1990 onwards who did not receive appropriate treatment; and we have already pointed out that before 1990 it was reasonable for the medical management option to be recommended because of the high mortality risk associated with surgery. We accept that in some cases surgery was delivered by other centres after a second opinion had been sought by the parents. In these cases it is impossible for us to know what would have happened if the child had remained at the RBH.
- 29.141 On reviewing the medical records, our independent paediatric cardiologists felt that the treatment had been at least satisfactory and often good. When children had been operated on at the RBH, the clinical and surgical management in each case was considered by them to have been of a high standard. The decisions not to offer surgical correction straight away in respect of cases with VSD were felt to be correct, as long as a follow-up appointment was made, as was the practice, to review the child's progress and consider surgery if the lesions did not get smaller or close spontaneously. We found that this approach was well recorded in the medical records from the earlier era of those families who went elsewhere for treatment.
- 29.142 In those patients from the earlier era who did not undergo surgery and who are being managed locally, there appears to have been a failure in some instances sufficiently to offer specialised treatment, guidance and support to families whose children were destined to decline in health in their teens. We have not been able to scrutinise district hospital case

notes to assess the evidence and establish whether the standard of follow-up care was suboptimal as the parents allege.

- 29.143 The establishment of the GUCH clinic by the RBH was a response to these needs in older children with cardiac conditions. We view this as a great improvement in the service for families with older children with Down's Syndrome who had attended RBH in the 1980s.
- 29.144 We found no evidence of discrimination in treatment delivered, and conclude that this was consistently satisfactory or good.

c) Was there discrimination in the provision of advice?

- 29.145 Most of the families believed that misleading or inappropriate advice had been given in their child's case. Some families claimed that risks for operations had sometimes been overstated in order to deter parents from consenting to surgery, and that the prognosis for a child who was managed medically was not accurately portrayed. For example, they felt that the gradual deterioration of these children as they became older, and suffered from the increasing effects of pulmonary vascular disease, had not been mentioned. Two families remembered being told that their child might develop Alzheimer's disease prematurely if he or she did survive surgery, but not that the alternative of medical management might result in an early death from pulmonary vascular disease and right heart failure, which could be slow and distressing.
- 29.146 Our doctors found no situation in which an inappropriately high risk had been quoted for surgery. Indeed, in some of the cases where a family had successfully sought surgical correction for their child elsewhere, parents accepted that their child's surgery had carried a high risk and that this risk had been taken in pursuing such a course of action. We realise that any child going elsewhere and dying as a result of surgery or prematurely after surgery would not be likely to come to this Inquiry's attention.
- 29.147 The infants who were managed medically in the late 1980s are now entering their teenage years. Their parents feel that they were not adequately informed about their child's quality of life with pulmonary vascular disease in the long term. In some instances, there appeared to be deficiencies in the arrangements or follow up for these patients, although it is not clear whose responsibility this was. These families are now having to cope with a young

adult suffering from very distressing symptoms for which they were inadequately prepared. Until their involvement in the GUCH clinic at RBH, they felt inadequately supported by the cardiological service. The opening of this clinic has done a great deal to support families in these situations and is much appreciated by the patients and parents who are warmly welcomed and given time and advice in a caring atmosphere. The GUCH clinic has been a major improvement in their care.

- 29.148 We suggest that the Trust undertakes a retrospective study to identify all children with Down's Syndrome who were treated medically and are now likely to be suffering from pulmonary vascular disease. This should include targeted follow up to identify their current needs, assess whether these are being met, and to plan their ongoing care needs, particularly in respect of terminal care.
- 29.149 It is clear from the published evidence (81) that well into the 1990s the merits of medical management for CAVSD were still being expressed by some RBH doctors at variance with most other centres. Some parents have complained that they were not given sufficient information on the benefits and risks of different treatments in order to make an informed choice, nor were they encouraged to seek a second opinion.
- 29.150 We conclude that in some cases there was a failure to provide a balanced view of all the options available to the families whom we saw. This meant that such children were less favoured in accessing treatment by reason of their Down's Syndrome.

d) Was there discrimination in doctors' attitudes?

- 29.151 The majority of the families we saw felt that communication in their child's case was at some time either inappropriate or insensitive. Remarks alleged to have been made by the staff carried for parents the implication that children with Down's Syndrome were of less value to society, or were less suitable recipients of scant NHS resources, than other children. This area of concern was commonly expressed in the group presentation but, as discussed above, we have been unable to investigate these allegations further.
- 29.152 The doctors are insistent that such insensitive remarks or inappropriate attitudes would not have been made or occurred. This area of parents' concern, and the intensity with which it was expressed to us, does however suggest that there may have been a breakdown in

communication between some doctors and these families and that consultations may in some cases have lacked the sense of partnership that parents reasonably expected.

- 29.153 Furthermore, it appears to us that there were cases where, in the course of advising on whether the surgical or medical management option would be chosen, reference was made to the non-cardiological possibility of the child developing early-onset Alzheimer's disease in adult life. For it to be implied in the 1990s, in the course of such advice, that the prospect of a shorter life unthreatened by the (now greatly reduced) risk of surgery was better than a long life with the risk of early onset of Alzheimer's disease was in our view inappropriate and unacceptable. We do not believe, for example, that a non-Down's Syndrome patient in his or her sixties requiring coronary by-pass surgery would, at a consultation, be advised of the likelihood of Alzheimer's disease in their late eighties, (an equivalent timespan), the potential burden of this probability on their family, let alone be steered away from such surgery as a result. It is our view that, even if it had been known that a particular child would contract Alzheimer's disease in adulthood, it would still be discriminatory to take account of that in deciding on their treatment.
- 29.154 From the consistency of oral evidence we have heard it is at least clear that there was a serious breakdown of trust and communication at the RBH between some clinicians and these families, which gave rise to a belief by parents that discrimination took place.
- 29.155 We are unable to conclude whether the impression of the families that some doctors at the RBH during these years were insensitive and displayed inappropriate attitudes towards children with Down's Syndrome was well founded. Although we understand why some parents believe that discrimination took place, the evidence was not available to substantiate this claim. Nevertheless, the implementation of our guidance on the prevention of discrimination against children with Down's Syndrome (see Appendix 14) should ensure that families in future have confidence in the services provided.
- 29.156 Finally, we wish to state that, in presenting our conclusions, we believe that throughout the period under review the doctors acted in good faith, believing that their actions were in the best interests of the children concerned. However, by the early 1990s, some of the views of individual doctors were, in our opinion, mistaken in the light of contemporary knowledge, but were not unprincipled. During the 1980s, public consensus on the subject of disability in general, and learning disability in particular, shifted considerably. It

became clear that children with Down's Syndrome had the same legal right to life as other children, and this must mean the same right to adult life. From the evidence we considered – from families, published papers and peer review – it appears that this shift in public thinking was not reflected consistently in the work of some of the RBH doctors.

29.157 In continuing until the mid 1990s – when surgical results for correction of AVSD had improved markedly - to advise parents of children with Down's Syndrome about the medical management option as an alternative to surgical intervention, as we find they did, we conclude that the practice of some RBH doctors was at variance with practice at many other centres. Although it is accepted that no discrimination was intended by this more cautious approach, the effect in some cases appeared to parents as reluctance to offer the opportunity for surgery. In some cases it appears, in our view, that some doctors failed to provide a balanced view of all the options available to families. Although we found no evidence that the risks of surgery were overstated, we were concerned that undue weight appeared to have been given in some cases to the possibility of earlier onset of Alzheimer's disease in adulthood, and the assumed needs and interests of the parents. While well intentioned, we believe that this was misconceived and paid insufficient regard to the basic rights of children with Down's Syndrome. We have been unable to draw findings in respect of parents' allegations about insensitive and inappropriate attitudes and remarks on the part of some RBH clinicians, and the clinicians deny such attitudes and remarks. However, the consistency of evidence from parents suggests to us that there was a serious breakdown in communication and trust between some doctors and these families, giving rise to a belief among parents that discrimination took place in the way that advice was given and treatment offered.

Guidance on the avoidance of discrimination

29.158 Although we found no evidence of discrimination in the treatment delivered, it is essential for the RBH to take steps to assure the public that its services for all children are open, transparent and free from discrimination. This will help to strengthen both the confidence of parents and children who attend the RBH, and of the staff providing treatment and care. It will also reassure families whose children will be referred to the RBH in the future. The Trust should also establish and maintain constructive dialogue with the organisations representing people with Down's Syndrome and their families.

- 29.159 Many of those with whom we have discussed the subject have said that both users and providers of health services would benefit from explicit guidance for health professionals on the avoidance of discrimination against children with Down's Syndrome. The aim would be for this to be introduced throughout the NHS in order to minimise the risk of discriminatory practices and treatment, however unintentional. In an Adjournment Debate on 4 July 2000, the Parliamentary Under-Secretary of State for Health referred to the 1998 guidance *Signposts for Success*, which required commissioners of services to ensure that there are guidelines for the sensitive sharing of information about a child's disability. More recently, in commenting on the case of Joanne Harris, now a young adult with Down's Syndrome, who was refused a heart transplant, the Secretary of State for Health stated on 29 September 2000 (88) that: '*No child should ever be discriminated against or refused treatment because they have Down's*. *We would expect every doctor to treat each child according to clinical necessity and that includes screening for heart defects at birth. All children should get the treatment they need when they need it'.*
- 29.160 In preparing guidance, we have been helped by the Down's Heart Group. We have also seen a 1998 report from the Royal College of Physicians on *Disabled People Using Hospitals* (89). This recommends the establishment of a disability advisory group accountable through the chief executive to the Trust Board. It also underlines the importance of medical staff supporting developments needed to improve the hospital environment for disabled people, and attending training sessions.
- 29.161 Our model guidance is set out in Appendix 14. Although it is drawn up to guarantee standards in treatment and care offered to children with Down's Syndrome, it will be applicable for all agencies purchasing, delivering and monitoring care for people with a disability.

RECOMMENDATIONS

The Panel recommends that:

109. The Trust takes steps to encourage clinical and other relevant staff at the RBH to work closely with organisations and support groups for children with Down's Syndrome and other disabilities, in order to promote understanding and confidence in the services provided for such children.

- 110. The Trust's policies confirm clearly that people with a disability are entitled to, and will be accorded in all departments and at every level, the same rights of access to services as those without a disability; and that consultants should take the lead in implementing policies and influencing attitudes regarding equality of access.
- 111. The Trust ensures that decisions about treatment are based on transparent criteria, with the individual patient's own needs and interests having primacy in the decision-making process.
- 112. The Trust ensures that consultants are accountable for the advice given to parents and for the resulting decisions, are prepared to demonstrate openly how their decisions were reached, and record in the child's medical records what was said to the parents, including the reasons given for any advice.
- 113. The Trust ensures that doctors regard the parents of children with a disability as partners in their child's care, providing them with information and advice that is clear and is followed up in writing. They should check that parents (and where appropriate the child) have fully understood the options for treatment, and have had the opportunity to express their own views in respect of all decisions about their child's treatment.
- 114. The Trust establishes mechanisms whereby patients or parents who are dissatisfied with a clinical decision, or about the manner in which it was reached, can raise their concerns with an independent person within the Trust without fear of recrimination; and that a non-Executive member of the Trust Board be given special responsibility for monitoring services for people with a disability.
- 115. The Trust ensures that, in complex decisions, parents are given the opportunity to return within a short time to discuss the situation further with the consultant if they so wish and also be offered a second opinion if uncertainty and confusion persists.
- 116. The Trust adopts a multi-disciplinary approach, as children with complex conditions often require a range of supports and interventions; and that other services (social services, psychology, counselling, support groups) should be alerted after diagnosis to ensure that as much assistance and advice as possible is provided for the family. We

recognise that in many cases these functions will be carried out in the community or through District General Hospitals. The responsibility of the Royal Brompton Hospital is to integrate with these agencies.

- 117. The Trust requires doctors to undergo special training in imparting difficult news to parents about their child's condition, emphasising that negative perceptions about the value of the life of a child who has any form of disability or special needs are unacceptable.
- 118. The Trust undertakes a retrospective study to identify all children with Down's Syndrome and associated CAVSD and similar lesions who were treated medically and who are now likely to be suffering from pulmonary vascular disease. This should include targeted follow up to identify their current needs, assessing whether and how these are being met, and incorporate plans to satisfy their ongoing care needs, particularly in respect of the provision of terminal care.
- 119. The Trust implements the model guidance on the avoidance of discrimination, as set out in Appendix 4 or this Summary and Appendix 14 of the main report, and commends this model guidance to the Department of Health for wider dissemination across the NHS.

Part Six

SUMMARY OF RECOMMENDATIONS

PART ONE: BACKGROUND

Chapter 2: GUIDING PRINCIPLES AND PROCEDURES

The Panel recommends that:

1. The Department of Health ensures that early attention be given by the Commission for Health Improvement to the preparation of guidance for those commissioned by government or an NHS Authority to conduct an independent review of the delivery of a clinical service.

PART TWO: ISSUES AT THE ROYAL BROMPTON HOSPITAL

Chapter 7: DIAGNOSIS

- 2. The Department of Health ensures there is no organisational or financial impediment within the NHS to parents exercising their right to a second opinion.
- 3. The Trust considers doctors providing tape-recordings of key consultations about diagnosis and treatment options, with a detailed follow-up letter being sent out within 20 days confirming what was said.
- 4. The Trust ensures that letters to GPs are copied to parents so that they can see any changes in the diagnosis or planned treatment.
- 5. The Trust devises ways of giving parents, guided by cardiac liaison nurses, access to appropriate sources of information including the hospital library, details of relevant websites, books, journal articles, reviews, nursing articles and teaching videos providing information on the diagnosis and treatment of congenital heart disease and details of relevant support organisations.
- 6. The Trust explores how restoration of pre-admission clinics might be funded, as an important contribution to parents' understanding of proposed treatment for their child.

- 7. The Trust makes it clear to parents or patients, through its information booklets and at consultations, that they have a right to ask for a second opinion.
- 8. The Trust approaches other paediatric cardiac centres in London with a view to rationalising the staffing of, and responsibility for, peripheral clinics, ensuring that medical, nursing and technical staffing levels are sufficient to allow adequate consultation time, appropriate investigation facilities and support for parents and patients.
- 9. The Trust discusses with local NHS Trusts the provision and funding of equipment at peripheral clinics so as to secure a uniform and high standard of service delivery.
- 10. The Trust ensures that accommodation and staffing levels are improved for outpatient consultations in paediatric cardiac services with the merger of the RBH and Harefield services in 2001.

Chapter 8: CONSENT

- 11. The Trust, specifically the Medical Director, determines with consultant staff how to secure and monitor compliance with the Trust's policy guidance on consent, with the objective of sharing information with parents about treatment options and risks in an open and sensitive manner and of achieving partnership in decision making.
- 12. The Trust should, in addition to the existing comprehensive consent procedure, prepare succinct and explicit guidelines making clear to all medical staff that:
 - Consent must be real and informed.
 - Consent must be obtained by the consultant or a senior doctor familiar with the child's case, who is competent to undertake the preferred treatment option.
 - Consent should be sought, except in an emergency, at a pre-arranged time and in a place where reasonable privacy and quiet can be provided.

- 13. The Trust commissions a formal audit of consent procedures in paediatric cardiology and cardiac surgery, and for research on children with congenital heart disease, from the RBH Audit Department, and repeats this on an annual basis.
- 14. The Trust implements a programme of training in obtaining consent for treatment and for involvement in a clinical research trial, with the Clinical Director and Research Director being accountable to the Trust Board for ensuring that relevant existing and new staff have been adequately trained.
- 15. The Trust ensures that, when giving parents information on risks, clinicians give details of both the national and hospital figures for the surgical procedure proposed in addition to their own outcome figures and the doctor's own assessment of risk in the light of this information.
- 16. The Trust builds on its reputation for pioneering treatments and research by having more detailed and readily available information on the quality of the service it provides in all areas. This includes not only surgical and interventional catheter short-term outcomes but also wider issues such as the provision of facilities for families, effectiveness of communication with referring hospitals and access to professional help with problems other than cardiac ones.
- 17. The Trust ensures that clinicians take whatever steps are necessary to be satisfied that a decision has been reached, with the parents, about how far their child should be included in discussions about his or her condition and future treatment, and that such a decision should have regard to the child's level of understanding.
- 18. The Trust ensures that consent for participation in a clinical research trial be sought in good time and with supporting information in writing for the parents to study before giving their consent.

Chapter 9: THE CHILD'S STAY IN HOSPITAL

- 19. The Department of Health conducts further national discussions about the right, under the NHS Plan, of patients to receive copies of letters between clinicians, with the aim of ensuring that information is conveyed to patients in a meaningful way without impeding effective communication between professionals.
- 20. The Department of Health addresses urgently the recruitment and retention of nurses trained in paediatric intensive care.
- 21. The Trust ensures that, except in a clinical emergency, the surgeon always see the parents of any child before the operation takes place and report post-operatively on surgery.
- 22. The Trust ensures that, where a child's operation is postponed, the parents and the GP are contacted within two days to explain the postponement and the proposed arrangements and timing for a new admission date.
- 23. The Trust ensures that the parents be informed without delay, personally by the surgeon wherever possible, of the reasons for any change to the operating list affecting their child, and of any untoward occurrence during the operation.
- 24. The Trust ensures that its plans for the transfer of services from Harefield Hospital to the RBH builds on Harefield Hospital's family-friendly facilities and atmosphere; specifically that there is provision for a waiting room for parents while their child is undergoing surgery, and for a room in or adjacent to the PICU for parents who wish to remain near their child.
- 25. The Trust reviews how paediatric services can best be focused on the needs of children and their families, and can record key concerns and discussions with parents about the clinical management of their child.
- 26. The Trust ensures the named nurse informs parents of any change in overall clinical responsibility for the child's medical management.

- 27. The Trust reviews its policy of excluding parents from ward rounds and ensures that, as a matter of general policy, parents who are present in the hospital when a ward round takes place are welcome to attend.
- 28. The Trust ensures that, before a child is discharged from hospital, the ward or PICU, the designated member of nursing staff on duty that day tells the parents what follow-up arrangements they can expect and checks that the parents have a sufficient understanding of their child's care needs.
- 29. The Trust asks patients and parents whether they experienced real partnership in care and what obstacles to effective communication they encountered, in future satisfaction surveys and audits of service quality.
- 30. The Trust's staffing arrangements and booking systems make due allowance for time to develop trust and understanding with patients and parents.
- 31. The Trust ensures that, at the start of any consultation, patients and/or parents be asked whether they agree to the presence of postgraduate students, and that all those present wear name badges, are introduced to the patient and/or parents and have their roles explained.
- 32. The Trust's plans for the redevelopment of facilities for children's services give consideration to including video linking for teaching purposes.
- 33. The Trust includes communication skills in the training and development of clinical staff at all levels and in all disciplines.

Chapter 10: WHEN A CHILD DIES

The Panel recommends that:

34. The Trust draws up a protocol for informing parents about the death of a child in hospital, and for passing that information with the minimum of delay to other hospital departments, the GP and any consultant who referred the child to the RBH.

- 35. The Trust ensures that, where both a cardiologist and a surgeon have been involved in the child's care, they agree between them who should give the parents the opportunity of a follow-up meeting.
- 36. Pending new government measures on organ retention announced in January 2001, the Trust ensures that consent for a hospital post mortem, and where necessary for retention of any organs, always be sought by a fully registered medical practitioner who is familiar with the child's case and known to the parents, who should be given enough information, support and time to consider what is being asked of them.
- 37. The Trust ensures that, at the follow-up meeting, the parents are told the results of any post mortem and the analysis reached at the mortality meeting, and that a letter is sent confirming the information given orally.
- 38. The Trust ensures that at least one of the nurses on duty for each shift in PICU and HDU is familiar with hospital procedures and experienced in dealing with bereavement, and that this be the responsibility of the nurse manager in charge of these units.
- 39. The Trust more closely integrates the work of the multi-disciplinary bereavement team and the clinical team.
- 40. The Trust ensures that cardiac liaison nurses, when in post, work closely with the parents and the clinical team to ensure that the bereavement service is sensitive to the parents' needs.
- 41. The Trust seeks to identify and consult parents of children who have died, when reviewing their arrangements for bereavement group meetings and before finalising changes to current practice.
- 42. The Trust's policy and arrangements for bereavement training for staff involved in heart services for children be overhauled, as a matter of priority, to ensure:
 - The participation of all members of the clinical team, including medical staff at all levels.
 - Active interest and support by senior management and board members.

- Input, where possible, from bereaved parents.
- Access for staff to counselling support.
- 43. The Trust approaches a parent or representative group, such as Heartline, for assistance in revising its *Guide to the Post Mortem Examination*.

Chapter 11: RESOURCES

- 44. The Department of Health issues a National Service Framework for Paediatric Cardiac Services within the next 12 months setting out the national standards which parents have a right to expect when using these services.
- 45. The Trust publishes a clear statement of service outlining what standards parents have a right to expect in terms of:
 - Accessing information (especially on risks upon which to base their decision about whether or not to proceed with life threatening surgery).
 - Residential accommodation in the hospital on the night before surgery and whilst their child is in intensive care.
 - Follow-up care for children after they have been discharged from hospital.
- 46. The Trust ensures that the Clinical Director assumes responsibility for annual service audit reporting to the Trust Board on how far these standards of service have been met, setting out the reasons for any under-performance and highlighting what, if any, resources, particularly increases in staffing levels, are needed to enable the service to meet these standards.
- 47. The Trust Board Chairman designates a non-Executive Director to be an advocate for paediatric cardiac services at Board level taking specific responsibility for ensuring that services are regularly reviewed and that they meet the needs of children and their parents.
- 48. The Trust Board ensures that, in redesigning services for the merger of the RBH and Harefield paediatric cardiac services on the RBH site and their potential further relocation

to the Paddington Basin development in 2006, the physical space allocated to the service is increased and improvements made in line with the recommendations set out in the Panel's interim report to the Kensington & Chelsea and Westminster Health Authority dated March 2000, reproduced at Appendix 7 of the main report.

- 49. The Trust Chief Executive investigates the effectiveness of peripheral clinics and assesses whether enough back up is available in terms of diagnostic capabilities.
- 50. The Trust investigates what package of benefits is needed to recruit and retain nursing staff, particularly intensive care nurses for the merged paediatric cardiac services, and considers re-investing part of the savings arising from the merger to fund accommodation options for nursing staff in Central London.

PART THREE: ISSUES AT HAREFIELD HOSPITAL

Chapter 14: DIAGNOSIS

In addition to the recommendations set out in Chapter 7 the Panel recommends that:

- 51. The Trust commissions research to evaluate different methods for conveying complex clinical information to parents in a form which they can easily understand and retain.
- 52. The Trust ensures that the paediatric clinical psychologist continues to be involved in difficult and complex cases right from the start, and that this service is periodically reviewed to ensure that sufficient resources are provided to enable this to happen.
- 53. The Trust puts in place arrangements for parents to be given access to a computer and helped to use the internet for the purpose of obtaining further information on their child's condition. This should include guidance on how to find and evaluate medical information.

Chapter 15: CONSENT

In addition to the recommendations set out in Chapter 8 the Panel recommends that:

- 54. The Trust reviews the operation of existing protocols on consent at Harefield Hospital to ensure that parents, and the child where appropriate, have an opportunity to meet the surgeon prior to giving consent for surgery.
- 55. The Trust ensures that all cases of children requiring surgery at Harefield Hospital are fully discussed by the surgeon with other members of the clinical team prior to a decision being made to proceed with surgery.
- 56. The Trust ensures that doctors, when giving information on risk factors, include how these figures are arrived at and provide parents with comparative information for their own outcomes, the Trust as a whole and the national position.

Chapter 16: DAY OF OPERATION

In addition to the recommendations set out in Chapter 9 the Panel recommends that:

57. The Trust reviews anaesthetic protocols to establish what should happen when surgery is delayed and a child's pre-medication has worn off before the child has been anaesthetised.

Chapter 17: POST-OPERATIVE CARE

In addition to the recommendations set out in Chapter 9 the Panel recommends that:

- 58. The Trust reviews medical staffing structures to ensure that adequate cover is provided to cope with staff sickness and holiday arrangements without requiring consultant staff to work a more than one in three rota.
- 59. The Trust ensures that new junior doctors coming onto the paediatric wards are given specific focused training in intensive care before being left in charge of the paediatric intensive care unit, even for only a short period.

- 60. The Trust considers reviewing specialist sources of advice in respect of known complications likely to arise from paediatric cardiac services, with the aim of ensuring that named doctors are identified who can respond promptly within 24 hours to requests for advice. A synopsis of these sources of advice should be made available to parents on their child's admission to hospital so that they are fully informed of the hospital's links with key sources of specialist advice.
- 61. The Trust continues to review its infection control policies and ensure staff are aware of the need to maintain vigilance.

Chapter 18: PARENTAL INVOLVEMENT

- 62. The Department of Health reviews arrangements for the provision of social work support to children attending tertiary referral centres and ensures that all children are provided with an appropriate level of support.
- 63. The Trust revises existing protocols to ensure that parents are fully involved in decisions on their child's care and treatment, particularly where this involves the adoption of heroic measures, and that such decisions be discussed at a full team meeting allowing the full range of options to be considered. In the event of there being any dissent within the team on the right way forward, the parents should be given the option of seeking independent advice from the Trust's Clinical Practice Committee on the course of action proposed.
- 64. The Trust assesses whether it is possible to establish a volunteer scheme on a readily accessible database to provide mentoring or peer group support from 'experienced' parents to parents whose child is undergoing planned surgery. In the case of emergency admissions, consideration to be given to whether a similar scheme would work in these more difficult circumstances.
- 65. The Trust ensures that early attention is given to reviewing the staffing levels for the clinical psychologist service so that the injection of additional resources can be considered in the next financial year if required.

Chapter 19: WHEN A CHILD DIES

In addition to the recommendations set out in Chapter 10 the Panel recommends that:

- 66. The Trust ensures that there is a member of staff or competent lay volunteer who will make all the necessary arrangements to ensure that, in the immediate aftermath of a child's death, the family are able to get home safely.
- 67. The Trust, in its current review of bereavement services, pays particular attention to the needs of children living in other parts of the country to ensure that ongoing sources of specialist advice are available to parents.
- 68. In cases where there was a genetic component to a child's illness and subsequent death, arrangements should be made for parents to have an early meeting with a foetal cardiologist so that they can discuss monitoring arrangements in respect of any future pregnancies and with a clinical geneticist so that they can make informed decisions about future pregnancies.

Chapter 20: RESOURCES

In addition to the recommendations set out in Chapter 11 the Panel recommends that:

- 69. The Department of Health gives early consideration to ensuring that the skills and expertise of staff currently working in the Harefield paediatric transplant service and the associated scientific research programme be retained within the NHS.
- 70. The Department of Health ensures that the development of any future highly specialist or complex paediatric services is funded in a way which recognises the need to include funding for parental support services.
- 71. The Department of Health ensures that, when considering the rolling out of any future innovative paediatric services, these services are added to the relevant National Service Framework, and that mandatory guidelines are issued as to the resources required to fund such services, including the number of clinical staff who must be in post to secure the provision of safe, family-centred services of a uniformly high standard.

PART FOUR: ISSUES AFFECTING BOTH HOSPITALS

Chapter 21: CHILDREN WITH NEUROLOGICAL INJURIES

- 72. The Department of Health introduces a national system of reporting serious injury arising from paediatric heart surgery. This should provide that every such event must be reported to a central agency, which maintains a comprehensive dataset permitting the comparison of one event with another.
- 73. The Department of Health establishes a transitional expenses fund available nationally on which families could draw to cover care, equipment and other expenses arising suddenly in a situation where they cannot easily adapt to caring for an injured child without such help. This should be retrospective.
- 74. The Department of Health ensures that families of children who are neurologically damaged in the course of medical treatment have the benefit of dedicated liaison services allowing them to access support services easily when the need arises.
- 75. The Trust ensures that cardiac liaison nurses or other designated staff be available on the ward and PICU on a daily basis to help families deal with the fear of and the development of neurological injury.
- 76. The Trust ensures that staff are trained to recognise that acknowledgement that a neurological injury may have or has occurred is vitally important to parents; frank communication of hopes as well as fears is the best policy.
- 77. The Trust ensures that paediatric neurologists be actively involved in the management of children who may have acquired neurological injury, with such management to include accurate advice and diagnosis to families.
- 78. The Trust ensures that physiotherapists trained in rehabilitation and others who are specialists in this field be available on the ward and in PICU to provide baseline

assessment, intensive therapy and demonstrate to parents the type of specialised physio support that they need to access on a local basis.

- 79. The Trust develops a protocol requiring notification of every instance of neurological injury following operation, a full investigation including recorded interviews with relevant staff, a morbidity meeting which is properly minuted and recorded, and a meeting with the parents to report on the results of the investigation and the meeting. This meeting should be minuted and the minute circulated to parents and clinicians.
- 80. The Trust's audit arrangements monitor these outcomes closely and develop links with other databases that are attempting to do the same.
- 81. The Trust locates a specially designated and trained social worker in the PICU, part of whose duties are to work alongside families and liaise directly with local social services departments, to ensure that plans are made to support the child and the family on their return home.

Chapter 22: CARDIAC LIAISON NURSES

- 82. The Department of Health embarks on a programme designed to secure a marked increase in the availability and retention of nurses trained in paediatric intensive care by reviewing grading and remuneration for specialist nurse posts.
- 83. The Trust commits itself to increasing the number of CLNs progressively over the next three years, including a significant expansion in the CLN service with the transfer of the Harefield paediatric cardiac service to the RBH site in 2001.
- 84. The Trust seeks advice from other paediatric cardiac centres in the UK to clarify the role of their CLNs prior to, during and after hospital treatment and care, particularly in respect of the provision of support for families.

Chapter 23: COMPLAINTS AND RELATED ISSUES

- 85. The Department of Health considers with all relevant interests our proposal that staff involved in a complaint or its investigation be identified in the response to the complainant unless, exceptionally, that might expose the member of staff to serious personal risk.
- 86. The Trust ensures that analysis of any complaint, for the purpose of the report to the Trust Board and for action, establishes whether poor communications were a contributory factor.
- 87. The Trust improves the content and display of complaints leaflets and posters to make them more accessible and welcoming to patients and relatives, and in doing so involves representatives of users of the service.
- 88. The Trust reviews the wording of the patient satisfaction survey questionnaires with a view to making them easier to follow.
- 89. The Trust considers sending a follow-up letter after six months, informing the complainant about changes that have been made as a result of the complaint and with what effect.
- 90. The Trust explores how to encourage medical staff to participate in complaints training, and to view complaints handling as an integral part of total patient care.
- 91. The Trust provides support systems including stress counselling for any staff involved in a complaint procedure.
- 92. The Trust develops a partnership with parents' organisations such as Heartline, the DSA and the DHG to ensure parents' views are at the heart of service development.

Chapter 24: MEDICAL RECORDS

The Panel recommends that:

- 93. The Department of Health ensures that, for any Inquiry established within the NHS, sufficient additional resources are allocated to enable copy records to be provided without detriment to the continuing responsibility to meet the day-to-day needs of the clinical service.
- 94. The Trust ensures that all clinical staff be reminded of the importance of recording key decisions, events and discussions affecting a patient's care and management.
- 95. The Trust underlines the importance of not removing documents from case-note folders, of keeping documents in proper sequence, and of notifying the records library immediately of any movement of records, to all NHS, academic and research staff working in the Trust's hospitals.
- 96. The Trust Medical Records Committee reviews arrangements for the training of clinical and other staff in record keeping.
- 97. The Trust includes monitoring of compliance with good record-keeping practice within its arrangements for clinical audit and performance.
- 98. The Trust ensures that any requests from patients or parents for copy records are logged and their handling monitored by the Patient Services Manager.
- 99. The Trust Board receives periodic reports on policies and performance in record keeping and maintenance.

Chapter 25: CLINICAL AUDIT

The Panel recommends that:

100. The Department of Health should pursue vigorously and support financially the development of a national system of coding and classification for congenital heart disease,

with a view to securing a database that enables meaningful comparisons and decisions to be made both within the UK and internationally. In addition the Department of Health should consider the staffing and pay structures for clinical audit staff to maintain their essential skills within the NHS.

- 101. The Department of Health should encourage the relevant Royal Colleges and specialist medical associations to define the timely and competent input of clinical data into audit databases as a core clinical responsibility, and regard evidence of such activity as a pre-requisite for individual professional accreditation and for a centre's accreditation for postgraduate specialist training.
- 102. The Trust's Clinical Audit Office should deliver support and services to the clinical directorates through annually reviewed service agreements, which require the directorates to provide the information required to support the audit process.
- 103. The Trust Board should receive regular progress reports on clinical audit arrangements and in particular on the development of, and results from, data relating to paediatric cardiac surgery.

Chapter 26: POLICY ON SPEAKING UP

- 104. The Trust revises its policy on 'Speaking Up' in the light of the Panel's comments and to reflect more closely the provisions of circular HSC 1999/19.
- 105. The Trust consults staff in preparing a revised policy, to ensure that the wording is clear and helpful.
- 106. The Trust Board ensures that adequate arrangements have been made for all RBH staff to be fully briefed on the policy and of their own responsibilities for raising genuine concerns in a responsible and timely manner.

PART FIVE: CHILDREN WITH DOWN'S SYNDROME

Chapter 27: SETTING THE CONTEXT

The Panel recommends that:

- 107. The Department of Health ensures that the training of all health professionals should include the process and issues involved in taking decisions on rationing and priorities, and how to carry out their practice in a way that is non-discriminatory. Discrimination should be defined as the unfair or unreasonable introduction into the decision-making process of factors which differentiate on subjective or value-driven grounds between people with like needs and which do not serve the best interests of the individual concerned.
- 108. The Trust invites the Department of Health, with relevant professional and consumer bodies, to draw up guiding principles and protocols for taking decisions on priorities in allocating resources and delivering health care at each level of the service.

Chapter 29: ALLEGED DISCRIMINATION AGAINST CHILDREN WITH DOWN'S SYNDROME

- 109. The Trust takes steps to encourage clinical and other relevant staff at the RBH to work closely with organisations and support groups for children with Down's Syndrome and other disabilities, in order to promote understanding and confidence in the services provided for such children.
- 110. The Trust's policies confirm clearly that people with a disability are entitled to, and will be accorded in all departments and at every level, the same rights of access to services as those without a disability; and that consultants should take the lead in implementing policies and influencing attitudes regarding equality of access.
- 111. The Trust ensures that decisions about treatment are based on transparent criteria, with the individual patient's own needs and interests having primacy in the decision-making process.

- 112. The Trust ensures that consultants are accountable for the advice given to parents and for the resulting decisions, are prepared to demonstrate openly how their decisions were reached, and record in the child's medical records what was said to the parents, including the reasons given for any advice.
- 113. The Trust ensures that doctors regard the parents of children with a disability as partners in their child's care, providing them with information and advice that is clear and is followed up in writing. They should check that parents (and where appropriate the child) have fully understood the options for treatment, and have had the opportunity to express their own views in respect of all decisions about their child's treatment.
- 114. The Trust establishes mechanisms whereby patients or parents who are dissatisfied with a clinical decision, or about the manner in which it was reached, can raise their concerns with an independent person within the Trust without fear of recrimination; and that a non-Executive member of the Trust Board be given special responsibility for monitoring services for people with a disability.
- 115. The Trust ensures that, in complex decisions, parents are given the opportunity to return within a short time to discuss the situation further with the consultant if they so wish and also be offered a second opinion if uncertainty and confusion persists.
- 116. The Trust adopts a multi-disciplinary approach, as children with complex conditions often require a range of supports and interventions; and that other services (social services, psychology, counselling, support groups) should be alerted after diagnosis to ensure that as much assistance and advice as possible is provided for the family. We recognise that in many cases these functions will be carried out in the community or through District General Hospitals. The responsibility of the Royal Brompton Hospital is to integrate with these agencies.
- 117. The Trust requires doctors to undergo special training in imparting difficult news to parents about their child's condition, emphasising that negative perceptions about the value of the life of a child who has any form of disability or special needs are unacceptable.
- 118. The Trust undertakes a retrospective study to identify all children with Down's Syndrome and associated CAVSD and similar lesions who were treated medically and who are now
likely to be suffering from pulmonary vascular disease. This should include targeted follow up to identify their current needs, assessing whether and how these are being met, and incorporate plans to satisfy their ongoing care needs, particularly in respect of the provision of terminal care.

119. The Trust implements the model guidance on the avoidance of discrimination, as set out in Appendix 14 of this report (Appendix 4 of our summary report), and commends this model guidance to the Department of Health for wider dissemination across the NHS.

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