

# Chapter 1 – The Background to and Conduct of the Public Inquiry

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## The Terms of Reference

- 1 On 18 June 1998 the Secretary of State for Health announced to Parliament the setting up of this Public Inquiry under Section 84 of the National Health Service Act 1977 (the 1977 Act) into events at the Bristol Royal Infirmary. The Terms of Reference of the Inquiry were:

‘To inquire into the management of the care of children receiving complex cardiac surgical services at the Bristol Royal Infirmary between 1984 and 1995 and relevant related issues; to make findings as to the adequacy of the services provided; to establish what action was taken both within and outside the hospital to deal with concerns raised about the surgery and to identify any failure to take appropriate action promptly; to reach conclusions from these events and to make recommendations which could help to secure high quality care across the NHS.’

- 2 The Inquiry, therefore, was not required to consider only the actions of certain doctors, or to focus only on cardiac services provided under the supra regional service (SRS) for children under 1 year of age: it was required to look at the complete cardiac surgical service provided for children at Bristol during the period 1984–1995, and any relevant related issues.
- 3 Before, during and since the period of the Inquiry’s Terms of Reference, Bristol has been served by a group of hospitals. Prior to 1 April 1991 this group comprised the United Bristol Hospitals (UBH),<sup>1</sup> and following the adoption of trust status, the United Bristol Healthcare (NHS) Trust (UBHT).<sup>2</sup> The term UBH/T is used hereafter to refer to the hospitals comprising the UBH and the UBHT, both before and after trust status.
- 4 The paediatric cardiac surgical service was provided at two hospitals in central Bristol: the Bristol Royal Infirmary (BRI) and the Bristol Royal Hospital for Sick Children (BRHSC)<sup>3</sup> and thus the Inquiry was concerned with events at both sites.
- 5 An examination of the paediatric cardiac surgical service demanded a focus beyond events in the operating theatre itself. Any parent would consider that the (Bristol) ‘service’ began with the referral of their child to the BRI or to the BRHSC, and did not conclude until discharge from in-patient care (and the conclusion of any necessary follow-up).

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<sup>1</sup> The Bristol Royal Infirmary, Bristol Royal Hospital for Sick Children, Bristol Eye Hospital, Bristol Maternity Hospital, Bristol General Hospital, University of Bristol Dental Hospital. Between 1960 and 1974 they were joined by: Bristol Homeopathic Hospital and Farleigh Hospital

<sup>2</sup> The Bristol Royal Infirmary, Bristol Royal Hospital for Sick Children, Bristol Eye Hospital, Bristol General Hospital, University of Bristol Dental Hospital, Barrow Hospital, Keynsham Hospital, St Michael’s Hospital, Bristol Oncology Centre

<sup>3</sup> The BRHSC was formerly known as the Bristol Royal Children’s Hospital (the BRCH). It was also referred to in evidence as the Bristol Children’s Hospital (the BCH)

## The powers of the Inquiry

- 6 The Inquiry was set up under the 1977 Act and had certain powers conferred on it by that Act.<sup>4</sup>
- 7 The Chairman had the power to summon any person to give evidence or to produce documents to the Inquiry.<sup>5</sup> The Chairman was also empowered to take evidence on oath or affirmation.<sup>6</sup>
- 8 The 1977 Act also provided for the Secretary of State to order the costs of parties to the Inquiry to be paid.<sup>7</sup>

## The Inquiry Panel

- 9 The Chairman, Professor Ian Kennedy, and the other members of the Panel (Professor Sir Brian Jarman OBE, Mavis Maclean and Rebecca Howard) were independent of government, the Department of Health (DoH), the National Health Service (NHS), and any other body or organisation, in the conduct of the Inquiry.
- 10 Professor Kennedy is Professor of Health Law, Ethics and Policy at the School of Public Policy, University College, London.<sup>8</sup> Professor Jarman is Emeritus Professor at Imperial College School of Medicine at St Mary's Hospital, London, a member of the Standing Medical Advisory Committee to the Government, and was a GP Principal at Lisson Grove Health Centre in London NW8 until October 1998.<sup>9</sup> Rebecca Howard was the Executive Director of Nursing at the Manchester Children's Hospitals NHS Trust and a registered sick children's nurse. From September 2000 she has been the Director of Nursing at the Royal Liverpool Children's NHS Trust.<sup>10</sup> Mavis Maclean is Director of the Oxford Centre for Family Law and Policy, Oxford University.<sup>11</sup>

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<sup>4</sup> Section 84(1), 1977 Act. Anyone who, once summoned, refused to attend, or to produce documents to the Inquiry, would have been liable to a fine and/or imprisonment of up to six months, Section 84(4), 1977 Act

<sup>5</sup> Section 84(2)(a), 1977 Act

<sup>6</sup> Section 84(2)(b), 1977 Act

<sup>7</sup> See below at [para 21](#)

<sup>8</sup> Professor Kennedy holds degrees in law from universities in the UK and USA and is a Barrister and Honorary Bencher of the Inner Temple. Until December 1996, he had been Dean of the Law School at King's College London for ten years and was Director and then President of the Centre of Medical Law and Ethics which he founded in 1978. He has been a member of the Medicines Commission, the General Medical Council (GMC) and the Department of Health's Expert Advisory Group on AIDS. He chaired the Secretary of State for Health's Advisory Group on Xenotransplantation and the Minister of Agriculture's Advisory Group on Quarantine. He is Chairman of the Nuffield Council on Bioethics and serves on the Archbishop of Canterbury's Advisory Group on Medical Ethics and the International Forum on Transplant Ethics. The Reith Lecturer in 1980, Professor Kennedy has taught and lectured throughout the world. He is the author of texts on medical law and ethics, and was, until 1998, co-editor of the leading journal on medical law. He is a member of the editorial board of ten national and international journals

<sup>9</sup> Professor Jarman was previously Head of Division, Primary Care and Population Health Sciences, at Imperial College School of Medicine. He is a Fellow of the Royal College of Physicians, a Fellow of the Royal College of General Practitioners and a Fellow of the Faculty of Public Health Medicine

<sup>10</sup> Rebecca Howard has contributed to the development of national policy in the area of children's services, and has a special interest in paediatric intensive care

<sup>11</sup> Mavis Maclean qualified in sociology and law. She has researched and written about compensation for accident victims, and now works in family law and family policy, with a particular interest in the children of separated parents. She is the academic advisor to the research secretariat of the Lord Chancellor's Department and a former member of the Lord Chancellor's Legal Aid Advisory Committee

## Secretary to the Inquiry and Secretariat

- 11** The role of the Inquiry's Secretariat was to support the Chairman and Panel in the planning and management of the Inquiry. This involved handling all non-legal aspects of the Inquiry's work. The Secretariat, for example, commissioned expert (including statistical) evidence and advice; organised the Clinical Case Note Review (CCNR); and planned and managed Phase Two of the Inquiry. The Inquiry's Secretary acted as secretary to meetings of the Panel.
- 12** The Secretariat was responsible for all practical and administrative arrangements. This included the project to find and commission an Inquiry office and hearing chamber; the organisation of IT support; the day-to-day management of the hearing chamber and matters concerning staffing, contractors and the Inquiry's finances. The Secretariat included a communications team responsible for liaising with the press and media and responding to their enquiries; producing regular newsletters for families; and for the management of the Inquiry's website. The Secretariat commissioned a video as a visual record of the Inquiry. It includes information about the Inquiry's procedure and the physical arrangements for the hearings. Copies will be available in due course and may be borrowed from the library of the Department of Health, HM Treasury Solicitor or the library of the Cabinet Office.
- 13** The Inquiry Secretary was Una O'Brien, a member of the Senior Civil Service; the Assistant Secretary was Zena Muth, also a civil servant. The size of the Secretariat varied depending on the stage of the Inquiry but, throughout the public stages of the Inquiry, it included between 15 and 20 members of staff.

## The Solicitor to the Inquiry

- 14** The Chairman decided that, in view of the probable involvement of the DoH as a participant in the Inquiry, it would be inappropriate for departmental lawyers to act on behalf of the Inquiry. Consequently, HM Treasury Solicitor was approached to provide legal assistance. Peter Whitehurst and Charlotte Martin, both from the Treasury Solicitor's Department, were appointed to head the Inquiry Solicitor's team.
- 15** They, in turn, recruited a team of lawyers to support them in obtaining evidence and witness statements, calling witnesses to give oral evidence, instructing and assisting Counsel to the Inquiry, and in writing the accounts of the evidence heard by the Inquiry which form the basis of this Annex.

## Counsel to the Inquiry

- 16** Brian Langstaff QC, Eleanor Grey and Alan Maclean were appointed as Counsel to the Inquiry. They did not represent any organisation or individual appearing before the Inquiry. It was not their role to prosecute or to prove any particular case.

- 17** As members of the independent Bar the role of Counsel was to provide independent impartial advice and assist the Panel by presenting and testing evidence, both oral and written.

## The Preliminary Hearing and the call for evidence

- 18** A Preliminary Hearing took place, in public, in Bristol<sup>12</sup> on 27 October 1998. The purpose of this hearing was to explain the function and procedures of the Inquiry and to consider any applications for legal representation to be paid out of public funds.
- 19** By that time, a number of organisations had already started to respond to the Inquiry's requests for documents relevant to the Terms of Reference. In addition, the Chairman publicly called for all who had relevant documentary evidence to send it to the Inquiry. He stressed that, if necessary, the Inquiry would use its statutory powers to require the production of documents and the attendance of witnesses.
- 20** The Chairman emphasised that the Inquiry was neither a trial nor a disciplinary hearing: there were to be neither 'parties' nor 'sides'. The Inquiry would not adopt the process of a criminal or civil court, but rather, an inquisitorial as opposed to an adversarial approach, since this was most suited to the Inquiry's duties under the Terms of Reference. Thus, those who were involved in the Inquiry were referred to as 'participants' rather than 'parties'.
- 21** The 1977 Act provides power for the Secretary of State for Health to order the payment of participants' costs out of the public purse, on the recommendation of the Chairman.<sup>13</sup>
- 22** In keeping with established conventions, the Chairman indicated that he would not recommend that public bodies, commercial organisations, trade unions and other bodies with substantial funds should have their costs met from the public purse.
- 23** Applications for funding from the public purse were received from the Bristol Heart Children Action Group (the BHCAG), the Bristol Surgeons Support Group (the BSSG), Mr Jim and Mrs Bronwen Stewart,<sup>14</sup> the Royal College of Nursing (RCN) and the Medical Defence Union (MDU). There were also a number of incomplete applications from individuals.
- 24** Subsequently the Secretary of State accepted the Chairman's recommendations that the costs of the BHCAG and the BSSG be met out of public funds.

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<sup>12</sup> The Council House, College Green, Bristol

<sup>13</sup> Section 84(6) of the 1977 Act provides:

'Where the Secretary of State causes an inquiry to be held under this section he may make orders –

'(a) as to the costs of the parties at the inquiry, and

'(b) as to the parties by whom the costs are to be paid ...'

<sup>14</sup> The parents of Ian Stewart, a patient who underwent open-heart surgery at the BRI

- 25 Where costs were to be met at public expense, they were paid at rates agreed by the HM Treasury Solicitor's Costs Department.<sup>15</sup> Prior approval of disbursements, including any expert's fee, above a minimal level, was also necessary. Bills of Costs were subject to scrutiny to ensure that it was proper to fund any work done out of public funds.
- 26 Additionally, a small number of witnesses were reimbursed for the expense of their attendance at the hearings.<sup>16</sup>
- 27 The Chairman emphasised to all participants that, unless there was a significant conflict of interest or other justification, the appearance of multiple teams of lawyers would be considered to be unnecessary. In the case of the BHCAG and the BSSG, in order to ensure that focused legal representation for parents and patients was available, it was agreed that one team of solicitors should represent each Group and instruct one team of barristers. This minimised costs, while achieving maximum efficiency.

### Early contact with participants

- 28 During the early months of the Inquiry, in late 1998, the Secretary made contact with representatives of the Executive of the BHCAG and the BSSG. In addition to meeting members of the Executives, meetings were also held with local groups of parents and some individuals.
- 29 The Solicitor also held a number of meetings with the participants' legal representatives.
- 30 The purpose of these meetings was to understand concerns, to explain the Inquiry's functions and to consult on processes and procedures.

### The Issues List

- 31 After considering the outcome of all the discussions with those involved and the documentation thus far obtained, the Inquiry identified the key issues to be investigated. A draft Issues List was prepared and sent out for consultation. Informed by this exercise, a final version was prepared and then issued in March 1999.<sup>17</sup>
- 32 The Issues List was intended to be a guide, identifying relevant issues in the system responsible for the management of care of children who received cardiac surgical services. It was designed to assist the process of examination and enquiry. It did not seek to pre-judge any issue before that process had taken place. It was not a statement of the methods that were to be used to examine each issue.

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<sup>15</sup> Based on local rates subject to level of case-holder

<sup>16</sup> A list of costs appears in the Appendices to the Final Report

<sup>17</sup> See Annex B

- 33** The length of the treatment of an issue in the List was not to be taken as an indication of its importance to the Inquiry nor did the List attempt to set out an order of priorities. Indeed, the weight given by the Inquiry to each issue varied, particularly as the evidence developed.

## The Bristol office and the hearing chamber

- 34** The Chairman and Panel considered that it was appropriate that Phase One of the Inquiry should be held in Bristol. In early autumn 1998 the Secretariat, with assistance from the DoH's estate management branch, viewed several buildings. In selecting suitable premises consideration was given to the following:

- central location and accessibility by public transport; and
- sufficient space to provide office accommodation and a hearing chamber on one site.

- 35** The premises selected consisted of three floors at 2–10 Temple Way, Bristol. The accommodation provided two floors of office space and a floor for use as a hearing chamber, with accommodation for participants, members of the public and the media.

- 36** The office space required little alteration, other than the erection of partition walling and the installation of cabling to support the IT infrastructure.

## Design of the hearing chamber

- 37** The hearing chamber required considerable work. In considering the requirements, much thought was given to those with a close interest in the Inquiry, particularly the families of children who had received paediatric cardiac surgical services at Bristol. The hearing chamber was specifically designed not to resemble a court and to ensure that members of the public who attended the hearings were able to follow proceedings closely.

- 38** The public seating was laid out in a semi-circular design with the Panel sitting on a slightly raised dais to the left of the witness. The witness sat at a table opposite the centre of the semi-circle, facing members of the public. Counsel to the Inquiry were placed to the witness's right. Legal representatives who attended the Inquiry sat behind the Inquiry's Counsel.

- 39** Voice-activated cameras were placed in the ceiling of the chamber and video screens were placed strategically throughout the room to assist the view of the public. In addition to the video screens, there were also document display screens that permitted all those in the chamber to view documents that were being discussed.



## Public facilities

- 40** The Inquiry recognised that families whose children had been treated at the BRI and BRHSC would wish to attend the Inquiry and it was with this in mind that the following facilities were also provided:
- family room with soft furnishings, toys, a television and videos suitable for children of all ages;
  - quiet room with soft furnishings where those attending the Inquiry could receive support from a trained counsellor;
  - overflow room so that, if the hearing chamber was full, members of the public were able to follow the proceedings via a video link;
  - waiting room with coffee machines, cold water dispenser, and refreshment machine;
  - a number of meeting rooms, which could be pre-booked, so that witnesses coming to give evidence were able to meet their legal representatives, family, or professional colleagues in private; and
  - smoking room.

## The media

- 41** The Chairman and Panel were anxious to ensure that the Inquiry was as open as possible. They recognised the legitimate interest which the media had in reporting what took place. It was with this in mind that they sought to extend every assistance to the media to aid them in their role. Copies of the written statement made by a witness were made available to the media at the time that they were made public. The Inquiry also made available the day's transcript on the Internet each evening. There were also members of the Secretariat, in the communications team, whose role was to liaise with the media.
- 42** There was a dedicated seating area in the hearing chamber with a media room adjacent with facilities such as an ISDN line and dedicated fax machine.
- 43** However, given the sensitive nature of much of the evidence, it was decided not to allow any photography or broadcasting, either by radio or television, of the hearings.

## Documentary evidence

- 44 The Inquiry received 42,071 documents,<sup>18</sup> a total of 219,828 pages, from over 30 sources. All documents provided were scanned into the Inquiry's database and each page given a unique identification number, denoting the source of the document, file and page number.<sup>19</sup>
- 45 One or more members of the Solicitor's team and/or Counsel initially read all documents. Duplicates and documents not falling within the Terms of Reference were removed. The remaining 'core bundle' of documents was then 'issue coded' by members of the Solicitor's team in preparation for the hearings. Issue coding involved recording on the database the issues (from the Issues List) to which each document was relevant. Thus, in preparation for the hearings it was possible to search the database for all documents addressing a particular issue.
- 46 Work on the 'core bundle' continued into 1999 as documents continued to be provided. The bundle was made available over that period to the Panel and to legal representatives of the participants by means of a series of CD-ROMs.<sup>20</sup>
- 47 Because it was considered essential that the confidentiality of patients be preserved, the Solicitor's team read all documents particularly with this in mind. Details of personal contact, references to individual patients, and references from which it was thought likely that a reader could identify a patient, were redacted, i.e. blocked out, on the scanned documents.<sup>21</sup>

## Witness statements

- 48 The Inquiry's legal team identified those organisations or individuals from which it wished to receive written witness statements.
- 49 In relation to evidence from parents of children who had been treated at Bristol, the Inquiry was anxious to hear from parents who had experience of the paediatric cardiac surgical services ranging throughout the period 1984–1995, whether they had positive or negative comment to make.
- 50 Parents were sent questionnaires enquiring whether they wished to take part in the Inquiry. All those who indicated that they wished to take part were invited to make written statements. Generally, where families were members of the BHCAG or the BSSG, the Groups' Solicitors took their statements. The Inquiry's Solicitor's team and local firms of solicitors also took statements, when it was appropriate.

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<sup>18</sup> Excluding medical records and witness statements and comments

<sup>19</sup> Thus 'UBHT 2000 0001' would denote page 1 of a document scanned in file 2000 provided by the UBHT

<sup>20</sup> In the case of participants, CD-ROMs were provided on receipt of strict undertakings as to confidentiality

<sup>21</sup> Where the parents of a patient, or patients themselves who had attained majority, had given express signed consent to the Inquiry to the publication of personal information, redaction was limited in accordance with their consent

- 51** Likewise, witnesses who were employed, for example by the UBHT, Avon Health Authority (Avon HA) or the DoH, provided statements through solicitors acting for the respective organisation. A number of clinicians were individually represented and statements were provided through their solicitors, often instructed by the Medical Defence Union (MDU) or the Medical Protection Society (MPS). A small number of witnesses provided their statements directly to the Inquiry, with or without assistance from the Inquiry Solicitor's team.
- 52** Witness statements were received from 577 witnesses. The Inquiry's Solicitor and Counsel read each statement. If it contained comments that were considered to be critical of any other person or body in a material way, a copy of the statement was sent to the person or body criticised to allow them to respond. Every statement and every factual comment was subsequently published.<sup>22</sup>
- 53** All statements and comments published by the Inquiry were scanned into the Inquiry's database and allocated a unique number, commencing with the identification code 'WIT'.<sup>23</sup>
- 54** Where the Inquiry decided it was not necessary to call a witness to give oral evidence, that witness statement was published on the Inquiry's website.
- 55** Where witnesses were called to give oral evidence, their statement was made public at the time that they gave their oral evidence. These statements were also made available, confidentially, in advance of publication to participants who might be affected by the content, who then had the opportunity to advise Counsel to the Inquiry or comment in writing.

## Other possible witnesses

- 56** The Inquiry sought to obtain evidence from clinicians who were members of the junior medical staff at the BRI or BRHSC during the period 1984–1995, in particular those whose rotations involved working in paediatrics, paediatric cardiology, cardiothoracic surgery and anaesthesia. It was hoped that their evidence would give an indication of their experiences at the time and whether any distinctions or comparisons could be made between the evidence of those who were there during different periods.
- 57** Several attempts were made to trace these former junior doctors. Evidence from those doctors who responded with pertinent comments is set out later in this Annex.
- 58** The initial search for former staff was assisted by lists of names of registrars and senior registrars provided by the UBHT. Unfortunately, the list did not give complete details of the names; in most cases it contained only a first initial and surname. The list

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<sup>22</sup> However, the Inquiry's Solicitors were authorised, if they considered that a statement or comment contained material (e.g. defamatory or scandalous matter) which could not reasonably assist the Inquiry in its task, to redact that material prior to publication

<sup>23</sup> Thus 'WIT 0200 0001' would denote page 1 of a statement produced by witness number 200

provided the Inquiry with approximately 378 individuals. These were compared against the current medical register and 188 individuals were found, to each of whom the Inquiry wrote. The Inquiry could not rely completely on having identified the correct individual, due to the duplication of common names and the lack of details of initials. When responses were received indicating that a doctor had been contacted in error, further letters were written in an attempt to contact the correct person.

- 59** A notice was placed in the *'British Medical Journal'* ('BMJ') on 29 May 1999 inviting anyone who had worked as a member of the junior medical staff at the BRI or BRHSC to contact the Inquiry. The notice stated that the Inquiry was particularly interested in the experiences of those whose rotations brought them into contact with the disciplines of paediatrics, paediatric cardiology, cardiothoracic surgery and anaesthesia. Five replies from clinicians were received. They were sent the Issues List and asked for comment, but no replies were forthcoming.
- 60** The Inquiry sent an alphabetical list of the names provided to the main medical organisations in the UK asking them, initially, to confirm whether any of the clinicians on the list were members of the organisation. The following were asked to assist in supplying contact details for the names on the lists:
- Royal College of Surgeons of England (RCSE)
  - Royal College of Anaesthetists (RCA)
  - Royal College of Physicians of London (RCP)
  - Royal College of Child Health Practitioners (RCCHP)
  - Society of Cardiothoracic Surgeons of Great Britain and Ireland (SCS)
  - British Paediatric Cardiac Association (BPCA)
  - Association of Anaesthetists of Great Britain & Ireland (AAGBI)
  - Association of Paediatric Anaesthetists of Great Britain and Ireland (APAGBI)
  - British Association of Paediatric Surgeons (BAPS)
- 61** These organisations were asked if they would be willing to forward letters to clinicians on behalf of the Inquiry, to avoid any problems arising from the confidentiality of the organisations' information. Those that responded, in fact, supplied the full names and addresses of their members, although the majority of these proved to be incorrect or out of date. (The names and addresses supplied were often those given to the organisation when a clinician first became a member and any subsequent move rendered the records held by the organisation inaccurate. There was again the recurring problem that the Inquiry had only a list with surname and first initial.

This produced a number of similar duplicate names.) The Royal College of Physicians of London and the Royal College of Surgeons of England supplied extensive lists of details of their members. Based on those lists, another letter was sent out on 12 August 1999 to approximately 140 clinicians.

- 62** A number of the organisations contacted by the Inquiry suggested the list of names should be sent to the GMC to check against more up-to-date records. The Inquiry wrote to the GMC to ask for its assistance in tracing former junior medical staff. The GMC responded to the effect that it could only provide contact details if the Inquiry was able to supply full names and the GMC registration number for each clinician. The Inquiry could not provide these details.
- 63** The assistance of a private company was also sought in tracing former junior doctors. The company, IMS Health, assured the Inquiry that it held databases on clinicians with information about where they trained, when they qualified and their specialties. The Inquiry was keen not to contact any clinicians by mistake a second time, especially if they had already indicated that they never worked in Bristol, and it was thought that this narrowing of the search would be more successful. Unfortunately, the Inquiry still received further negative responses from clinicians who had never worked in Bristol.
- 64** The Inquiry received a poor response to its letters, as regards both the numbers who replied and the accuracy in reaching the intended recipients. The reason for this stemmed from the original staff lists supplied by the UBHT. Not surprisingly, the form of those lists changed over the years and it made the task of identifying registrars and senior registrars difficult and time consuming, especially where only surnames were recorded. The majority of the responses were from clinicians indicating they had been written to in error (due to duplication of the names) or that they had never worked at the BRI/BRHSC at any time in their career. Of the responses from clinicians who worked at the BRI/BRHSC during the relevant period, the information provided was very limited, because of the time that had elapsed or the fact that the majority were junior at the time and did not feel they could add any useful insight into the paediatric cardiac surgical service at Bristol.
- 65** The Inquiry also contacted referring clinicians in the Bristol catchment area, and their letters in response are considered in [Chapter 11](#) of this Annex.

## The Expert Group

- 66** It was considered crucial for the Inquiry to hear expert advice on a variety of issues, including medical and nursing care. It was therefore decided that the Inquiry would appoint a group of experts of its own to provide this advice, rather than have to rely on experts commissioned by the various participants.<sup>24</sup> The approach was intended to move away from the adversarial model, in which experts tended to represent 'parties', and to ensure that the Inquiry had access to a wide range of impartial advice.

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<sup>24</sup> A list of the members of the Expert Group and a full account of the purpose of the Group is in Annex B

- 67** As expert advisors to the Inquiry, members of the Expert Group could, as with all other witnesses, only be called to give evidence by the Inquiry itself. They were asked to assist the Inquiry in a number of ways:
- by providing written opinions, which were subsequently published by the Inquiry;
  - by providing background information and briefing to the legal team to assist them in preparing for the oral hearings; and
  - by attending the hearings, either to give evidence themselves or to assist Inquiry Counsel when a witness was giving oral evidence.
- 68** In addition, the members of the Expert Group were asked to make themselves available to give occasional seminars to the BHCAG and BSSG, in order to assist them in understanding the issues and preparing their contributions to the Inquiry.
- 69** Other organisations with a direct interest in the Inquiry were also free to seek advice from the Expert Group. However, in keeping with the non-adversarial approach, all such requests were made via the Secretariat who arranged meetings and forwarded requests for information.
- 70** The experts included paediatric cardiac surgeons, paediatric cardiologists, anaesthetists, paediatric intensive care nurses, paediatric nurses, pathologists, statisticians, health service managers and accountants. Because so many members of the Expert Group were also in full-time practice, the Inquiry recognised the need to have a large enough pool of experts to call upon so as not to make unreasonable demands upon the time of a small group of people.
- 71** A large number of the clinical members of the Expert Group assisted with the Clinical Case Note Review (CCNR).<sup>25</sup>

## The information technology systems

### Background

- 72** It was evident from the beginning that one of the greatest challenges that the Inquiry would face would be to manage the large volume of information that it would receive. Initially, the Chairman and Secretariat visited other public inquiries then in progress to become familiar with the technology in use.<sup>26</sup>

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<sup>25</sup> See Annex B

<sup>26</sup> The *'Inquiry into the Matters Arising from the Death of Stephen Lawrence'*, and the *'BSE Inquiry'*

- 73** The DoH's IT systems were provided by ICL. Within the terms of the Department's contract with ICL it was possible to extend the service to include a bespoke IT system for the Inquiry. In October 1998 the Secretariat, with support from the Department's Information Services Division, drew up a specification of the IT requirements. However, a number of services that were required by the Inquiry could not be directly provided by ICL, namely, a document management system and a real-time transcription service, and an invitation to tender for these services was issued.
- 74** In November 1998 ICL appointed two partner organisations, Legal Technologies (a company which specialises in document management systems for large trials) and Smith Bernal (a company specialising in the provision of a real-time transcription service). Together these three organisations met the Inquiry's IT needs.

## Office systems

- 75** The Inquiry required an IT system for use by the Inquiry Chairman, Panel, Legal Team and Secretariat which was independent of all other systems. This system was based around Microsoft Office and gave the Inquiry full confidential e-mail and Internet access. Additionally, Legal Technologies provided the database of scanned images of all documents received by the Inquiry. Prior to scanning the images, guidelines were drawn up so that information such as the name of the author of the document and the recipient were included in the database. The creation of this database allowed the Inquiry staff to carry out detailed searches of all the images scanned.

## Hearing chamber

- 76** Extensive use was made of IT in the hearing chamber. In particular, use was made of the document database that allowed scanned images to be displayed on a number of computer screens instantaneously within and outside the chamber. This allowed the witness, the Chairman and Panel, members of the public and legal representatives simultaneously to see the document being discussed. These images were also displayed on screens in other rooms on the hearing chamber floor, namely the waiting room and the overflow room. They were also relayed to the Secretariat and the Solicitor's team on the floor below, who also had an e-mail link to Counsel to the Inquiry.

## Transmission of proceedings to other locations

- 77** It was recognised that, given the large catchment area of the BRI/BRHSC, there would be many people living in the South West and South Wales who would wish to follow the proceedings, but would be unable to attend the Inquiry.
- 78** Therefore, the Inquiry contacted a number of Community Health Councils (CHC) within the South West and South Wales seeking their agreement to host a live video link from the hearing chamber to a room within the local CHC office. Three CHCs (Truro, Barnstaple and Cardiff) were able to assist and received a live video link of the proceedings.

- 79** Additionally, on a weekly basis, the Inquiry provided copies of the transcripts and witness statements to CHCs and public libraries in the South West and South Wales.

## Commissioned work

- 80** The Inquiry commissioned work from external sources and from members of the Inquiry's Expert Group.
- 81** One particular, extensive piece of work was that of obtaining all the available clinical records relating to children receiving cardiac surgical services in Bristol between 1984 and 1995. This involved 1,827 cases falling within the Terms of Reference.<sup>27</sup> An expert coder, using a standardised set of codes, coded each of the clinical records,<sup>28</sup> so that an independent database could be established for the Inquiry. The results were then subject to analysis, and contributed to a statistical evaluation of the adequacy of the service at Bristol.

### The Clinical Case Note Review (CCNR)

- 82** There was no template against which the adequacy of the service provided at Bristol could readily be measured. The Inquiry, therefore, had to make its own assessment from a variety of sources. These included a statistical review of the main data sources which might inform the Inquiry of comparative outcomes at Bristol, both relative to other units and to its own performance over time; evidence of individuals of their contemporaneous views; evidence given with hindsight (with its limitations); contemporaneous documentation; the inferences properly to be drawn from the documentary and oral evidence given to the Inquiry; and the knowledge base of clinicians at the relevant time.
- 83** Additionally, the Panel asked clinical experts to review a sample of the clinical case notes of children whose care fell within the Terms of Reference. The purpose of the CCNR was to provide the Panel with a qualitative perspective on what the notes revealed about the overall pattern of care, and to highlight areas where it appeared, from the notes, that services were adequate or less than adequate.<sup>29</sup>
- 84** Teams of clinicians drawn from the Expert Group undertook the exercise. The teams reviewed a weighted sample, initially, of the clinical case notes of 80 children; these included children who had died within 30 days of surgery and children who were alive at that time. The weighting of the sample was designed to reflect the principal

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<sup>27</sup> The Inquiry received 2,056 children's records, comprising 3,497 individual files (as children treated at the BRI and BRHSC had a separate set of notes from each hospital): a total of 673,963 pages of medical records

<sup>28</sup> The codes used were those routinely used by hospital administrative systems at the time: ICD9 for diagnosis and OPCS4 for procedure

<sup>29</sup> See Annex B for an explanation of the methodology employed in the CCNR



issues of concern to the Inquiry. Due consideration was given to any distortions caused by the process of weighting when the final conclusions were advanced.

- 85** The clinicians were grouped into six multidisciplinary review teams, and each team was asked to review a set of clinical case notes.
- 86** Each review team consisted of five members:
- paediatric cardiac surgeon;
  - paediatric cardiologist;
  - paediatric anaesthetist/intensivist;
  - paediatric pathologist; and
  - paediatric nurse or intensive care nurse.
- 87** The Inquiry's approach to the CCNR was deliberately qualitative and acknowledged that, for the years from 1984 to 1995, there were no clearly set down, nationally agreed standards for paediatric cardiac surgical services. Therefore, the members of each review team were asked, as far as possible, to apply their best clinical judgement drawing on their understanding and knowledge of received professional standards at the time at which the care was delivered. In determining the most appropriate method for the review, the Inquiry took the advice of members of the Expert Group and then tested that advice in a pilot exercise.
- 88** The CCNR consisted of four stages: reading; reaching a tentative independent view; discussing those views at a multidisciplinary meeting; and reporting on the outcome of the discussions.
- 89** All members of a review team were given access to the clinical notes. To the extent that they could be located, relevant perfusion and Intensive Care Unit (ICU) charts, echocardiograms and angiograms, and X-rays were made available to the clinicians on each team as necessary. Each expert read the notes and developed a tentative view of what they showed, from the perspective of his or her own clinical expertise.
- 90** Each team held review meetings, where case histories were discussed, following a short introduction. Each member of the team contributed from his or her own expertise, drawing on an understanding and knowledge of professional practice at the time. The team collectively reached a view about the adequacy of care in relation to specific aspects of care, as well as in relation to the overall management of the case, including cases in which two or three operations took place.

- 91** The Inquiry was mindful that differences of approach between the review teams could occur. In order to make any such differences transparent, and to help with the overall interpretation of the exercise, the Inquiry distributed a number of the same case notes across the teams. Teams were not aware when looking at case notes that another team may have already considered them.
- 92** It needs to be emphasised that the CCNR was a review of that which the notes showed. Accordingly, evidence extraneous to the notes that tended to support or falsify a view taken of the quality of treatment which the notes showed, did not, and could not, itself invalidate conclusions reached as to what the notes themselves showed. It was the pattern of care revealed by the notes, rather than the appropriateness of its conclusions when a case was examined by using evidence extrinsic to the notes, that was of importance.

## Phases in the public hearings

- 93** The Inquiry had two phases of public hearings. Phase One, which commenced on 16 March 1999 and concluded on 9 February 2000, involved hearing evidence about the paediatric cardiac surgical services provided at Bristol between 1984 and 1995. It also dealt with aspects of the provision of paediatric cardiac surgical care nationally, so as to provide a background to events in Bristol. Phase Two took the form of seminars, held between January and April 2000. The Panel read papers and, in public session, heard a range of views about the future and examined the broader issues affecting the NHS, to assist them in making general recommendations.

## Phase One hearings

### Oral evidence

- 94** The Inquiry heard 96 days of evidence in Phase One, from 120 witnesses and from experts. Hearings were, generally, held on Mondays to Thursdays, initially three weeks in every four, although as Phase One neared its conclusion hearings were held on seven consecutive weeks.
- 95** A real-time transcript was produced. Where reference is made in this Annex to the transcript of the evidence, the day and page referred to identify it and the witness.<sup>30</sup>

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18 <sup>30</sup> Thus 'T47 p. 65' denotes page 65 of the transcript for day 47. A full copy of the Phase One (Oral Hearings) transcript is available in Annex D

- 96** During the course of the Inquiry a total of 900 documents were displayed in the hearing chamber.
- 97** When witnesses were called to give oral evidence they were advised in advance, in broad terms, of the areas on which their questioning was likely to concentrate. They were given the opportunity to visit the Inquiry's offices to familiarise themselves with the hearing chamber and to meet the Inquiry Counsel who was to examine them.
- 98** Each witness called to give evidence could be accompanied by a legal representative. However, as the approach adopted was inquisitorial, Counsel to the Inquiry initially questioned all witnesses. This was sometimes supplemented by questions from the Panel.
- 99** Participants were entitled to make applications to cross-examine a witness. However, since legal representatives of participants were invited to suggest questions, or lines of questioning, for Counsel to the Inquiry to put to the witness and to identify areas which they wished to be explored, it was anticipated that the occasions on which applications for cross-examination would be made would be limited. In the event, Counsel to the Inquiry were able to meet the requests raised with them by participants and, consequently, no application to cross-examine was in fact made.
- 100** At the end of questioning by Counsel to the Inquiry, the witness's legal representative had an opportunity to put questions by way of re-examination. The purpose of this was to clarify any area of evidence and to enable the representative to ensure that the witness had given a proper account of him or herself. For that reason it was anticipated that any such re-examination should not generally exceed 15 to 20 minutes and this was the case.
- 101** Additionally, the legal representative of a witness was given the opportunity to make a short submission to the Panel on the day following the evidence, ordinarily in writing but exceptionally, and at the Chairman's discretion, orally. Where the submission was made in writing and it raised a matter that, in the Panel's view was unclear, clarification was sought. All such written submissions were made public.
- 102** At the end of Phase One those witnesses who chose to do so, by themselves or through their legal representatives, were also given the opportunity to make a final presentation to the Panel in writing, which was made public, together with a short oral presentation.
- 103** A feature of the oral hearings was their public and accessible nature. This was achieved, in particular, by the extensive use of information technology. This enabled members of the public in the hearing chamber, in an overflow room on site and in the South West and Wales, to follow the proceedings as they occurred, seeing both the witness or questioner and a copy of any document under discussion. Copies of the transcripts of the evidence and documents displayed during the hearing were available at the hearing and also on the Internet.

- 104** This openness was important both to satisfy the Panel’s duty to hold a public hearing, and to ensure fairness. Any participant, or interested person, could follow what was being said in full detail.
- 105** Again, as part of the commitment to openness and fairness, all material seen by the Panel has been made public (subject only to redaction in the interests of individual’s entitlement to confidentiality).
- 106** During the oral hearings various innovations were used to help the Panel to hear from a range of witnesses on the same occasion. For example, when clinicians gave evidence one or two experts were usually present. The experts could address questions put by Counsel and they, in turn, could raise questions to clarify or discuss with the clinician, or they could confirm a point of evidence. The dialogue thus created between the witness, expert, and sometimes the Panel, was designed to avoid the adversarial model in which separate experts advise contesting parties. It was intended to be more informed, more transparent and more economical of time. Those legal representatives who expressed a view found it to be entirely beneficial. Another example was the occasion of the last day of the oral hearings, when 11 parents gave evidence in two separate group sessions. Essentially, the physical arrangements of the hearing chamber were changed so that up to six parents could give their evidence at the same session. Counsel put questions to each of the parents in turn and sought to generate a degree of discussion and dialogue on particular matters. The Panel found this particularly helpful.

## Visit to the BRI and the BRHSC

- 107** The Panel visited the BRI and the BRHSC on 22 July 1999, accompanied by members of the Inquiry staff. In particular, at the BRI they saw Wards 5A and 5B (the ICU), the Relatives’ Room and the lift used to move children pre- and post- operatively. At the BRHSC, having walked up the hill from the BRI, they visited the Cardiac Catheter Unit, the Echo Room, Ward 36, the ICU, the Main Surgical Ward and the operating theatres, including that built in 1995 to allow open-heart surgery to be performed at the BRHSC.<sup>31</sup>

## Phase Two Seminars

- 108** Phase Two of the Inquiry consisted of seven public seminars that took place in London and Bristol between January and April 2000.

- 109** The objectives of Phase Two were to assist the Panel in meeting the requirement in their Terms of Reference that they make recommendations for the future and to ensure that those recommendations were relevant, practical and achievable.
- 110** The seven themes identified for Phase Two were:
- *Acute Healthcare Services for Children:* The quality of children’s healthcare and health services.
  - *Determinants of Performance:* The factors determining the level of performance of organisations, especially in healthcare and the public sector generally.
  - *Culture:* Professional and managerial cultures and their impact on the quality of service.
  - *Leadership:* Leadership, vision, change and learning from experience.
  - *People:* Education, training, development and governance.
  - *Systems:* Safety and risk management, quality and information.
  - *Service:* Empowering the public in the healthcare process.
- 111** Written papers on the selected themes were commissioned from a wide range of organisations and individuals, within and outside the healthcare sector.
- 112** Day-long seminars were held to discuss each theme. After short presentations from the participants, an invited leader conducted the seminar on the Panel’s behalf.<sup>32</sup> There were opportunities for members of the public to put questions to the seminar participants, and members of the news media were in attendance.
- 113** The seminar participants were drawn from the public and private sector and academic and voluntary organisations and were invited to attend to raise points for discussion and share their relevant expertise. The Panel was advised by one of the Inquiry’s Counsel on points of law.
- 114** The written papers were published, and a summary of each seminar’s discussion was prepared and published on the Inquiry’s website and made available through libraries and Community Health Council (CHC) offices.

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<sup>32</sup> See Annex B for a list of seminar participants

## Preparation of the Final Report

- 115** The purpose of the Inquiry was not to conduct a trial of those associated with the events under scrutiny but to inquire, make findings and draw lessons. For this reason, and because there is no right to appeal against the views taken and conclusions reached in the Report, it was considered fair that those witnesses whom the Panel were minded to criticise should be aware of the Panel's concerns in advance and given the opportunity to comment.
- 116** Therefore once a first draft of the Report had been prepared, letters were sent, subject to an undertaking as to confidentiality, to a number of individuals briefly setting out intended criticisms with notice of the evidence on which these were based. Witnesses were given a period of 21 days to respond. The Panel in finalising the Report then considered those responses. This is the only occasion when the Inquiry Panel saw submissions that were not revealed publicly, since to have revealed them in any case where the Panel modified its conclusion would have been unjust to the individual concerned.

### Structure of Annex A

- 117** Annex A is an account of the evidence that the Inquiry took to assist it in discharging its duty under the Terms of Reference. The entirety of the Phase One (Oral Hearings) evidence that went before the Panel is available verbatim in Annex D. This Annex constitutes a permanent record of the salient parts of it.
- 118** Inevitably, any account is bound to be selective. Even in an account as extensive as this, there may be occasions on which evidence which had some impact upon the Panel in reaching its conclusions will necessarily be touched on only briefly, or even not restated. This does not mean that it was ignored. However, this Annex sets out with the intention of presenting that evidence which was regarded as being of greatest importance to the Panel in making its determination.
- 119** The broad context within which the specific events at Bristol must be set is first examined from the national context (though, inevitably, there will be frequent references to Bristol, for the sake of economy of text and clarity). Thus this Annex starts with an examination of the manner in which the national, regional and local bodies of the NHS, and national regulatory and professional bodies, functioned in exercising responsibility for health services.
- 120** The Annex then sets out the mechanisms of audit which were applicable on a national and regional basis, and the national and regional financial organisation that may have had an impact upon Bristol.

- 121** The Annex then offers an outline of congenital heart disease, its diagnosis and treatment, and examines the evidence of the organisation of neonatal and infant cardiac surgery (NICS) – the treatment of congenital heart disease in the under-1-year-olds – as a supra regional service (SRS), the designation of the BRI as a supra regional centre (SRC) to perform NICS, and the impact of developments in Wales upon the development of Bristol as such a centre.
- 122** Having set the scene nationally and regionally, the Annex then focuses upon Bristol: first, generally, the organisation of care within the hospital; and, secondly, the delivery of the paediatric cardiac surgical services within it. The care given to children who were patients is set out (broadly speaking) in the order of a child’s journey through the process of care: referral, pre-operative care, surgical care, post-operative care, and counselling and support for parents.
- 123** Towards the end of the account of the evidence, there appears a specific focus first upon the adequacy of the surgical services provided at Bristol, and then on the expression of concerns, and the way in which they were handled, which ultimately led to the setting up of this Inquiry.
- 124** In order, however, to set the scene, there follows an Introduction giving a short history of the principal developments in the structure and organisation of the NHS that preceded the years covered by the Inquiry’s Terms of Reference. It notes some of the milestones during that period, so that the context for the rest of the evidence is properly set.

## Structure of Annex B

- 125** Annex B contains a range of background papers, expert evidence and documents covering four broad areas: the conduct of the Inquiry, the Statistical Evidence to the Inquiry, other background expert papers, and assorted documents relating to the Clinical Case Note Review.

## Annex C

Annex C contains The Inquiry’s Interim Report “Removal and retention of human material.” May 2000.

## Annex D

Annex D is a verbatim transcript of the oral evidence heard during Phase One (Oral Hearings).





## Chapter 2 – A Historical Background to the NHS

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## Introduction

- 1 The services provided to children undergoing paediatric cardiac surgery at Bristol from 1984 to 1995 could not be properly examined without an understanding of the context within which the Bristol Paediatric Cardiac Unit functioned. To inform itself of that context, and to assist the Inquiry in its task to ‘make recommendations which could help secure high quality care across the National Health Service’ (NHS), the Inquiry sought evidence from interested bodies or individuals, upon the national, regional and local scene. This evidence concentrated upon the years 1984–1995, although it looked also at the years immediately preceding 1984, and also at the changes and developments that have taken place since 1995. The account that follows sets out the evidence relating to 1984–1995 which was received by the Inquiry. But the service that existed in 1984 was shaped by the history of the NHS prior to that date. For this reason, we have attempted to summarise the main features of the history of the NHS from 1948 onwards. This brief history is intended to serve as a useful introduction to the more detailed survey of the years 1984–1995 which follows it.
- 2 We concentrate principally on care in hospital. In fact, three basic elements make up the NHS. They are: the hospital service, the family practitioner services and community-based services. During its hearings, the Inquiry heard evidence of matters that touched upon all three elements. Children were referred for more specialised investigation and treatment by hospital-based consultants by their general practitioners. After discharge from hospital, they and their families received care from general practitioners, and support from community-based practitioners. Parents whose children had died spoke of the services that were available to help them in the community; or the absence of such support. However, the greatest bulk of the evidence received related to services provided by the hospital sector. This is reflected in the following account which deals at greater length with that sector. Equally, the discussion is restricted to the NHS in England and Wales. The Inquiry’s Terms of Reference do not deal with Scotland.

## The creation of the National Health Service

- 3 The structure of the NHS in England and Wales was established by the National Health Service Act 1946 (1946 Act). The new arrangements were launched on 5 July 1948.
- 4 The delivery of healthcare prior to that date had been achieved through a patchwork of fragmented arrangements. Voluntary hospitals, supported in part by charitable donation, provided care to those covered by insurance or contributory schemes, or

who could otherwise afford to pay for care. Other hospitals were owned and managed by local authorities.<sup>1</sup> Hospital surveys carried out during the Second World War revealed not only shortages of beds and buildings in a poor state, but that services were not provided in the areas which most needed them.<sup>2</sup>

- 5 Family practitioner services were provided then, as now, by general practitioners. The National Insurance Act of 1911 gave, for the first time, entitlement to free access to a general practitioner working on the doctor's panel. Some 21 million workers, but not their families, were covered by this insurance scheme in 1942. The quality of services provided varied widely, as it did in the hospital sector. The distribution of general practitioners did not necessarily correspond to the areas where their services were most needed. General practitioners were independent contractors, not salaried employees of a state-provided medical service. This was a status that they would successfully preserve under the new NHS.
- 6 The late nineteenth century and early twentieth century saw developments towards establishing the professional status of nurses, opticians, midwives, pharmacists and other providers of medical services. But the provision of community health services was highly fragmented. This was particularly so because the levels of services provided to local inhabitants by local authorities varied greatly.
- 7 Against this background, Sir William Beveridge's report '*Social Insurance and Allied Services*'<sup>3</sup> recommended the creation of a comprehensive health service, in which the full range of medical and nursing services would be free to each citizen who needed them. These aims were accepted in the White Paper published in 1944, '*A National Health Service*',<sup>4</sup> and maintained after the Coalition Government of the Second World War years was replaced by a Labour Government in 1945.
- 8 Under the 1946 Act, it was to be 'the duty of the Minister ... to promote the establishment in England and Wales of a comprehensive Health Service designed to secure the improvement of the physical and mental health of the people of England and Wales and the prevention, diagnosis and treatment of illness'. The services to be provided to meet these aims were to be free of charge. For the first time, the Minister of Health was made personally accountable to Parliament for hospital and other specialised services. He was indirectly responsible for family practitioner and local health services.

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<sup>1</sup> The hospitals run by local authorities had evolved from the workhouses provided under the Poor Laws. They tended to provide lower standards of care. Voluntary hospitals tended to concentrate on the needs of the acutely ill, rather than those with infectious diseases or the chronically ill. See Ham C., '*Health Policy in Britain*', p. 8 (4th edition, 1999), Macmillan Press Ltd

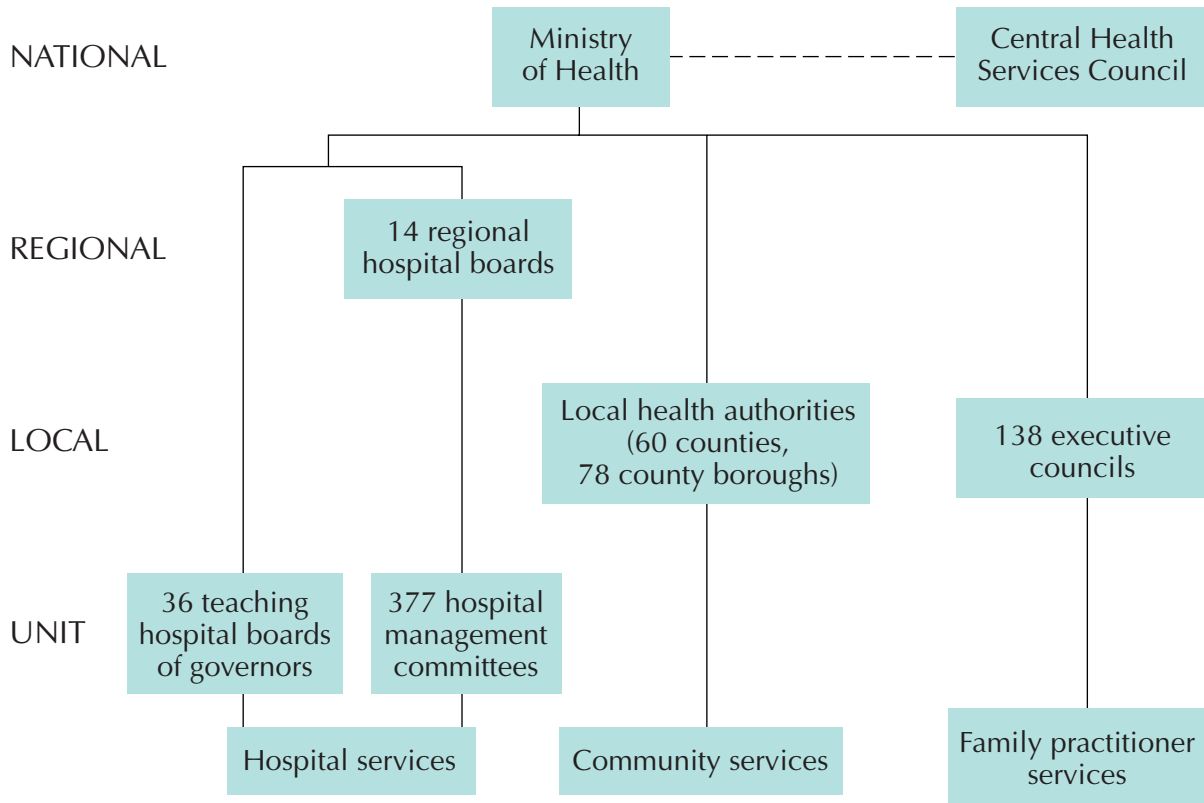
<sup>2</sup> See the survey of the hospital sector from the Nuffield Provincial Hospitals Trust (1946), '*The Hospital Surveys: the Domesday Book of the Hospital Services*', OUP

<sup>3</sup> Beveridge, W. '*Social Insurance and Allied Services*' (1942), London: HMSO (Cmnd 6404)

<sup>4</sup> '*A National Health Service*' (1944), London: HMSO (Cmnd 6502)

9 The structure of the NHS from 1948–1974 may be summarised as follows:

Table 1: The National Health Service 1948–74 (England and Wales)<sup>5</sup>



- 10 Hospitals were nationalised. They were managed either by hospital management committees and regional hospital boards, or, in the case of teaching hospitals, by boards of governors responsible directly to the Minister of Health. Funding for the hospitals came from the Ministry of Health directly to the boards of governors of teaching hospitals, or to regional health boards, which in turn passed it to the hospital management committees.
- 11 Executive councils administered local family practitioner services: that is, general medical, dental and ophthalmic services, and pharmaceutical services. Local authorities were responsible for community health services, including health visitors and district nurses, vaccinations and immunisations, maternal and child welfare, ambulance services and services for the mentally ill and those with learning disabilities who were not in hospital.<sup>6</sup>
- 12 Negotiations with interested parties, and in particular representatives of the medical profession, ensured that general practitioners retained their status as independent contractors. They had a contract with the local executive councils, rather than being employed by either central or local government. General practitioners were allowed

<sup>5</sup> Levitt R, Wall A, Appleby J. *The Reorganised National Health Service* (6th edition, 1999), Stanley Thornes (Publishers) Ltd. Reproduced with the permission of Nelson Thornes Ltd from *The Reorganised National Health Service 6e*, Levitt, Wall and Appleby, 1999

<sup>6</sup> National Health Service Act 1946, Sections 19–30

to do an unlimited amount of private work (although there was very little demand for private general practitioner services from the general public). Furthermore, salaried hospital doctors were allowed to undertake private work in hospital pay beds, in addition to their contractual duties to the NHS. A system of merit or distinction awards was introduced: hospital specialists who were judged to be meritorious by their peers were given special payments over and above their basic salaries.

- 13** While there were differences between various groups, there were broad areas of agreement. In particular:

‘Implicit in the consensus about the general aims of policy was a shared, optimistic faith in progress through the application of diagnostic and curative techniques. In turn, this mirrored the belief that medical science had not only triumphed over disease and illness in the past but would continue to do so in future. On this view, the only problem was how best to create an institutional framework which would bring the benefits of medical science more efficiently and equitably to the people of Britain.’<sup>7</sup>

- 14** Thus, there was little anticipation that the experience of freely available healthcare would stimulate demand. On the contrary, it was thought that expenditure would gradually decline as the nation became healthier.

## The National Health Service from 1948 to 1974

- 15** During the 1950s policy-makers, administrators and healthcare professionals were given an opportunity for consolidation. Many aspects of the operation of the freshly established service required detailed attention and technical rule-making. Little information was available, for instance, about many features of the institutions that were brought under the new regional boards. Partly as a result of the paucity of data, considerable local autonomy was given to the regional boards and hospital management committees. Within the limits of a fixed budget set by national government, local diversity was considerable, and national policy-making frequently proceeded by exhortation. Administrative staff were recruited by the local boards and committees; there was no national cadre of National Health Service administrators. Medical staff made up a significant proportion of the membership of these administrative bodies.
- 16** At the level at which doctors treated patients, or that of clinical decision-making, the autonomy of the medical professional was unchallenged. Thus: ‘While central government controlled the budget, doctors controlled what happened within that budget’.<sup>8</sup> When, in 1974, the office of the Health Service Commissioner was

<sup>7</sup> Klein, R. *The New Politics of the National Health Service*, p. 25 (3rd edition, 1995), Longman

<sup>8</sup> Klein, R. *The New Politics of the National Health Service*, p. 75 (3rd edition, 1995), Longman

established to investigate patients' complaints, its jurisdiction did not extend to investigating issues of clinical judgment. These were to be dealt with by means of the professional self-regulatory machinery (see Chapter 4), or by the courts.

- 17** Contrary to the early expectations of steady or reducing costs, the cost of the NHS soon became an issue, as expenditure began to outstrip estimates. Despite the commitment to a free service, charges for spectacles and dentures, for some people, were first introduced in 1951. Prescription charges were first introduced in 1952. Concern over rising costs led to the appointment of the Guillebaud Committee of Enquiry in 1953, with a remit to see how health expenditure could be contained. But it found no evidence of extravagance or inefficiency. On the contrary, although the service had inherited old buildings in poor condition, little money had been spent improving such stock during the 1950s. It was not until the 1960s that the 1962 Hospital Plan led to an expansion of the hospital sector, with proposals for the creation of large district general hospitals serving a population of 100,000–150,000.<sup>9</sup>
- 18** The Plan demonstrated a growing emphasis upon the need to plan services within the NHS, as well as a faith in the ability of such planning to achieve greater efficiency and rationality in the use of NHS resources. Such an emphasis reflected the pressures on resources exerted by the rising costs of care. The reasons for such rises were debated. They included developments in medical technology and medical pressure to keep pace with such developments; rising expectations on the part of the population; pressures for higher wages and salaries within the service; and the demographic changes caused by an ageing population.
- 19** The Plan also sought to build on the advantages that the creation of hospital management committees had been able to bring to the organisation and planning of local hospital services. The creation of a national health service, with national pay scales and conditions of service for hospital consultants, had helped to even out the distribution of hospital staff around the country. At the same time, however, professional gulfs between the hospital consultant and the general practitioner began to widen. One of the members of the Guillebaud Committee recorded a concern that the tripartite organisation of the NHS (see Table 1 at para 9) unduly emphasised the importance of the hospitals at the expense of the other two branches of the service. Suggestions that the divisions ought to be reduced by the creation of a more unified management structure followed.<sup>10</sup>

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<sup>9</sup> Although a programme of hospital expansion followed, not all the aims of the Plan were fulfilled, either in terms of numbers of hospitals, or their standards. In May 1970 the *'Hospital Building Maintenance: Report of the Committee, 1968–70'* (the Woodbine Parish Report), London: HMSO, was published. It criticised hospital maintenance standards and the lack of any overall strategy in the development of health service estates

<sup>10</sup> See for example *'A Review of the Medical Services in Great Britain: Report of the Medical Services Review Committee'* (the Porritt Report), (1962), London: Social Assay; and *'The Administrative Structure of Medical and Related Services in England and Wales'* (published by the Minister for Health in 1968)

- 20** In 1967 the Joint Working Party on the Organisation of Medical Work in Hospitals issued its first report.<sup>11</sup> The 'Cogwheel' Report<sup>12</sup> saw a need for a more corporate approach to medical administration. It recommended the creation within hospitals of clinical divisions of broadly linked specialties, to ensure efficient deployment of resources and to cope with the management issues that arose within clinical fields. Divisions would be represented on a medical executive committee that would consider major medical policy and planning issues, co-ordinate hospital clinical activities and provide links to nursing and administration. It was hoped that the sharing of information produced by such links would improve the use of resources. In the same vein, hospital activity analyses would provide consultants with better data on the patterns of activity within their hospitals. The Salmon Report, in 1967, set up a new structure for nursing, when it recommended a new hospital nursing structure under the direction of a chief nursing officer.<sup>13</sup>
- 21** During the 1960s, securing co-ordination and integration between the three wings of the NHS (see Table 1 at para 9) came to be perceived as an increasing problem. Hospital authorities, local authorities and executive councils did not work together to achieve integrated solutions to problems of patient care, such as long-term care for the elderly, that spanned all three sectors. Furthermore, certain services came to be recognised as neglected or 'Cinderella' services, where low standards of care for patients were common. The care of the elderly, the mentally ill and those with learning disabilities were examples. But it proved difficult to shift priorities and spending towards these disadvantaged groups. Medical advocates of such groups, such as consultant psychiatrists and geriatricians, were less influential than doctors in the acute specialties. In general, the provision of community-based services lagged behind hospital services.
- 22** On 1 November 1968 the Ministries of Health and Social Security were amalgamated to form the Department of Health and Social Security (DHSS). On 1 April 1969 responsibility for the NHS for Wales was transferred from the Welsh Board of Health to the Secretary of State for Wales.
- 23** By the end of the 1960s a consensus was developing that the tripartite structure of the NHS, established in 1948, was a source of problems. A series of reviews<sup>14</sup> proposed a more integrated system of management. These discussions culminated in the passage of the National Health Service Reorganisation Act 1973 (1973 Act), which introduced changes with effect from 1 April 1974.

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<sup>11</sup> 'First Report of the Joint Working Party on the Organisation of Medical Work in Hospitals' (the Cogwheel Report), (1967), London: HMSO

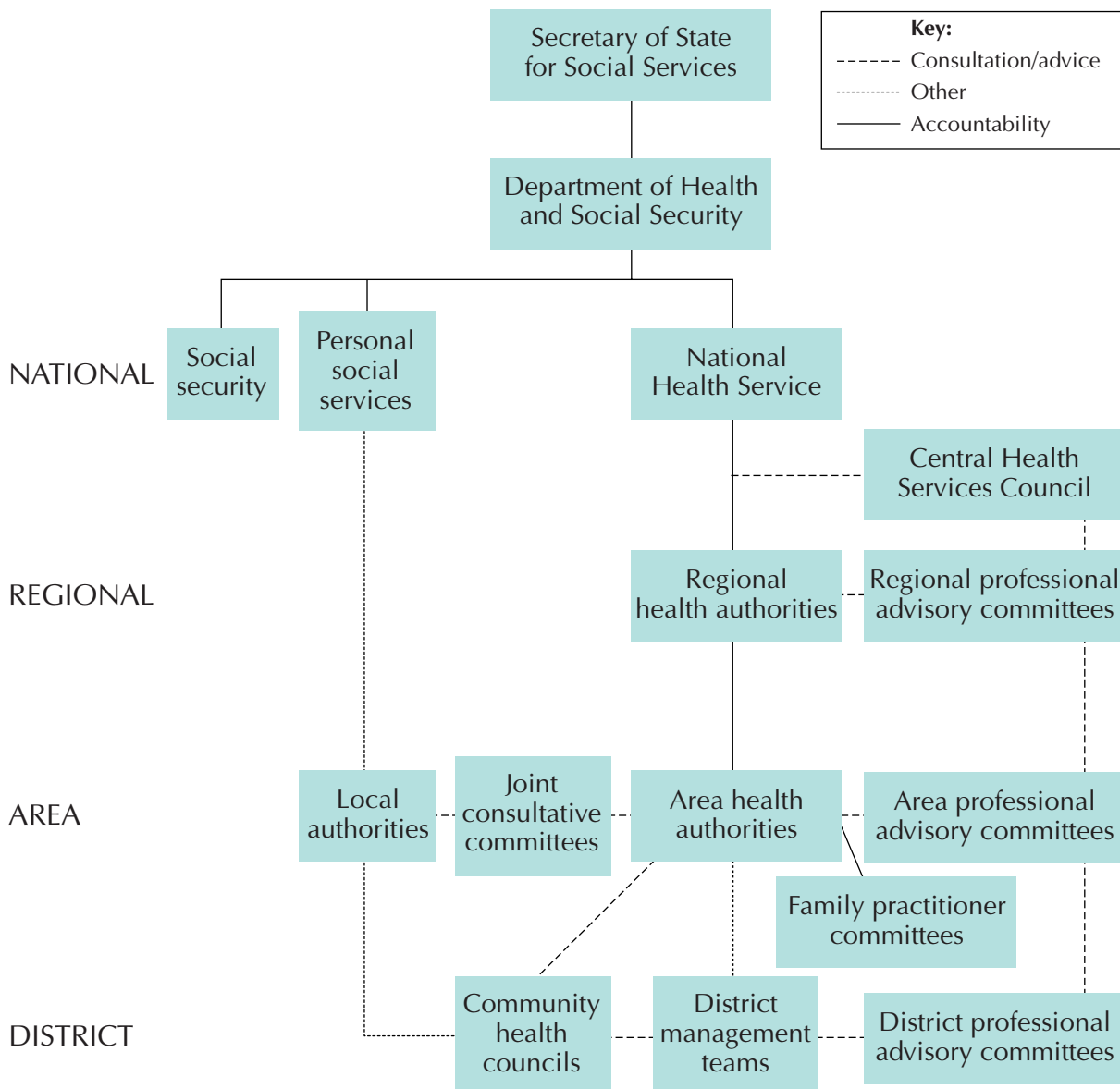
<sup>12</sup> The report, and its successors, received the name because of the design of wheels on the cover

<sup>13</sup> Ministry of Health and Scottish Home and Health Departments, 'Report of the Committee on Senior Nursing Staff Structure' (the Salmon Report), (1966), London: HMSO

<sup>14</sup> The independent 'Review of the Medical Services in Great Britain' (the Porritt Report) had suggested redesign in 1962. The Ministry of Health published a Green Paper, 'The Administrative Structure of Medical and Related Services in England and Wales' in 1968. A further paper followed in 1970, 'The Future Structure of the National Health Service'. In May 1971, the DHSS published a consultative document, 'The National Health Service Reorganisation', setting out further proposals on NHS reorganisation

**24** Under the 1973 Act, 14 regional health authorities (RHAs) were created in England; amongst them was the South Western RHA (SWRHA). Members of the RHAs were appointed by the Secretary of State for Social Services. They were responsible for planning local health services. Under them, 90 area health authorities (in England) were established, with a Chair appointed by the Secretary of State and non-executive members appointed by the RHA and by local authorities. An area team of officers was established, made up of an administrator, a nurse, a public health doctor and a finance officer. Areas were expected to liaise with local authorities. Most areas were further divided into health districts administered by district management teams. The structure is set out in the following table:

**Table 2: The Reorganised National Health Service 1974<sup>15</sup>**



<sup>15</sup> Levitt R, Wall A, Appleby J. *The Reorganised National Health Service* (6th edition, 1999), Stanley Thornes (Publishers) Ltd. Reproduced with the permission of Nelson Thornes Ltd from *The Reorganised National Health Service 6e*, Levitt, Wall and Appleby, 1999



- 25** In Wales, area health authorities were established but no RHA was deemed necessary. Instead, the Welsh Office played the role of both central government, and a regional health authority.
- 26** The reorganisation aimed to unify health services by bringing under one authority all the services which had previously been administered by regional hospital boards, hospital management committees, executive councils and local health authorities (see Table 1 at para 9). However, in a departure from this principle, general practitioners remained independent contractors. The role of the executive councils was taken over by family practitioner committees (FPCs), responsible for GPs, dentists, pharmacists and opticians. A small number of postgraduate teaching hospitals retained separate boards of governors.
- 27** It was intended that this reorganisation would bring about better co-ordination between the health authorities and local authorities. To foster this end, the boundaries of the area health authorities were designed to match those of the local authorities providing social services. The two were also required to set up joint consultative committees to assist the process of consultation and collaboration.<sup>16</sup>
- 28** At a district level, community health councils (CHCs) were introduced to represent the views of the public.
- 29** In the South West, in addition to the establishment of the South Western Regional Health Authority (SWRHA), the 1973 Act gave rise to other changes. Within the SWRHA, the Avon Area Health Authority (Teaching) was created and, below it, a number of health districts. The Avon Area Health Authority (Teaching) area included some 800,000 people in Bristol, South Gloucestershire and North Somerset but excluded Bath. One of the health districts, Bristol Health District (Teaching), included the Bristol Royal Infirmary and the Bristol Royal Hospital for Sick Children, and served about 360,000 people, mostly within the Bristol area.<sup>17</sup>

## 1974–1984

- 30** The reorganised structure did not meet with widespread approval. It was rapidly criticised for containing too many tiers of administrative decision-making; it was said that these led to bureaucracy and delays.<sup>18</sup> District management teams ‘tended to clash with their AHAs on matters of strategic direction.’<sup>19</sup> Administrative costs rose and staff morale suffered. Industrial unrest in the NHS increased. Against this

<sup>16</sup> The NHS Reorganisation Act 1973 coincided with the reorganisation of local government under the Local Government Act 1972

<sup>17</sup> WIT 0038 0005 Ms Charlwood

<sup>18</sup> The Royal Commission (see footnote 20) summed up the criticisms as (a) too many tiers; (b) too many administrators, in all disciplines; (c) failure to take quick decisions; and (d) money wasted

<sup>19</sup> Levitt R, Wall A, Appleby J. *The Reorganised National Health Service* (6th edition, 1999), Stanley Thornes (Publishers) Ltd

background, a Royal Commission was established in 1976.<sup>20</sup> It was asked to consider 'the best use and management of the financial and manpower resources of the National Health Services'. When it reported in 1979, it recommended that there should be only one level of administrative authority below the level of the regional health authority.

- 31** In December 1979 the DHSS and Welsh Office published a consultative paper entitled '*Patients First*'.<sup>21</sup> This proposed a strengthening of management at a local level, with greater delegation of responsibility to hospital and community levels; and removing the area tier and establishing district health authorities to combine the functions of areas and the existing districts. The professional advisory machinery and the planning system would also be simplified, to ensure that voices were better heard within regional and other health authorities.
- 32** These discussions resulted in the Health Services Act 1980 (1980 Act). The 1980 Act prepared the way for disbanding the AHAs and enabled the creation of 192 new district health authorities (DHAs) in England.<sup>22</sup> These DHAs came into operation on 1 April 1982. In many parts of the country, the correspondence between the boundaries of health authorities' areas of responsibility, and those of the local authorities, was however lost. Within districts, an emphasis was placed upon devolving management down to smaller units of management. These might be hospital or service based; there was considerable local variation.
- 33** FPCs were given an independent status as employing authorities as a result of changes announced in November 1981.<sup>23</sup>
- 34** The changes made in the structure of the NHS may be seen in Table 3.

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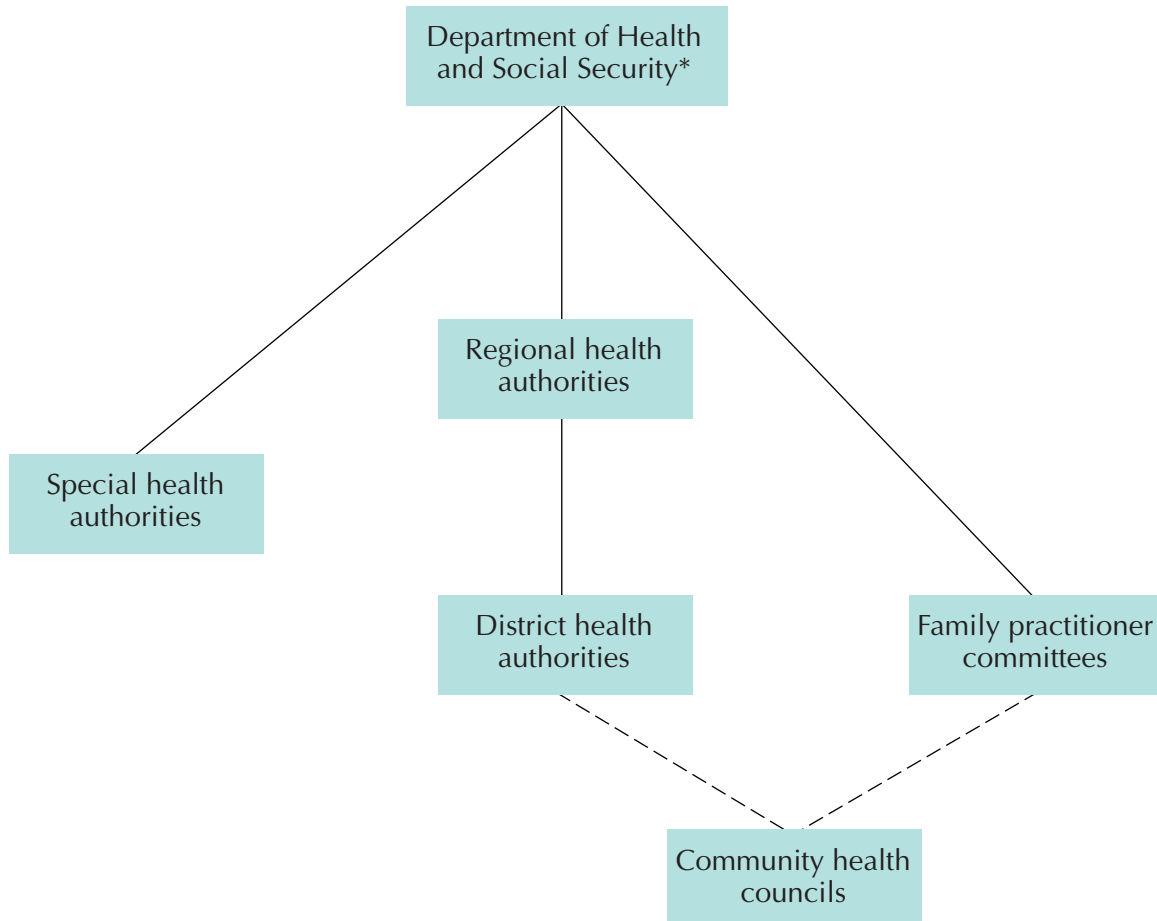
<sup>20</sup> Royal Commission on the National Health Service, '*Report of the Royal Commission*' (1979), London: HMSO (Cmnd 7615)

<sup>21</sup> DHSS and Welsh Office, '*Patients First*' (1979), London: HMSO

<sup>22</sup> Changes followed a review of local arrangements by the regional health authorities

<sup>23</sup> The changes were made in the Health and Social Security Act 1984. They were effective from 1 April 1985

**Table 3: The structure of the NHS, 1982–91<sup>24</sup>**



\*The DHSS became the Department of Health in 1988.

- 35** The main responsibility of Special health authorities (SHAs) was to run postgraduate teaching hospitals in London.
- 36** Slightly different arrangements were made in Wales. In respect of Wales, *Patients First*<sup>25</sup> noted that there was already only one tier of health authorities below the Welsh Office. These AHAs had the advantage of boundaries that were fully coterminous with county councils, but they were comparable in population and resources to the DHAs proposed for England. Stability was therefore possible. A review by areas of their district sub-structures was however proposed, with a view to eliminating formal district structures whilst remaining sensitive to the needs of local communities and to the need to delegate decision-making, so far as possible, to the level at which patient services were provided.<sup>25</sup>

<sup>24</sup> Ham C. *Health Policy in Britain* (4th edition, 1999), Macmillan Limited. Illustration reproduced with the kind permission of Macmillan Limited

<sup>25</sup> DHSS and Welsh Office, *Patients First* (1979), London: HMSO

- 37** In the South West, the Avon Area Health Authority (Teaching) was abolished on 1 April 1982 and replaced by the Bristol & Weston District Health Authority (B&WDHA). The B&WDHA consisted of the former Bristol Health District (Teaching) and Weston Health District (which had merged in 1978). The B&WDHA formed one of 11 DHAs under the SWRHA. Others included Frenchay DHA and Southmead DHA.<sup>26</sup>
- 38** The attempts to increase delegation to the periphery and to decrease central prescription that may be seen in the 1982 reforms did not endure.<sup>27</sup> Rather, central scrutiny and direction intensified, as Ministers sought to wrest greater efficiency or higher outputs from the NHS. In 1982, a system of annual performance reviews was launched. Ministers held meetings with regional Chairs, to set and then monitor progress towards targets. The regional Chairs in turn held similar meetings with the districts within their constituencies, setting up a chain of review.
- 39** During the financial year 1981/82 area health authorities were required to make efficiency savings in order to generate funds for new developments. Subsequently, in 1984, the efficiency savings programmes were renamed 'Cost Improvement Programmes'. It was calculated that the administrative costs of the service fell, as a result of the reduction in the number of management tiers effected by the 1982 reorganisation.
- 40** From 1982 NHS managers carried out a series of cost-effectiveness scrutinies into issues such as transport services and residential accommodation. They were modelled on the studies carried out by the retailer Sir Derek Rayner into the Civil Service. In August 1982 a review of NHS audit arrangements was announced.
- 41** In September 1983 the first set of performance indicators was published. These included information about clinical services, finance, manpower and estate management. The purpose of their development was to allow health authorities to compare performance with other health authorities. The performance indicators were criticised for various reasons. Some of the criticism centred on the fact that they contained data about activity or outputs but not outcome; presentation was late; there were doubts as to their accuracy; and they were unable to measure quality.<sup>28</sup>
- 42** In September 1983 the DHAs were required to invite tenders from in-house staff and outside contractors in order to test the cost-effectiveness of their own catering, domestic and laundry services.
- 43** In 1983 the Griffiths Report was published.<sup>29</sup> It found the lack of a clearly defined general management function to be a weakness in the NHS. At each level of management, no one person was accountable for action. It recommended that all

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<sup>26</sup> WIT 0038 0005 Ms Charlwood

<sup>27</sup> Klein, R. *The New Politics of the National Health Service*, p. 143 (3rd edition, 1995), Longman

<sup>28</sup> See also WIT 0038 0006 Ms Charlwood, which notes that the DoH subsequently shifted emphasis from performance indicators to health service indicators, 'which were more concerned with helping HAs to plan and monitor the delivery of services'

<sup>29</sup> *The NHS Management Inquiry* (October 1983), London: DHSS; HOME 0003 0001. See also Chapter 4

levels within the NHS should operate under the control of a single general manager or chief executive. The report sought to introduce a new management culture into the NHS and thereby give managers more prominence. Hospital doctors should be involved in this: such clinicians should accept that with clinical freedom came a management responsibility. Further, according to Klein:

‘One of the report’s central arguments was that the management task revolved around delivering a good product to the consumer: “Businessmen have a keen sense of how they are looking after their customers. Whether the NHS is meeting the needs of the patient and the community, and can prove that it is doing so, is open to question.” Thus Griffiths put two new questions on the NHS agenda, which became increasingly salient over the following decade. First, was the NHS producing the right kind of goods? Second, was the quality of the goods being produced adequate?’<sup>30</sup>

- 44 The report also recommended the establishment of a Health Services Supervisory Board, to determine policy and objectives, and an NHS Management Board, to perform an executive role. The regional and district Chairs were to ensure that the process of securing accountability and review extended through to unit level.
- 45 In June 1984 the circular *‘Implementation of the NHS Management Inquiry’*<sup>31</sup> authorised the adoption of these recommendations and required DHAs and units to appoint a general manager. In Bristol, Dr John Roylance was appointed District General Manager of the B&WDHA in January 1985. He was instructed to produce a management structure for the B&WDHA by 30 April 1985. B&WDHA approved this in May 1985.<sup>32</sup>

## Main events, 1984–1996

- 46 The chapters that follow develop particular features of the structure that has been outlined, and deal with it in some detail from 1984 onward.
- 47 However, it may be helpful to identify briefly some of the main events affecting the structure of the NHS after 1984, until just after the end of 1995, so as to provide a reference point for much of the evidence later set out in this Annex.

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<sup>30</sup> Klein, R. *The New Politics of the National Health Service*, p. 151 (3rd edition, 1995), Longman

<sup>31</sup> *Health Services Management: the Implementation of the NHS Management Inquiry*, Circular HC 84(13), London: DHSS

<sup>32</sup> WIT 0038 0009 Ms Charlwood

- 48** The period was dominated by the development and introduction of the ‘*Working for Patients*’ reforms announced by the Government in 1989.<sup>33</sup> This process of reform began when in January 1988, following extremely high levels of expressed concern about health service funding and its inadequacies in the late 1980s, the Prime Minister announced a fundamental review of the NHS. The review took place quickly. The reviewing team were members of a Cabinet Committee. They worked without the public consultation and participation that had characterised, for instance, previous Royal Commissions. This exclusion of the professional and public interest groups was one of the reasons why the changes proposed attracted unprecedented levels of denunciation when they were announced.
- 49** In January 1989 the work of the Committee was published in the form of the White Paper, ‘*Working for Patients*’.<sup>34</sup> It rejected models of privately funded healthcare. Instead, it proposed an ‘internal market’ in the NHS by separating ‘purchasers’ from ‘providers’. Health authorities would purchase services from independent NHS trusts, after assessing local needs and developing a strategic assessment of, or plan for, those needs. They would also monitor the delivery of the services that they had agreed to commission. GPs also would be offered the option of becoming ‘fundholders’, able to purchase most services on behalf of their patients. Such a system of funding would, it was said, create an incentive towards the more efficient use of resources, with more attention paid to the services that patients, or ‘consumers’, wanted.
- 50** The details of the new system proposed were further developed in a series of ‘Working Papers’ published by the DoH. These covered topics such as fundholding, the structure and responsibilities of NHS trusts, and medical audit. The Working Paper No 6, ‘*Medical Audit*’,<sup>35</sup> established as a government policy the principle that all clinicians should participate in review and audit of their practices. A professionally led Audit Advisory Committee should support medical audit at a regional level. By April 1991, each district should also have established a District Medical Advisory Committee to plan and monitor a comprehensive programme of medical audit. But such audit programmes should be medically led, by an advisory committee chaired by a senior clinician.<sup>36</sup>

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<sup>33</sup> Other developments included the split of the DHSS, in July 1988, into separate departments covering Health (DoH) and Social Security (DSS); and efficiency initiatives such as the income generation programme launched in 1988 to discover ways in which health authorities could generate additional funds by means such as placing retail outlets in hospital premises. On the former, see also Chapter 6

<sup>34</sup> DoH, ‘*Working for Patients*’ (1989), London: HMSO (Cm 555)

<sup>35</sup> HOME 0003 0124

<sup>36</sup> For further details, see Chapter 18

- 51** The concept of NHS trusts was further explained in Working Paper No 1.<sup>37</sup> Each would be a self-governing trust, headed by a trust board whose chairman was appointed by the Secretary of State. The board was responsible for the management of the hospital. Specifically, it was required to submit an annual report to the Secretary of State; to ensure that revenue matched outgoings, and to achieve the financial objectives that might, from time to time, be set by the Secretary of State.<sup>38</sup> Ultimately, the Secretary of State remained in control, at least in so far as he was able to remove trust officers from post in specified circumstances. The trust, a provider of services, would derive its income from contracts with purchasers, notably local health authorities and general practitioner fundholders. Further, consultants' contracts would in the future be held directly by such trusts, rather than by RHAs, and there would be discretion to make local financial settlements or introduce non-standard terms of employment.
- 52** Although the Working Papers clarified some aspects of the changes that the Government sought to introduce, many aspects of the new system remained unclear. Further, following the passage through Parliament of the National Health Service and Community Care Act 1990 (1990 Act), the reforms were to take effect on 1 April 1991: a demanding timetable for change. Thus, as the reforms were introduced, local health authority staff, hospital managers and clinicians were required to exercise discretion in deciding how they should take effect at a local level.<sup>39</sup>
- 53** Funding for some specialised, supra regional services remained centralised. The work of the Supra Regional Services Advisory Group (SRSAG) continued. Thus, until early 1994 the purchaser-provider split did not affect the funding of paediatric cardiac surgery for the under-1s.<sup>40</sup>
- 54** In May 1989 the NHS Policy Board was created in the place of the old Health Service Supervisory Board, with the Secretary of State as the Chairman. The NHS Management Executive (the NHSME) was also created in the place of the former NHS Management Board.<sup>41</sup> It was chaired by the Chief Executive of the NHS. The intention was to sharpen and focus the split between responsibilities for policy, on the one hand, and

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<sup>37</sup> 'Self-Governing Hospitals'; HOME 0003 0028

<sup>38</sup> See the NHS and Community Care Act 1990, which established the legal framework of hospital trusts, especially Section 10, and also regulations made under this Act, especially the 'NHS Trusts (Membership and Procedure) Regulations 1990', SI 1990/2024 (amended by SI 1990/2160). These regulations set the maximum number of directors at 11. Two were to be appointed by the RHA. The Secretary of State appointed the remainder. The tenure was not to exceed four years, but reappointment was allowed. The regulations set out circumstances in which disqualification would occur (e.g. bankruptcy, sentences of imprisonment, loss of independence as a result of Trade Union office or membership of a health service body. The executive directors of the trust were to include the chief officer, the finance officer, a medical practitioner and a registered nurse or midwife. A committee composed of the chairman and non-executive directors of the trust appointed the chief officer. Once appointed, the chief officer joined that committee in order to appoint the other executive directors of the trust. Standards were generally clarified when in April 1994, the Secretary of State issued a Code of Conduct addressing issues of accountability, probity and openness: DoH 'Code of Conduct, Code of Accountability' (1994); circulated with EL(94)40, DoH, London

<sup>39</sup> 'The DoH was able to issue only general guidance on the implementation of the 1990 Act; it was left to NHS managers to work out the details. This gave them even more power than they had assumed under Griffiths, but exacerbated tensions between them and their clinical colleagues despite the increased opportunities for doctors themselves to be become involved in managerial decision-making.' Levitt R, Wall A, Appleby J. 'The Reorganised National Health Service' p. 20 (6th edition, 1999), Stanley Thornes (Publishers) Ltd. See also Ham C. 'Health Policy in Britain' p. 42 (4th edition, 1999), Macmillan Limited

<sup>40</sup> This topic is dealt with in further detail at Chapter 7

<sup>41</sup> See also Chapter 4

management or implementation on the other. The distinction was symbolised by the move (in 1992/93) of the NHSME from London to Leeds.<sup>42</sup>

**55** During 1990 the NHSME set up seven regional 'outposts' to assist in establishing the NHS trusts and monitoring their performance.<sup>43</sup> One such outpost was set up in Bristol, in a separate location from the RHA.<sup>44</sup>

**56** The nature of the accountability and scrutiny arrangements for trusts which developed can be seen in an account of such arrangements written by the NHS Executive in 1994:

'Trusts will remain primarily accountable to purchasers for the delivery of care through NHS contracts. They will be held to account by the provider arm of the NHS Executive regional office for meeting their statutory financial duties ... Monitoring of Trusts' financial duties and approval of annual and strategic business plans will be undertaken by the provider arm of regional offices following the approach developed by the former outposts ...'<sup>45</sup>

**57** On 1 April 1991 the 1990 Act came into effect. The 'first wave' of 57 NHS trusts and 306 GP fundholders was launched. The structure of the NHS from 1991 to 1996 is set out in the following table:

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<sup>42</sup> See Chapter 4

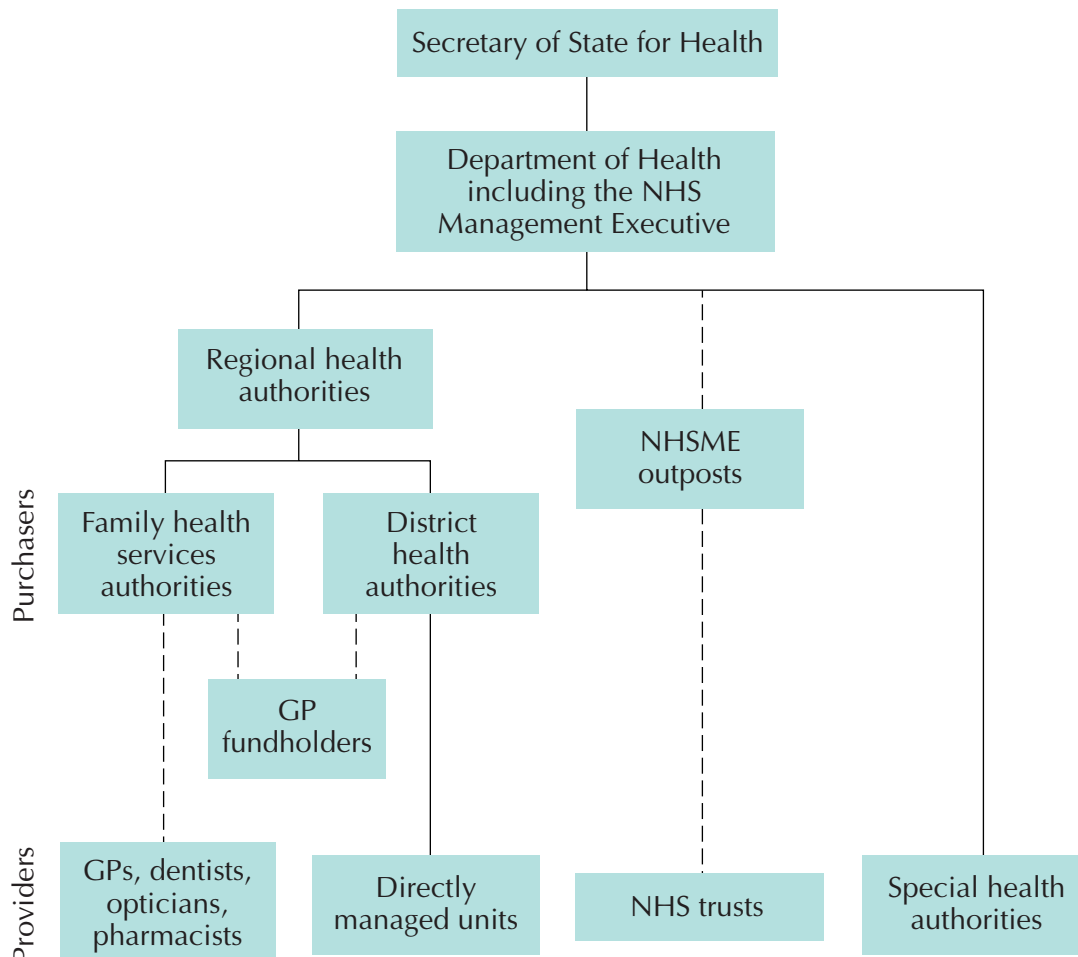
<sup>43</sup> See Chapter 5 for further details of the functions of the regional outposts

<sup>44</sup> Until 1994, when it was resited within the RHA's premises

<sup>45</sup> *Managing the New NHS: Functions and Responsibilities in the New NHS* (1994), NHSE. The paragraph continued: 'There will be limited direct monitoring by regional offices of certain non-financial aspects of Trusts' performance which cannot be pursued through NHS contracts, including national policy initiatives such as Opportunity 2000 and junior doctors' hours.' See also paras 68–73 below for the structural changes proposed and implemented in 1993–1996



**Table 4: The structure of the NHS in England, 1991–96<sup>46</sup>**



- 58** The United Bristol Healthcare (NHS) Trust (UBHT) and Weston Area NHS Trust, which had existed in ‘shadow’ form from 21 December 1990, were formally established on 1 April 1991. Property rights and liabilities, including contracts of employment, were transferred to these trusts.
- 59** Several other local changes occurred. The B&WDHA was abolished with effect from 1 October 1991. In its place, Bristol & Weston, Frenchay and Southmead DHAs merged to form a new Bristol and District Health Authority (B&DHA), serving about 840,000 people. The B&DHA became responsible for strategic health policy and planning, and for the purchase of services from NHS trusts using service agreements.<sup>47</sup> In addition, it retained direct managerial responsibility for those hospitals or units that had not opted for self-governing status as at 1 April 1991.

<sup>46</sup> Ham C. *Health Policy in Britain* (4th edition, 1999), Macmillan Limited. Illustrations reproduced with the kind permission of Macmillan Limited

<sup>47</sup> WIT 0038 0007 Ms Charlwood

- 60** The regions were also remodelled, by being given boards of executive and non-executive directors. The chairman of the board and the five non-executive members (who included a chairman of a family health service authority (FHSA) and a person connected to the local medical school) were appointed by the Secretary of State. The strategic role of the region, in setting performance criteria and ensuring that plans were being achieved, was further emphasised. They were also expected to take a lead in ensuring that the changes set out in the 1990 Act were successfully implemented.
- 61** DHAs were now required to place contracts with local NHS trusts for the purchase of services required by the resident population. These contracts were not legally binding;<sup>48</sup> they might better have been described as ‘service agreements’. ‘Extra-contractual’ referrals catered for those patients who needed a particular treatment, operation or package of care not already provided for in a contract between their DHA, and the institution to which they were to be referred. Such additional costs had to be met by the DHAs on an individual basis.
- 62** Prior to placing contracts, however, the DHA was expected to assess what local health needs were, and to develop, with the assistance of its public health team, a strategy for meeting them. But:

‘In practice, the impact and influence of the needs assessment process on the priorities and purchasing decisions of districts was limited, for a number of reasons. First, districts were under enormous time pressure to complete their annual contracting rounds. Many public health departments lagged behind because it takes time to carry out properly informed needs assessments. Second, health authorities had problems with the lack of epidemiological and medical information required to do proper needs assessments ... Third, it was necessary to reconcile results of needs assessments with spending budgets to produce a set of actual purchasing priorities. Although a needs assessment may reveal a “need” for medical care and treatment, it does not (and cannot) reveal anything about whether and how one particular need should be met in preference to another.’<sup>49</sup>

- 63** The ‘internal market’ was slow to develop. Initially, achieving a ‘steady-state’ rather than risking disruption of existing services was considered to be particularly important. The health authorities’ first year’s contracts were therefore based upon the existing referral patterns to trusts. Further change was slow or limited, for a number of reasons. First, the information needed to compare services and their costs often did not exist. If it did, it tended to lie in the hands of the providers rather than the purchasers. Second, many services were not readily amenable to ‘competition’ from alternative providers. When factors such as access (or travel costs) by the local population were taken into account, many local trusts were natural monopoly providers of many services. Block contracts for services tended to be used, sometimes differing little from the global budget allocations they had replaced. Patients might then follow contracts, rather than vice versa. Thus, limited progress was made towards

<sup>48</sup> Where purchaser and provider were in dispute, the region was expected to act as arbitrator

<sup>49</sup> Levitt R, Wall A, Appleby J. *The Reorganised National Health Service*, p. 42 (6th edition, 1999), Stanley Thornes (Publishers) Ltd

developing an internal market, and co-operation and partnership in service development between purchasers and large local providers was a common approach.<sup>50</sup>

- 64** In October 1991 the Patient's Charter<sup>51</sup> was published as part of a national policy initiative to define standards of service within public services. It set out a list of rights or guarantees of service for patients, but these standards were not legally enforceable. Purchasers, however, did use them to monitor the quality of care or levels of service being provided under the contracts with their providers. For example, the guarantee that patients should wait no longer than two years for an operation was one of the waiting list indicators that was scrutinised.
- 65** On 1 April 1992 a second wave of NHS trusts and GP fundholders began operation.
- 66** The 1992 White Paper, *'The Health of the Nation'*,<sup>52</sup> adopted a wide public-health approach to securing a 'continuing improvement in the general health of the community'. The paper recognised that health was the product of a wide range of factors, including lifestyle and the environment; achieving good health required more, therefore, than managing a service which aimed to cure illness or disease. All government action should be co-ordinated to assist in the aims of producing a healthy environment, healthy homes and healthy workplaces. These general aims were also more closely focused in 25 specific targets; for example, securing a reduction in the number of deaths from coronary heart disease, or in the percentage of the population that was overweight. There was, in other words, a new interest from the government in tackling the causes of disease and premature death.
- 67** Also in 1992 the Clinical Outcomes Group was established to promote a multi-professional approach to clinical audit. No longer would doctors, nurses and other professional groups conduct audit separately. The group placed an emphasis on linking clinical audit to other programmes such as resource or risk management, quality assurance, research, development and education.<sup>53</sup>
- 68** In April 1993, 139 new NHS trusts came into being, making a total for England of 289. By 1 April 1994, there were a total of 419 NHS trusts and 96 per cent of hospital and community health funding was spent on services provided by trusts. Further, some 9,000 GPs had become fundholders, representing over half of all eligible practices and serving approximately 36 per cent of the population.<sup>54</sup>

<sup>50</sup> 'Whatever the preferred approach, the outcome was the same: the internal market became a *managed* market in which competition and planning went hand in hand.' Ham C. *'Health Policy in Britain'*, p. 43 (4th edition, 1999), Macmillan Limited

<sup>51</sup> HOME 0001 0001 – 0013

<sup>52</sup> DoH (1992), London: HMSO (Cm 1986)

<sup>53</sup> See Chapter 18 for a more detailed account of aspects of audit during this period

<sup>54</sup> The process had been assisted by periodic reductions in the number of patients required to be on a GP's practice list before the practice became eligible for fundholding status, and by the development of different models of fundholding

**69** The implementation of the changes first outlined in 1989 provoked further examination of the structure of the NHS and whether its shape was apt to manage the reorganised system. In October 1993, in *'Managing the New NHS,'* the Government announced plans for a further restructuring exercise. Its ultimate aim was to abolish the regional health authorities and to reorganise the existing NHS Management Executive so as to create eight regional offices, each headed by a regional director, which would replace the RHAs and the existing NHSME outposts. However, new legislation would be required to abolish the RHAs. In the interim, the Secretary of State proposed that, from 1 April 1994, RHAs should be reduced in number from fourteen to eight, thus creating common boundaries with the NHSME's new regional offices. The Government commented that, as a result of the reforms:

'RHAs no longer have the wide-ranging planning and line management responsibilities that they had in the previous hierarchical system. In recent years they have played a key role in implementing the NHS reforms, but that role is diminishing as purchasers build up their skills and experience. Monitoring of Trusts, which will make up the vast majority of service providers by April 1994, is the responsibility of seven NHSME outposts. RHAs have already reduced in size.'<sup>55</sup>

**70** The reforms announced also aimed to support the developing liaison between DHAs and FHSAs, in order to strengthen local purchasing arrangements. Mergers of these two bodies would not only be permitted for the first time, but encouraged by the creation of integrated DHAs/FHSAs, in the shape of new area health authorities, to enable integration of purchasing across primary and secondary care boundaries.

**71** Accordingly, the boundaries of the fourteen RHAs in England were altered on 1 April 1994 to reduce their numbers to eight. The SWRHA and Wessex RHA were re-formed into the South & West RHA (S&WRHA). On the same date, NHS Executive regional offices were established, sharing common boundaries with the remaining regional health authorities.

**72** The Health Authorities Act 1995 (1995 Act) gave the necessary statutory authority to the abolition of the RHAs and to mergers of DHAs and FHSAs. B&DHA and Avon FHSA anticipated these developments by making arrangements to meet jointly, under the name of the Avon Health Commission, in order to conduct business. Formal meetings of the two authorities ratified the Commission's decisions immediately afterwards.<sup>56</sup>

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<sup>55</sup> *'Managing the New NHS: a Consultation Document'*, NHSME, 1 November 1993, para 2.3

<sup>56</sup> WIT 0038 0007 Ms Charlwood

- 73** When on 1 April 1996 the 1995 Act came into force, the S&WRHA, the B&DHA and the Avon FHSA were abolished. The South and West Regional Office of the NHS Executive inherited most of the functions and responsibilities of the former SWRHA.<sup>57</sup> The Avon Health Authority (Avon HA) was established, serving a population of some 982,000 in the areas of the new unitary local authorities of Bath & North and East Somerset, City of Bristol, North Somerset and South Gloucestershire.<sup>58</sup> The Avon HA continued the tasks of planning, and purchasing or commissioning, services that had been the function of the B&DHA since 1991, but with additional responsibility for people residing in the Bath area.

## Conclusion

- 74** The paragraphs above have given the briefest sketch of the changes that were implemented in the NHS from its inception, and then from 1984 to 1996. The account has not sought to summarise the many and varied views, or research performed, upon the nature and effect of the far-reaching changes introduced in the middle of the period of the Inquiry's Terms of Reference. It is hoped that a short introduction to these changes may assist by reminding readers of the backdrop to the more detailed account of events in Bristol, to which the following chapters now turn.

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<sup>57</sup> WIT 0038 0008 Ms Charlwood. See also *'Managing the New NHS: a Consultation Document'* (NHSME, 1 November 1993), and *'Managing the New NHS: Functions and Responsibilities in the New NHS'* (NHMSE, 1994). These documents noted that the regional offices would take over the functions of the RHAs; would develop the purchasing function in the NHS; and would take over the monitoring of NHS trusts from the NHSME outposts. They would not be involved in detailed operational management and would be smaller than the old regional health authorities

<sup>58</sup> WIT 0038 0008 Ms Charlwood



# Chapter 3 – Developments in the UK, in the Diagnosis and Treatment of Congenital Heart Abnormalities in Children, 1984–1995

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This chapter was written for the Inquiry by Dr Eric D Silove, MD, FRCP, FRCP(E), FRCPCH, consultant paediatric cardiologist, Birmingham Children's Hospital.

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## Introduction

- 1 This is a concise account of the history of the development of diagnosis and treatment of congenital heart disease<sup>1</sup> in children in the United Kingdom, with special reference to the period 1984 to 1995. It is written for the lay person.<sup>2</sup> It presents:
  - a concise history of the development of cardiac surgical services for children with congenital heart disease in the United Kingdom, with special reference to the period 1984 to 1995;
  - a description of methods of diagnosis and strategies of management in general terms;
  - the differences between the normal heart and hearts with congenital abnormalities;
  - a discussion of specific heart abnormalities in terms of the problems that they present, the symptoms they cause, the methods by which they are diagnosed and the strategies of their management; and
  - in general terms, the consequences of not operating compared with the benefits and risks of operations for specific abnormalities.
- 2 In any medical service, there is no precise point at which a new development takes place. It is an evolutionary process, determined by numerous factors which may occur separately or together. These include human technical skills, technological advances, new drugs and new strategies. There are also intangible factors such as new ideas, the courage to pursue them, research, organisation of multidisciplinary teams, and the application to the service in question of techniques and skills used in other disciplines. The many related ethical issues demand constant review.
- 3 Until the latter part of the 1950s very little surgical treatment was available to children with congenital heart abnormalities anywhere in the world. In 1954, W Lillehei, an American cardiac surgeon at the University of Minnesota, first used a machine to take

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<sup>1</sup> The terms 'congenital heart abnormality' and 'congenital heart disease' are usually interchangeable

<sup>2</sup> This chapter does not include the range of detailed references which would be found in an academic article. The reader requiring further detail should consult Kirklin JW, Barratt-Boyes BG. *Cardiac Surgery: Morphology, Diagnostic, Natural History, Techniques, Results and Indications* (2nd edition, 1993), Edinburgh and New York: Churchill Livingstone

over the work of the heart while he stopped it and opened it in order to repair an abnormality. This was soon emulated in a number of centres around the world. In 1958 the first open-heart operation on a child in the United Kingdom was performed using the heart-lung bypass machine. During the early 1960s surgery was performed on increasing numbers of children in the UK, in an increasing number of centres. There were few publications of surgical results and little was known of the expectations of survival. Operations continued to be undertaken because there was the wide recognition that without such attempts, children with the more serious congenital heart abnormalities had very little chance of surviving into adulthood. During the latter part of the 1960s and early 1970s there was an explosion of reports of surgical results and by the early 1970s paediatric cardiac surgery had been established in around half of the major regions in the UK. Patients with more complicated abnormalities tended to be referred to two or three centres with the greatest experience.

- 4 In the late 1970s there was increasing recognition of the need to concentrate paediatric cardiac surgery in a limited number of 'supra regional' centres, especially in the case of infants under the age of 1 year. In 1983 the Department of Health established a mechanism, the Supra Regional Services Advisory Group (SRSAG), for funding a small number of highly specialised services. In 1984 the services funded in this way were expanded to include paediatric cardiac surgery, and nine centres were funded to provide this service.<sup>3</sup>

## The perspective of children with congenital heart disease

- 5 The birth of a baby with congenital heart disease (CHD) can be devastating news for the parents. A congenital heart abnormality occurs in six to eight of every 1,000 livebirths.<sup>4</sup> In other words, every year in the UK, around 3,500 babies are born with congenital heart abnormalities. Approximately 50% of these babies have a relatively mild abnormality which may cause no problems for the child at any stage in life and may even 'cure' itself spontaneously. In some, it may require a surgical procedure later in life which can be curative. At the other extreme, some babies will die within hours or days if they do not have emergency medical and surgical treatment. Overall, about 50% of babies born with congenital heart disease will not survive into adult life without surgery. Thus, a heart abnormality can have far more serious consequences than most other physical problems that may be present at birth.

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<sup>3</sup> See Chapter 7

<sup>4</sup> Dickinson DF, Arnold R, Wilkinson JL. 'Congenital Heart Disease among 160,480 Liveborn Children in Liverpool 1960 to 1969. Implications for Surgical Treatment'. *British Heart Journal* July 1981; 46(1): 55–62

- 6 Children who are born with heart disease need and receive care from many different nurses and doctors at any one time and over the years.
- 7 Cardiologists and surgeons have a significant role in the care of children who have congenital heart disease. Many other clinicians and healthcare workers are also likely to be involved in a hospital care episode, not least nurses, anaesthetists, perfusionists (technicians who run the heart-lung bypass machine), pharmacists and physiotherapists. If the child dies, a pathologist is also likely to be directly involved.
- 8 For a few children, a heart problem can be diagnosed, treated, and indeed cured, in one episode of care in hospital.
- 9 For many children, the care process is complicated and protracted: it may involve an initial diagnosis followed by a series of surgical procedures and other treatment over a period of years. An operation in early infancy may only be an initial operation in a plan of treatment.
- 10 Children with heart abnormalities who need heart surgery may have either 'closed-' or 'open-' heart surgery. A 'closed' operation means that the heart or major arteries are operated on whilst the heart is still beating. An 'open-' heart operation means that the heart is stopped whilst the surgery takes place, and the blood flow to the child's vital organs is supported by a heart-lung bypass machine.
- 11 There is a wide spectrum of heart abnormalities. Even though diagnostic labels are given to individual children, no two children's hearts are identical. Thus the best operative management is not always clear, and normally the relevant clinicians would come together to discuss and agree a plan of treatment for each child. There may be several options both for the type of surgery and for its timing.

## Diagnosis and initial assessment

- 12 A serious congenital heart abnormality will usually be recognised or suspected within a few days after birth, often while the baby is still in the newborn unit of the hospital. In that case the paediatrician will ordinarily make early contact with a paediatric cardiologist.
- 13 In some babies there may be no obvious symptoms and signs for several days or weeks. In those cases, the parents, the midwife, health visitor or general practitioner will be involved in recognising a problem. Referral to a paediatrician usually follows. If a heart abnormality is judged to be likely, the paediatrician will also decide how urgently a paediatric cardiologist should be consulted.

- 14 The paediatric cardiologist is responsible for the initial assessment and diagnosis of a congenital heart abnormality. When necessary, he initiates emergency medical treatment and at an early stage involves a surgeon in planning the timing and strategy of management. Perhaps the cardiologist's most important function is the identification and diagnosis of heart abnormalities and heart disease. The decision to proceed with cardiac surgery is a decision made between the family, the cardiologist and the cardiac surgeon, and of course the patient, to the level of his understanding.
- 15 If it is thought that surgery may be required, the cardiologist is expected to provide a clear picture of the cardiac abnormality. In order to make a diagnosis, the paediatric cardiologist will use various technologies which have advanced significantly during the past 20 years. They are principally: (1) the use of ultrasound scanning which is non-invasive (known as echocardiography), and (2) cardiac catheterisation which is invasive and consequently involves some risk to the patient.<sup>5</sup>

## Echocardiography

- 16 Echocardiography is the name given to the use of ultrasound scanning to produce images of the heart. During the late 1970s and early 1980s echocardiography became widely used to define congenital heart abnormalities and by 1982–1984 some definitive articles and textbooks had been written on the subject. By 1984 most paediatric cardiologists in the UK were using echocardiography in order to provide a reasonably accurate initial diagnosis. This was true as regards most of the abnormalities that have been of particular concern to the Inquiry: Atrial Septal Defect (ASD), Ventricular Septal Defect (VSD), Atrio-Ventricular Septal Defect (AVSD), Tetralogy of Fallot,<sup>6</sup> Transposition of the Great Arteries (TGA), hearts with one effective ventricle and Truncus Arteriosus. Others, such as Coarctation of the Aorta and Total Anomalous Pulmonary Venous Drainage (TAPVD), could be diagnosed by the use of echocardiography, but less easily. It was expected that in some cases there would be uncertainty about the diagnosis and the finer details. In such cases, it was then necessary to supplement the echocardiographic diagnosis by using the techniques of cardiac catheterisation.

## Doppler echocardiography

- 17 During the mid-1980s, an ultrasound 'Doppler' technique became available which enabled cardiologists to measure the velocity of blood flow within blood vessels. From these measurements it became possible to calculate pressures in certain chambers of the heart which previously could only be derived from direct measurements using cardiac catheterisation (see [para 20](#)).

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<sup>5</sup> Ultrasound scanning is a procedure in which some jelly is placed on the chest and a small pencil-like probe is held lightly on the skin. A cardiac catheterisation is invasive in the sense that the skin is punctured with a needle which is then guided into a blood vessel. A thin tube (or catheter) is then guided by various manoeuvres into the blood vessel and is advanced along the larger blood vessels into the heart

<sup>6</sup> Also referred to as 'Fallot's Tetralogy'

## Colour-flow mapping of Doppler echocardiography

- 18** Towards the end of the 1980s and during the early 1990s, colour mapping of the ultrasound Doppler signals created the facility to observe the nature of blood flow in the heart and major blood vessels and enabled clearer demonstration of abnormal holes and valves as well as abnormal connections of blood vessels. By around 1992 these techniques had become sufficiently well developed for virtually all paediatric cardiologists to be able to rely on them. Many of the patients who in earlier years would have been subjected to cardiac catheterisation could now have their condition diagnosed by these modern ultrasound techniques. Echocardiography, with all of its developments, is also an ideal method for assessing the post-operative state of the heart, both in the operating theatre and later in the intensive care unit (ICU), the wards and the outpatient department.

## Transoesophageal echocardiography

- 19** In the early 1990s, ultrasound probes were designed which could be passed from the mouth into the oesophagus (food-pipe or gullet) which runs through the chest, just behind the heart. This has enabled cardiologists to obtain very clear pictures of those structures of the heart that are reasonably close to the oesophagus. The technique has also become very useful for looking at the structures of the heart during surgery without interfering with the surgeon's operating field.

## Cardiac catheterisation

- 20** This invasive investigation has always been the 'gold standard' for diagnosing congenital heart abnormalities. It involves inserting a long, fine tube (catheter) into either the vein or artery (or both), usually at the top of the leg (femoral vein and artery), usually through a needle puncture, and then guiding the catheter into the heart. Pressures are measured within the different chambers of the heart and the blood vessels leading into and out of the heart. Blood samples are taken to measure their oxygen content. In order to obtain pictures of the structure of the heart and its abnormalities, an imaging technique called 'angiocardiology' came into widespread use around the 1950s. X-ray contrast material or dye is injected into specified chambers of the heart through the catheter and its passage through the chambers and the blood vessels is recorded on X-ray film or by video techniques.
- 21** The overall risk to the patient of cardiac catheterisation has been low throughout the 1980s and onwards, the mortality being around 1%. However, the risk to the small infant is significantly greater for several reasons. Any procedure in an infant who is already sick and in heart failure adds to the risk. A general anaesthetic is usually given. The blood vessels and heart are small structures and there is a risk of damaging them during the procedure. It is preferable to avoid doing a cardiac catheterisation if sufficient information can be obtained by non-invasive methods. However, it must always be remembered that a cardiac surgeon requires as complete a diagnostic picture as is possible before embarking on an operation.

## Management strategies

- 22** All members of the cardiac team, including paediatric cardiologists, cardiac surgeons, anaesthetists, intensivists (doctors who specialise in intensive care), nurses and perfusion technicians, must work closely together in caring for each patient. There is an important reliance on the cardiologist for an accurate clinical assessment and detailed diagnosis of the abnormalities. Common practice during the period 1984–1995 was that discussions between cardiologists and surgeons took place on a formal basis at least once a week in conferences concerning groups of patients, and more frequently on an informal basis concerning individual patients. The decision concerning an operation depended upon open discussions and teamwork, especially when existing techniques were modified or when new methods were introduced. As indicated above, the decision to proceed with cardiac surgery was a decision made between the family, the cardiologist, the cardiac surgeon and of course the patient where able.
- 23** Emergency management of a baby with a cardiac abnormality is primarily undertaken by the paediatric cardiologist. There is usually a telephone discussion between the paediatric cardiologist and the referring paediatrician in order that appropriate initial treatment can be instituted both before and during the transfer to the cardiac unit. Depending on the condition of the baby, the cardiologist might also discuss the case with an intensivist or anaesthetist and arrangements might be made for admission to the ICU. The cardiologist and the intensivist together will then administer appropriate drugs to support the baby's heart, lungs and other organs while further investigations and discussions are undertaken. Throughout this period, support from nursing staff will be given together with the necessary counselling. All aspects of the baby's care and their impact on all members of the family will be considered.
- 24** From the 1980s onwards, the trends towards the use of newer technologies and towards earlier surgery for certain cardiac abnormalities created increased demands on paediatric cardiologists. These demands include diagnostic accuracy, intra-operative support by means of echocardiography in theatre, and also the diagnostic assessment of the post-operative result.
- 25** At the appropriate time, the surgeon will undertake either an 'open' or a 'closed' operation. Closed-heart surgery is mostly concerned with operating on structures close to the heart, without the need to stop the heart from beating and open the heart itself. Examples include: creating connections between blood vessels in order to promote an increased flow of blood to the lungs (shunt operations); relieving or removing narrowed areas of blood vessels (e.g. repair of Coarctation of the Aorta); creating a narrowing of the main artery to the lungs in order to reduce the blood flow (pulmonary artery banding); and tying off abnormal blood vessels (e.g. ligation of a Patent Arterial Duct). Open-heart surgery usually involves opening the heart. It thus requires the heart to be stopped after blood flow has been diverted from the heart and

lungs through a heart-lung bypass machine which, as the name suggests, takes over the role of the heart and lungs in providing oxygen to, and removing carbon dioxide from, the blood. The particular advantages to the surgeon are that there is a clear field of vision, and that the necessary valuable time is available for the repair in question to be undertaken.

- 26** Surgical techniques constantly evolved during the 1980s and 1990s. Important new operations were more widely undertaken in the UK including, for example, the Arterial Switch and the Fontan procedure. There were trends towards earlier surgery for specific lesions (e.g. Truncus Arteriosus and CAVSD) and towards primary correction rather than interim procedures (e.g. for VSD). Many of these trends were made possible by improvements in equipment and technology. Some of the more important of these were improvements in the cannulae<sup>7</sup> used for heart-lung bypass and in improved design of the heart-lung bypass machine used to support children who had open-heart surgery. There were also significant improvements in control and correction of clotting defects resulting in the shorter duration of operation and less bleeding post-operatively. In addition, there were improvements in illumination (surgical headlights) and magnification (surgical glasses).
- 27** It is not only the surgeon who performs interventions on the cardiovascular structures. It was during the mid-1960s that cardiologists first created a hole in the wall between the two upper chambers of the heart (the atriums) in babies with TGA. From about 1982 cardiologists began to undertake more interventions by means of cardiac catheterisation within the heart using newer technology. This meant that some operations which involved opening the chest, and which previously would have been done by a surgeon, were no longer necessary. Examples include: the stretching of narrow valves by means of an inflated balloon at the tip of the catheter; inserting devices into the heart or blood vessels in order to close holes or block off blood vessels; and inserting devices (known as 'stents') into the heart or blood vessels in order to open up narrowed areas.
- 28** A child who undergoes a surgical procedure, or a diagnostic procedure such as cardiac catheterisation, requires an anaesthetic. Anaesthetists have expertise in the various techniques and treatments needed to maintain patients in a state whereby the necessary surgical procedures can be carried out in a safe manner. They are responsible for determining whether a patient is in a condition to be safely anaesthetised and undergo an operation. They are important members of the team during cardiac operations, especially during open-heart procedures. Together with the perfusionists they monitor the condition of the patient and advise on the use of drugs to maintain the stability of the patient. They maintain observation of the monitors that are attached to the patient, recording the electrocardiogram (electrical heart tracing), blood pressure in different parts of the body, blood oxygen values, inhaled and exhaled gases and other measurements.

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<sup>7</sup> For the purpose of cardiopulmonary bypass, a cannula is a plastic or metal tube connected to tubing that leads to the heart-lung bypass machine. It is inserted into the aorta, or the right atrium, or the great veins. Blood is pumped through the tubing and the cannula into the aorta, and is drained from the right atrium or great veins through a cannula and tubing back to the heart-lung bypass machine

## Post-operative care

- 29** There have been significant changes in intensive care, most notably an improved understanding of cardiovascular physiology in neonates and infants, which has contributed to the significant improvement in mortality rates amongst these babies. In the early years covered by the Inquiry it would have been the practice in the majority of units for surgeons to take primary responsibility for post-operative care while anaesthetists were chiefly involved in managing the child's ventilatory support. From the early 1990s onwards, some centres started to involve anaesthetists more fully in the management of the care of children in intensive care, with anaesthetists taking on clinical sessions dedicated to the ICU. In some units this had, by 1995, evolved to the point where a full-time intensivist (usually an anaesthetist) had been appointed to the ICU.
- 30** From the early days of cardiac surgery it has normally been the practice for all members of the multidisciplinary team to be fully involved in the management of the child in the ICU, all providing their particular skills. During the early 1980s these arrangements tended to become more formalised in most of the major centres. Commonly at least one ward round would occur every day, attended by the cardiac surgeon, cardiologist and anaesthetist or intensivist, and often by other members of the multidisciplinary team. Decisions were made as a result of discussion on those ward rounds. Examples of such decisions include the need for the cardiologist to perform an echocardiogram, for the surgeon to insert a chest drain, for the anaesthetist or intensivist to change the ventilator settings or for changes to be made in intravenous therapy.

### The cardiac nurse

- 31** The role of the cardiac nurse deserves special mention. Nursing is obviously an activity involved in all aspects of care. Apart from routine observations and administration of various treatments, the nurse has an important role in providing appropriate explanations to the child, where possible, and to the family, and in preparing them for the anticipated hospital admission, investigation or operation, and for their expectations on the ICU. In particular, the nurse needs to make an interpretation of observations which is appropriate for the age of the child and to take appropriate action in response to changes in observations. There needs to be an appreciation of when the child is in pain and how that should be managed. Communication with parents and giving them care, support and counselling are essential. In those sad cases when a child dies, the nurse is usually the first professional to be involved in supporting the parents in their bereavement.



## Long-term post-operative management

- 32** After discharge from hospital, the results of the operation continue to need careful assessment for many years. This is generally undertaken by the paediatric cardiologist, often sharing the care with the consultant paediatrician in the referring hospital. Non-invasive investigations are undertaken in order to assist with the longer-term assessment. From time to time, the cardiologist ordinarily discusses the development of any problems in an individual case with the cardiac surgeon. It is often necessary to plan further hospital admissions at certain designated times for investigations that cannot be undertaken in the outpatient department. Many patients need follow-up into adult life, and for that purpose there has been a trend during the latter part of the 1990s for some cardiologists to specialise in the management of adults with congenital heart disease.

## An outline of some of the types of congenital heart disease

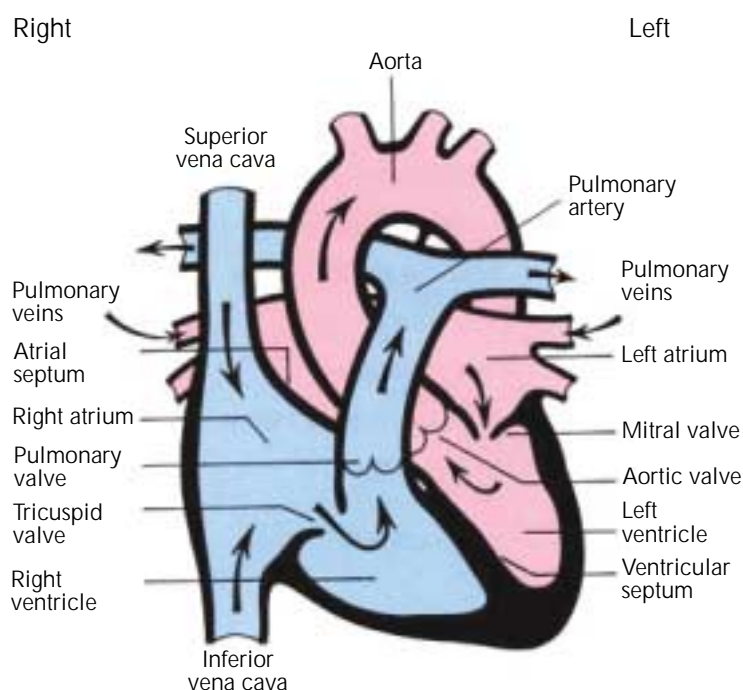
- 33** In order to understand the process by which paediatric cardiac surgical services developed in the UK over the past two decades, it is helpful to explain and review the development of many of the operations that were highlighted during the Inquiry. This, in turn, requires a brief account of the structure and function of the normal heart and circulation so that congenital heart abnormalities and their treatment can be better appreciated. An excellent account of the abnormalities is given in the booklet '*Heart Children*' published by a parents' group, the Heart Line Association.<sup>8</sup> The Association has most helpfully given the Inquiry permission to use the illustrations from the booklet which are reproduced below.

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<sup>8</sup> '*Heart Children: A Practical Handbook for Parents of Children with Congenital Heart Problems*' (1992), Heart Line Association. Available from the Heart Line Association, Rossmore House, 26 Park Street, Camberley GU15 3PL

## The normal heart

Figure 1: Normal circulation



The overall size of the heart in a newborn baby, weighing 3kg, is roughly the size of a walnut (4 x 2 x 3cm). In this diagram the individual chambers and blood vessels are not shown correctly to scale.

- 34 Figure 1 and subsequent diagrams show the heart as viewed from the front of the patient, so that all the structures that are on the right side of the patient are on the reader's left, and vice versa. In the normal heart, the left ventricle pumps blood, rich in oxygen, into the aorta which then gives branches known as arteries to all of the body. The oxygen is taken up by the muscles and organs of the body, and the blood with reduced oxygen then flows back to the heart in the veins which lead to two larger veins, the superior and inferior vena cava, and then into a chamber of the heart, the right atrium. The blood then flows into the right ventricle, which pumps it into the pulmonary artery, and into the small blood vessels in the lungs. As the blood passes through the lungs it absorbs oxygen and then returns to the left atrium of the heart. It then flows into the left ventricle which again pumps the oxygenated blood through the aorta to the body. Within the heart are valves which ensure that blood normally flows from atriums to ventricles, and from left ventricle to aorta, and from right ventricle to pulmonary artery, and does not flow backwards into the chamber from which it had originated or had been pumped. In all the diagrams, it is convenient to show the blood rich in oxygen as pink, and the blood from which oxygen has been extracted as blue.

## The heart with a congenital abnormality

**35** There are two principal consequences ((a) and (b)) of being born with a heart abnormality. These are set out below. It is essential to understand them as background to the descriptions of the specific abnormalities which follow.

(a) The abnormality may cause one of the pumping chambers (ventricles) to fail to work properly. In general terms this is known as 'heart failure'. A patient may be in heart failure for days, months or years depending on how severely the ventricle's function is compromised. Congenital heart abnormalities may cause heart failure for a number of possible reasons:

- There may be too much blood flowing through the ventricle, causing it to be 'volume loaded'.
- There may be too little blood flowing through the ventricle, causing it to be too small to function normally.
- The ventricle may be required to pump blood against a higher resistance than normal (such as through a narrow valve) causing it to be stretched and put under strain.

(b) The blood which returns in the main veins from the body to the heart and which should flow to the lungs in order to be re-oxygenated, may be diverted and be pumped to the body again without additional oxygen. This causes the skin of the baby or child to have a blue appearance, known as 'cyanosis'. More important, all of the organs then receive less oxygen than normal. If the lack of oxygenation is mild, the baby or child will not be seriously affected, apart from tiring more easily than normal children, and being at risk of other complications, especially in the presence of a serious infection. If the lack of oxygenation is more profound, the function of the other organs may also be affected and this can be most serious for the brain, liver or kidneys.

Generally a child will have one or other of these types of abnormality, but there are some rare conditions where a child may have both types.

## The specific heart abnormalities and procedures referred to in the Inquiry

### Introductory comments

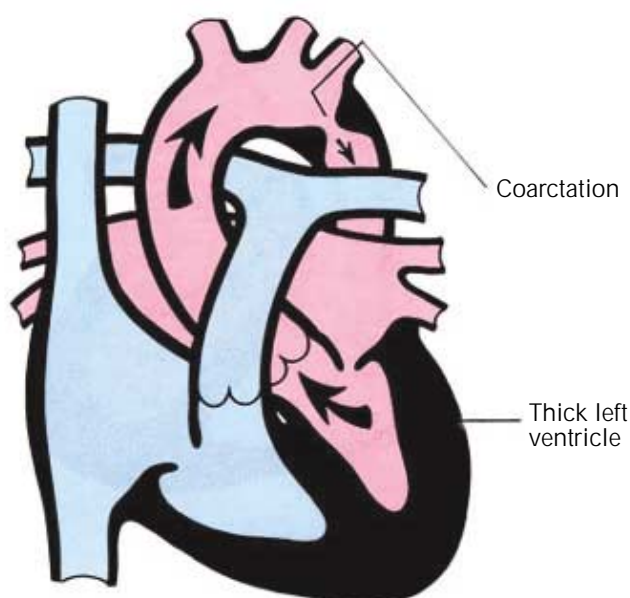
- 36** The heart abnormalities discussed in the following text include most of those that have been of special interest to the Inquiry. They help to illustrate trends in the development of cardiac services and approaches to management of children with abnormal hearts. Each abnormality is discussed in relation to the structural problem, its effect on the function of the heart and the overall effect on the patient. Methods of diagnosis and their development are also described. The surgical approach and any changes over the period 1984 to 1995 are touched on briefly. Important trends are identified in relation to some of the abnormalities and surgical procedures. The text does not address in any detail the mortality rates, the longer-term effects of some of the operations, or other risks. Comprehensive information on mortality rates in the UK between 1984 and 1995, including an evaluation of the strengths and weaknesses of the data sources on which they are based, can be found in a paper by Dr David Spiegelhalter et al, commissioned for this Inquiry.<sup>9</sup>
- 37** In general terms, post-operative complications may occur after any operation but are more likely after the more complex procedures. Complications may involve the heart itself or may affect other organs. The more common serious cardiac complications include heart failure; damage to the blood vessels that actually supply the heart muscle with blood (the coronary arteries); disturbance of the heart rhythm such as 'heart block' when the heart beats very slowly or alternatively when it has episodes of beating very fast or irregularly. Organs that may be seriously affected include the brain, kidneys, liver and gut. Some of the complications which affect other organs may be more serious than complications affecting the heart itself.

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<sup>9</sup> Spiegelhalter D, et al. 'Overview of Statistical Evidence Presented to the Bristol Royal Infirmary Inquiry Concerning the Nature and Outcomes of Paediatric Cardiac Surgical Services at Bristol Relative to other Specialist Centres from 1984 to 1995'. See Annex B

## Coarctation of the Aorta

Figure 2: Coarctation of the Aorta



### The problem

- 38** There is a narrowing of the aorta, usually just below the first main branches of the aorta to the head and arms. Coarctation of the Aorta usually occurs on its own, with no other associated abnormality. Commonly it is recognised in a baby between the ages of around 1 to 4 weeks. The narrowing causes the left ventricle to work much harder than normal in order to pump blood to the lower part of the body. Consequently the left ventricle may fail to pump blood adequately (heart failure). If the narrowing is less severe, the baby may not show signs of heart failure, but over a period of months or occasionally years, will usually develop a high blood pressure in the upper part of the body. This can have all of the serious complications commonly found in older people with high blood pressure. These complications include stroke, coronary artery disease, heart failure and kidney failure.

### Diagnosis

- 39** The baby becomes very breathless and unwell. Coarctation is usually suspected when the cardiologist cannot feel the pulses in the legs. The diagnosis is confirmed by echocardiography. Occasionally it is necessary to proceed to cardiac catheterisation in order to be certain of the diagnosis.

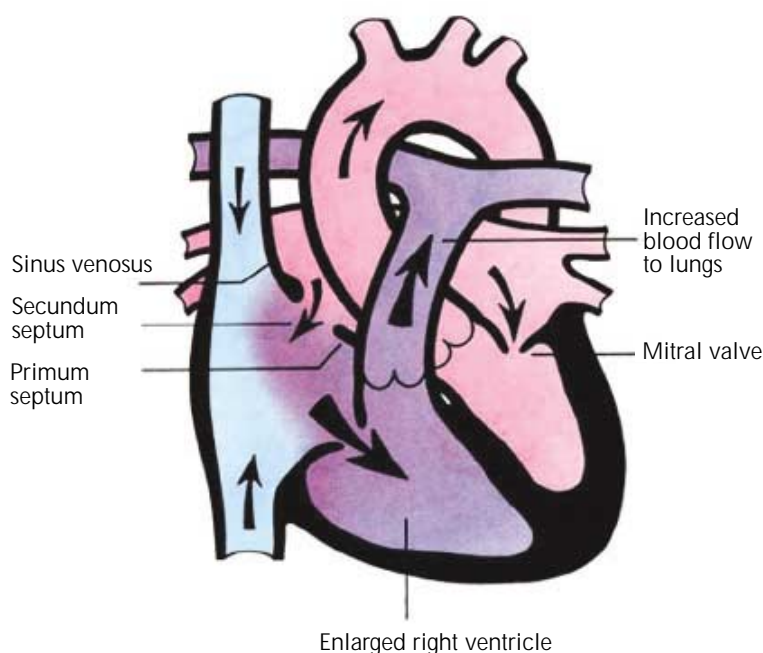
### Management

- 40** In the newborn baby who is in heart failure, an operation is undertaken as an emergency in order to relieve the narrowing of the aorta. It is almost always a closed operation but in some cases it may be necessary to use heart-lung bypass. The expected survival rate after surgery during the 1980s was reasonably good. It has improved during the 1990s, largely due to better facilities for accurate diagnosis,

newer techniques and, particularly, improvements in post-operative care. It was less good during the 1970s, largely because post-operative intensive care was less sophisticated. Occasionally, coarctation can occur in association with several other common congenital heart abnormalities and when it does, the risks are compounded over and above the expected sum of the risks for coarctation and the other abnormality.

## Atrial Septal Defect (ASD)

Figure 3: Atrial Septal Defect



### The problem

**41** There is a defect or hole in the wall (septum) between the two upper chambers of the heart, the left and right atriums. The hole might occur in any part of the atrial septum. The common defect is the one illustrated, known as a secundum ASD. In the presence of an abnormal hole, blood flows along the path of least resistance. Normally the resistance to flow is much lower in the blood vessels to the lungs than in those to the body. Therefore, in an ASD, blood flows from the left atrium to the right atrium, so that a larger volume of blood than normal then flows into the right ventricle and to the lungs. The chambers of the right side of the heart become 'volume loaded' but it is rare for heart failure to develop during infancy or early childhood.

### Diagnosis

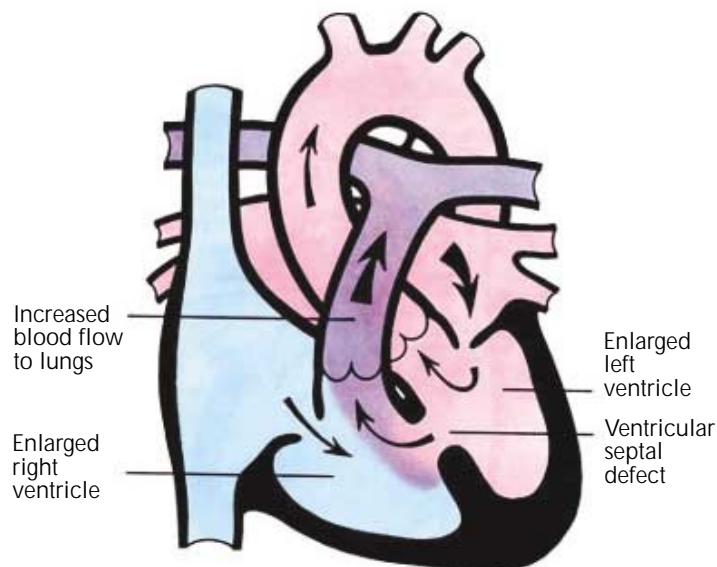
**42** The diagnosis has been made reliably by echocardiography since the early 1980s. The advances in technology have served to enhance the precision and accuracy of demonstrating the site and nature of the defect. It is rare for the cardiologist to need to resort to cardiac catheterisation.

## Management

- 43** It is recommended that the defect should be closed during childhood in order to prevent problems in adolescence or early adult life. During the period of the Inquiry's Terms of Reference, an ASD would be closed by means of an open-heart operation but since the mid-1990s technology has evolved to allow just over a third of these defects to be closed by means of cardiac catheter devices. Throughout the 1980s and onwards, the risk of undertaking open-heart surgery in order to close an ASD has generally been regarded as very low.

## Ventricular Septal Defect (VSD)

**Figure 4: Ventricular Septal Defect**



## The problem

- 44** There is a hole (defect) in the wall between the two ventricles of the heart. The size of the hole determines whether or not the function of the heart will be compromised. It has been estimated that approximately 65% of all VSDs are too small to create a problem for the child and will probably become smaller with the passage of time, some even closing spontaneously. The VSDs with which the Inquiry was concerned were those which were large and therefore required surgical closure.
- 45** With each heartbeat, the two ventricles together pump blood out of the heart, the left ventricle to the body and the right to the lungs. In VSD, the blood flows normally from both ventricles, and also through the hole along the pathway of least resistance, i.e. from left to right ventricle and into the blood vessels to the lungs. The increased volume of blood flowing to the lungs then returns to the left atrium and to the left ventricle. The increased volume load on the left ventricle contributes to that chamber of the heart becoming 'stretched' with consequent reduced function or 'heart failure'.
- 46** There are some babies in whom a large VSD does not cause heart failure because the blood vessels to the lungs behave abnormally and provide an increased resistance to

lung blood flow. In those cases, the expected increased flow of blood to the lungs with the consequent increased return of flow to the left heart chambers does not occur. Therefore, the left ventricle does not become sufficiently volume loaded for its function to become compromised. However, the problem is equally serious because the pressure in the blood vessels to the lungs increases and, in time, permanent changes take place in those vessels. This condition is known as pulmonary hypertension or pulmonary vascular disease and it progresses over the years, causing death in late adolescence or early adulthood. It is essential to recognise this problem within the first few months of life before pulmonary vascular disease becomes permanent.

### Diagnosis

**47** The baby becomes progressively more breathless to the extent that he is unable to complete feeds, fails to gain weight and becomes more hungry, requiring more frequent feeds and eventually becomes so exhausted that he has to be helped temporarily by being fed through a tube passed from the nose, down the oesophagus and into the stomach. The diagnosis is made by examining the baby and is confirmed by echocardiography. As explained above under 'Echocardiography', advances in technology have considerably enhanced the accuracy of identifying the site and nature of the defect. From the mid-1980s it was common for babies to be subjected to cardiac catheterisation in addition to echocardiography. By the mid-1990s, evolving technology and experience enabled the diagnosis, in most cases, to be made sufficiently accurately using echocardiography alone. However, there continue to be some babies in whom it is necessary to obtain additional information by cardiac catheterisation.

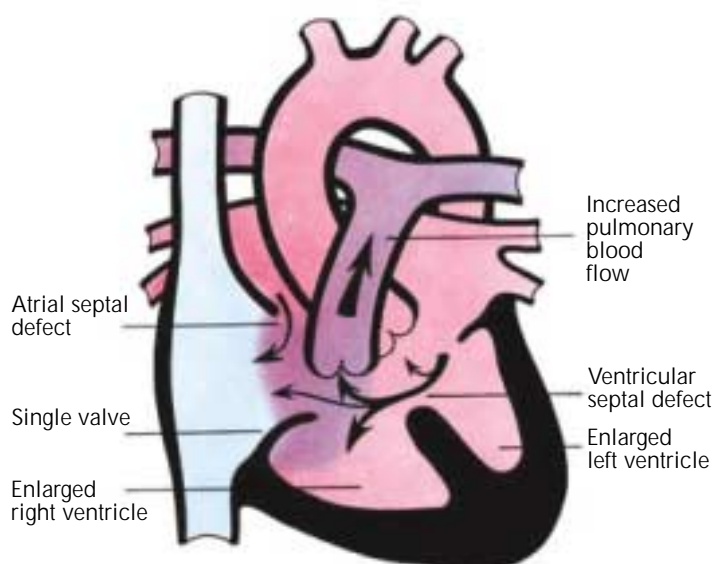
### Management

**48** In the presence of heart failure, medical treatment is only of temporary value and a relatively early surgical operation becomes necessary. Surgical closure of a VSD is an open-heart procedure. The technical difficulty, if any, relates to the nature and position of the defect within the ventricular septum. The age and the size of the baby are also factors. During the early to mid-1980s, the mortality rate in the UK for closure of a VSD in infancy was significantly higher than in older children. During the 1990s the mortality rate reduced substantially for all age groups.



## Complete Atrio-Ventricular Septal Defect (CAVSD)

Figure 5: Complete Atrio-Ventricular Septal Defect



### The problem

**49** The defect involves the whole area of the junction of the upper and lower chambers of the heart, i.e. where the atriums join the ventricles. There is a large hole between the lower portion of the atriums and the upper or 'inlet' portion of the ventricles and this is associated with a significant abnormality of the valves separating the atriums from the ventricles. The valves in effect become a common atrio-ventricular valve, and the severity of the defect depends largely on the supporting attachments of the valve to the ventricles and whether the valve allows dominant flow from the right atrium to right ventricle and from left atrium to left ventricle. The overall problems are similar to those of VSD but are more complicated. There is an increased flow of blood to the lungs through both the ventricular and atrial components of the defect. In addition, the abnormal atrio-ventricular valve invariably leaks, so that when the ventricles contract, blood flows not only forwards to the body and the lungs, but also backwards into the atriums. The back-pressure effect on the atriums causes congestion of blood in the left atrium in particular, and this in turn causes congestion in the veins draining the lungs. The effect on the baby is to worsen the heart failure that is associated with an isolated VSD and to hasten the onset of pulmonary hypertension. It should be mentioned that CAVSD is found in approximately one-third of babies who have Down's syndrome, but it also occurs as an isolated abnormality.

### Diagnosis

**50** The symptoms are similar to those of VSD with breathlessness, difficulty in feeding and failure to gain weight. The diagnosis may be anticipated by examining the baby and by a characteristic abnormality of the electrocardiogram (ECG) but the confirmation is obtained by echocardiography. In the present day, and even from the mid-1980s to the mid-1990s, a complete diagnosis could usually be made by echocardiography alone. From the late 1980s onwards, technological advances have

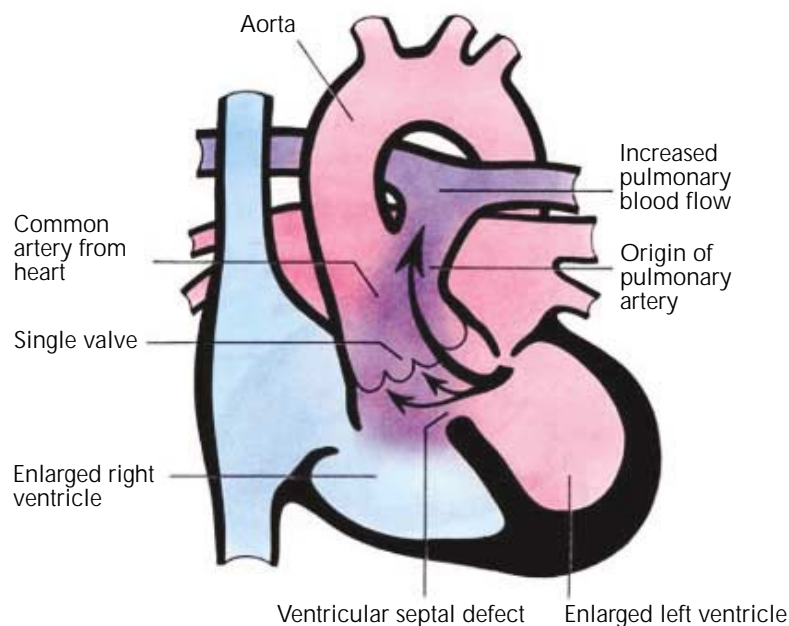
helped to improve the accuracy of recognising all components of the abnormality. In some cases, it may also be necessary to do cardiac catheterisation in order to assess the question of pulmonary hypertension and to obtain a clearer impression of whether the two ventricles are each of adequate size to allow for surgical closure of the defect.

## Management

- 51** The initial management is the medical treatment of heart failure and usually tube-feeding in order to encourage growth. The surgical procedure is a complicated open-heart operation involving closure of the defects between the atriums and the ventricles, and separation of the common atrio-ventricular valve into two separate valves. Since the time when surgical treatment first became possible, it has been recognised that surgical correction is the ideal approach, preferably during the first few months of life in order to cure the heart failure and to prevent the high incidence of the progression of pulmonary hypertension.
- 52** In the mid-1980s cardiologists and surgeons were faced with the quandary of knowing that surgical correction of CAVSD carried a high risk, especially in babies under the age of 1 year. There was a tendency to delay the operation until the baby had grown because it was considered that the risk would then be lower. However, it was recognised that this was often at the cost of the baby developing irreversible pulmonary vascular disease (pulmonary hypertension) in which case an operation was no longer possible.
- 53** Towards the beginning of the 1990s changes in the operative technique and probably other factors in management of care led to a significant reduction in reported mortality and by the mid-1990s most centres in the UK were able to achieve good results.
- 54** It is important to recognise that even after an apparently successful corrective operation, problems can continue for children with CAVSD. Usually these relate to a continued leak back through the atrio-ventricular valve from the left ventricle to left atrium. In those cases, later surgical repair or even replacement of the valve may become necessary, often some years after the original operation.

## Truncus Arteriosus

Figure 6: Truncus Arteriosus



### The problem

- 55** Truncus Arteriosus is very rare, occurring in fewer than 1% of congenital heart abnormalities, but it has provoked a great deal of interest. In order to understand the nature of the abnormality it is helpful to recall that in the normal heart the aorta arises from the left ventricle and the pulmonary artery from the right. In Truncus Arteriosus, a single large arterial trunk arises from both ventricles, and there is a large VSD just below the trunk. Soon after its origin from the ventricles, the arterial trunk gives rise to large pulmonary arteries and then it continues as the aorta. Both ventricles pump blood simultaneously into the trunk which consequently receives both deoxygenated blood from the right ventricle and oxygenated blood from the left. If this blood were evenly mixed, one would expect that the relatively high contribution of deoxygenated blood would cause obvious blueness or cyanosis (see [para 35](#)). Indeed, careful measurement of the blood oxygen content does reveal some degree of deoxygenation but this is usually very mild.
- 56** The more important effect of the abnormality is that there is the usual tendency for blood flow to take the path of least resistance, i.e. to flow preferentially into the pulmonary arteries and to the lungs. Blood flow to the lungs tends to be torrential with a large return of oxygenated blood to the left heart. Therefore the flow of oxygenated blood from the left ventricle into the common trunk is many times more than that from the right ventricle. Consequently, the effect of the deoxygenated blood flowing to the aorta is considerably reduced, accounting for the relative lack of cyanosis.
- 57** The presenting effects on the baby are similar to those seen when there is a large VSD. The increased volume of blood flowing to the lungs and returning to the left side of

the heart causes heart failure in the same way as described for VSD. The heart failure tends to develop much more rapidly and with greater severity with the result that 70% of babies with Truncus Arteriosus do not survive beyond the age of 3 months if left untreated.

- 58 Not uncommonly, there is another related problem involving the valve between the arterial trunk and the two ventricles. The valve may open well but may not close fully, with the consequence that blood that has been pumped from the ventricles into the arterial trunk may leak back into the ventricles. This adds to the amount of work done by the ventricles and hastens the development of heart failure.
- 59 Another associated abnormality that may accompany Truncus Arteriosus is known as 'interrupted aortic arch', which is an extreme form of Coarctation of the Aorta. Babies with this combination usually present during the first week of life and their general condition may deteriorate quite rapidly without intensive treatment and early surgery.

### Diagnosis

- 60 The baby usually presents during the first few weeks of life with evidence of severe heart failure. The diagnosis can usually be made quite accurately by echocardiography alone. At least this has been true since the early 1990s when colour-flow Doppler mapping of blood flow became routinely available. During the 1980s it was usually possible to diagnose the presence of Truncus Arteriosus with echocardiography but the precise nature of the origin of the pulmonary arteries from the arterial trunk could not always be defined. In some patients there is the additional problem of an associated interrupted aortic arch which may be very difficult to diagnose. In those cases, both then and today, additional investigation by cardiac catheterisation may need to be undertaken.

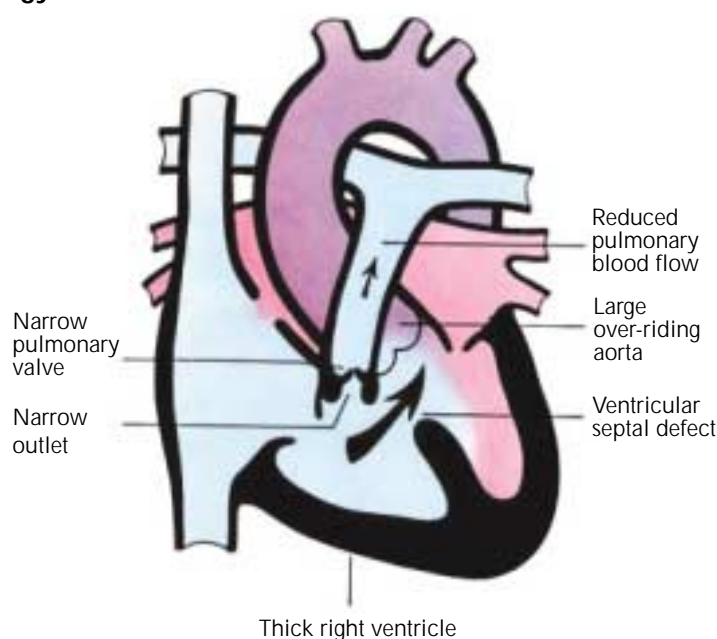
### Management

- 61 Because the newborn infant with Truncus Arteriosus is usually so ill, the standard drugs for the treatment of heart failure are of limited value. The baby often, but not always, requires early treatment in the ICU with the support of a ventilator. Surgical correction is usually undertaken in babies who are less than 6 weeks old. The operation is a major open-heart procedure and is complex. Essentially the VSD is closed in such a way that all the blood flow from the left ventricle is directed into the common arterial trunk. The pulmonary arteries are separated from the trunk, which is then reconstituted as a single large artery, and it becomes the new aorta. The pulmonary arteries are connected to a tube or conduit, if possible a piece of donated human aorta or pig's aorta, and the conduit is connected to a surgically created opening in the right ventricle. In some cases a conduit with a human or pig's valve is used. In this way the right ventricle pumps blood directly to the pulmonary arteries while the left ventricle pumps to the aorta. If the truncal valve is leaking it may need to be repaired and this can be a significant complicating factor in determining outcome.
- 62 Because Truncus Arteriosus is such a rare condition, very few operations are done in any one centre each year. It is therefore difficult to assess with certainty the mortality

rates across the UK during the period covered by the Inquiry's Terms of Reference. In the mid-1980s corrective operations on babies under the age of 1 year were considered to carry a very high risk of death. The results improved during the late 1980s to the early 1990s but by 1995 the operation still carried a very high risk, even in those cases in which there were no associated complicating problems.

## Tetralogy of Fallot

Figure 7: Tetralogy of Fallot



### The problem

**63** This abnormality is the commonest form of cyanotic congenital heart disease. It occurs in just under 10% of all babies with congenital heart abnormalities. There is a large VSD in the same portion of the ventricular septum as was described for Truncus Arteriosus. The aorta arises dominantly from the left ventricle but overrides the VSD so that there is a tendency for blood to flow into the aorta from both the left and the right ventricle. There is also a narrowing of the outflow from the right ventricle to the pulmonary artery (pulmonary stenosis). The severity of the narrowing varies from one patient to another. Its effect is to increase the resistance to blood flow from the right ventricle to the lungs. The flow of blood to the lungs is reduced and instead, blood then flows along the path of least resistance. In that case it is from the right ventricle, through the VSD and into the aorta. In other words, deoxygenated blood flows from the right ventricle to the body, together with the oxygenated blood from the left ventricle. Consequently, the child shows the features of cyanosis.<sup>10</sup> The greater the severity of the pulmonary stenosis, the more severe is the degree of cyanosis.

<sup>10</sup> See para 35

- 64** Those babies who have severe reduction in blood flow to the lungs and more profound cyanosis present early in the newborn period and require early measures to improve pulmonary blood flow. Others, whose pulmonary stenosis is less severe, may not show any symptoms until they are several months old, or not even until they become toddlers. All children with Fallot's Tetralogy are limited in their physical activities and are at risk of complications. The most common of these is the occurrence of 'spells' in which the baby suddenly becomes extremely blue and floppy and often loses consciousness for a few minutes. Recovery is usually rapid but on rare occasions an attack can be fatal. Spells are caused by the outflow tract of the right ventricle becoming suddenly narrower as a result of a form of 'spasm' of the right ventricular muscle below the pulmonary valve. When the spasm is relieved, the baby recovers from the spell. Another most serious complication is related to bacteria entering the blood stream from an apparently mild infection of the skin or throat. Instead of passing normally to the lungs where the bacteria are trapped and often cause a minor or occasionally more severe lung infection, they pass from the right ventricle, through the VSD to the body and may settle in the brain causing an abscess which can prove fatal. For all of these reasons it is desirable that a child with Fallot's Tetralogy should have a corrective operation as early as it can safely be done.

### Diagnosis

- 65** The diagnosis is usually suspected on the basis of the presenting symptoms and by examination of the patient. It is usually confirmed by echocardiography and on that basis, the initial plan of management can be undertaken. Before proceeding to corrective surgery, additional investigation by cardiac catheterisation has been regarded as mandatory in some centres in order to demonstrate every fine detail of the abnormality. In the mid-1980s the diagnosis could usually be made confidently using echocardiography. The evolution of ultrasound technology during the late 1980s and towards the mid-1990s has enabled cardiologists to be even more confident of some of the finer details of the abnormality. Nevertheless a number of questions that are important to the technical approach of a corrective operation are better answered by proceeding to cardiac catheterisation.

### Management

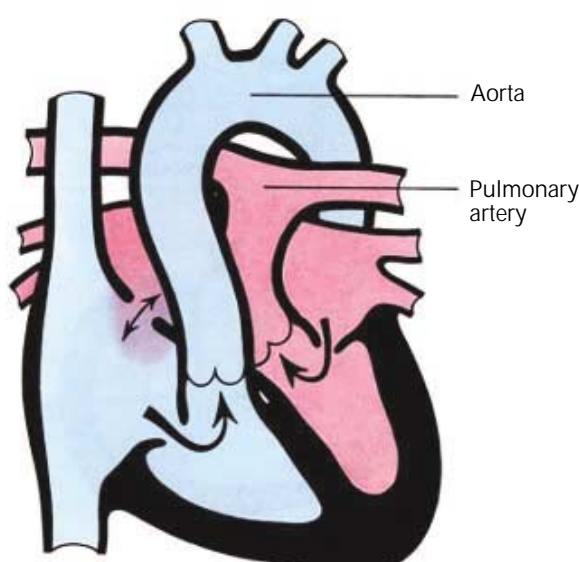
- 66** Throughout the period covered by the Inquiry's Terms of Reference, i.e. from the mid-1980s to the mid-1990s, the management of the child with Fallot's Tetralogy would have followed a similar pattern in most centres.
- 67** The newborn baby with severe cyanosis initially requires an increase in the blood flow to the lungs. During fetal life, an artery known as the arterial duct normally connects the aorta and the pulmonary artery. It normally closes within the first two to three days of life but it can be kept open by using a drug, prostaglandin E. By keeping the duct open, blood flows from the aorta through the duct into the pulmonary artery and even if this is the only source of blood flow to the lungs, it is usually sufficient for survival and stability in the short term. However, it is unusual for a baby with Fallot's Tetralogy to become severely cyanosed so soon after birth and it is more usual that the duct will have closed by the time that he is first seen. In such a case it is necessary to undertake

an emergency operation known as a 'shunt' in which a small tube is used to connect a branch of the aorta to the pulmonary artery. This is the type of operation first described in 1945 by Blalock and Taussig. Shunt operations have improved in both technological and technical terms since the mid-1980s and the mortality has fallen significantly since then.

- 68** It is more usual for the cardiac team to be faced with a baby whose cyanosis has increased significantly around the age of 2 to 4 months, often associated with cyanotic spells. In those babies it has been usual to begin medical treatment initially with a drug known as a beta-blocker in order to try to reduce spasm of the right ventricular outflow tract. This is a temporary measure and is followed within days or weeks by a shunt operation. In those circumstances the risk of a shunt operation is somewhat lower than when performed in the newborn period.
- 69** Corrective operations are 'open-heart' procedures. Some babies may undergo primary corrective repair if they are large enough and if the abnormality is not too complicated. If they have had a previous shunt operation, it is necessary to close the shunt. The VSD is closed using a patch so that left ventricular blood flows entirely into the aorta. The pulmonary stenosis is relieved, both by cutting open the pulmonary valve, and usually by opening the right ventricular outflow tract and widening it by inserting a gusset. The pulmonary artery branches themselves may be narrowed and often need to be reconstructed. The operation can be relatively routine or quite complicated, depending on how much reconstructive work is necessary. The mortality rate in the UK fell significantly between the mid-1980s and the mid-1990s. There had been many reports from centres of excellence in the United States of low mortality rates in the mid-1980s and in the centres of excellence in the UK similar results were expected.

## Transposition of the Great Arteries (TGA)

**Figure 8: Transposition of the Great Arteries**



## The problem

**70** This is one of the commonest of the cyanotic congenital heart abnormalities. For a clearer understanding of the abnormality, a brief recapitulation may be helpful. The great arteries are the aorta and the pulmonary artery. The left ventricle normally connects to the aorta into which it pumps oxygenated blood, and the right ventricle connects to the pulmonary artery into which it pumps deoxygenated blood. When the great arteries are transposed, the left ventricle connects to the pulmonary artery and the right ventricle to the aorta. Deoxygenated blood returns from the body to the right side of the heart and should then flow to the lungs to be oxygenated. Instead it is again pumped out to the body. Similarly, oxygenated blood returning from the lungs to the left side of the heart is pumped again to the lungs. In order for the baby with TGA to survive, it is essential that some of the oxygenated blood should cross over to the right side of the heart and then to the body. Similarly some of the deoxygenated blood should cross over to the left side of the heart in order to flow to the lungs to become oxygenated. In the fetus there is normally a hole in the wall between the left and right atriums, and there is also an arterial duct<sup>11</sup> connecting the aorta and the pulmonary artery. These fetal structures normally remain open for several hours after birth and the blood flow through them allows for the necessary crossover of blood between the left and right sides of the heart. The baby is usually slightly blue at birth, and the cyanosis increases as the communications between the two sides of the heart become smaller. Unless emergency measures are undertaken the baby's condition deteriorates rapidly and he does not survive. Some babies with TGA are born with additional abnormalities, one of the commonest being VSD. In that case, an additional communication between the two sides of the heart may result in the cyanosis being quite mild but the baby then suffers from the additional problems associated with a VSD. The term 'Taussig-Bing' syndrome is used to describe a VSD which is just beneath the pulmonary artery so that there tends to be a considerable flow of blood to the lungs.<sup>12</sup> Other associated abnormalities that occur not uncommonly are pulmonary stenosis, and Coarctation of the Aorta, and they add additional problems in the overall progress and management of the baby.

**71** There is a particular problem relevant to the management of TGA which is important. The heart requires a blood supply to the heart muscle. This comes from the coronary arteries, which branch off from the aorta almost as soon as that great artery arises from the left ventricle in the normal heart, or from the right ventricle in TGA. The flow into the coronary arteries depends on the blood pressure in the aorta being at least normal, and it is important that oxygenated blood flows to the heart muscle. The logical operation in TGA is one in which the great arteries are disconnected from their transposed positions and reconnected so that they receive blood respectively from the correct ventricles. Therefore it is clear that during the operation the coronary arteries need to be moved over together with the aorta. There are technical difficulties associated with this delicate part of the operation and it is important that the cardiologist and the surgeon both have as clear an understanding as possible of the branching of the coronary arteries in each individual case.

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<sup>11</sup> See the section on the management of Tetralogy of Fallot in this chapter

<sup>12</sup> See the section on the diagnosis of Ventricular Septal Defect (VSD) in this chapter



## Diagnosis

**72** Transposition of the Great Arteries was one of the earliest of the diagnoses that could be made confidently using echocardiography. Throughout the period covered by the Inquiry's Terms of Reference, almost all centres in the UK would have used echocardiography alone in order to obtain a complete diagnosis of TGA together with most of the other associated abnormalities. The sensitivity and accuracy of detecting the associated abnormalities have been enhanced by the use of ultrasound Doppler and colour-flow mapping. An important element of the echocardiographic diagnosis is to try to visualise the origins and branching of the coronary arteries in order to alert the surgeon if there is likely to be anything unusual. There are always a few cases in which cardiac catheterisation still becomes necessary as, for example, when there is any uncertainty about certain diagnostic details.

## Management

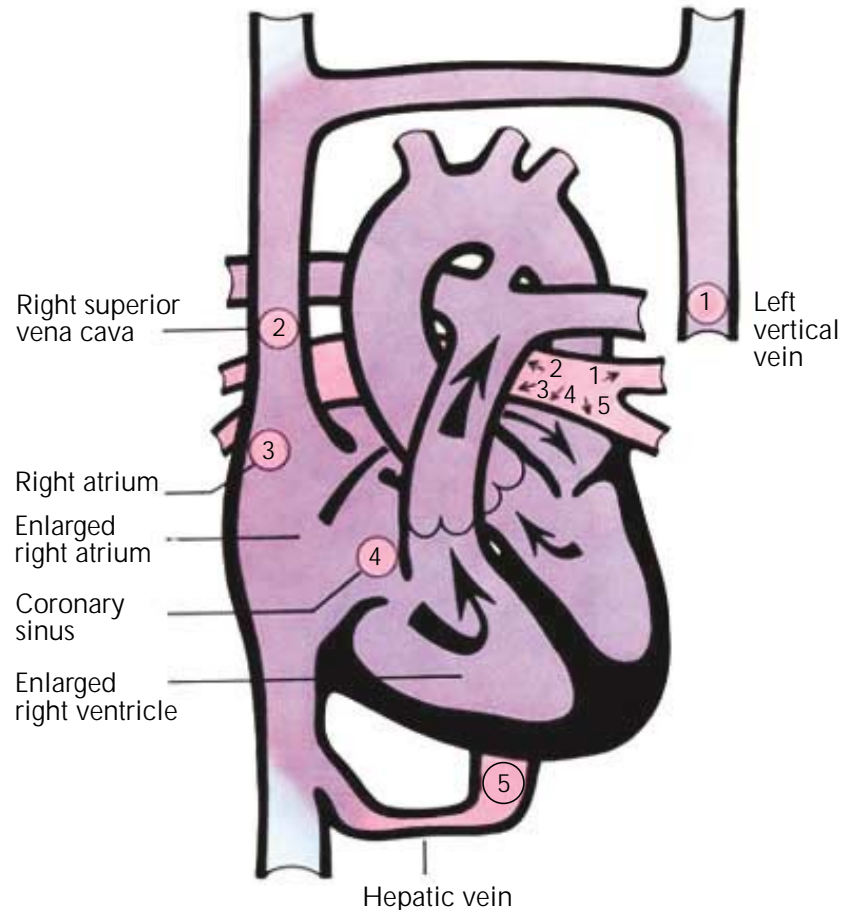
- 73** From the late 1970s, the initial emergency management of almost all newborn babies with severe cyanotic congenital heart disease has been to treat with prostaglandin E in order to keep the arterial duct open. In TGA this is usually rapidly effective in improving the blood oxygenation by encouraging more blood flow to the lungs and more flow through the hole between the two atriums. Then, by means of a cardiac catheterisation technique, a larger hole is created in the wall between the atriums. This is known as 'balloon atrial septostomy'. Improvements in the design of the equipment for this procedure have simplified it significantly and it is now regarded as relatively safe and routine. There have been minor developments related to balloon atrial septostomy between the mid-1980s and mid-1990s. They have been influenced largely by improvements in intensive care management. Instead of moving the baby to the cardiac catheterisation theatre, the procedure is often performed in the intensive care unit using echocardiography in order to visualise the cardiac catheter and the cardiac structures. Most babies with an adequate hole in the atrial septum can survive and thrive for many months.
- 74** In the mid-1980s the standard approach after balloon atrial septostomy was to discharge the baby home, then plan further investigations with a view to an operation at around 6 months of age. The precise timing depended on the general condition of the baby and on the degree of cyanosis during the period of follow-up. Although it was recognised that the logical operation would have been to 'switch' the great arteries to their 'correct' ventricles, the technicalities of moving the coronary arteries had not been adequately mastered. Therefore the type of operation that had been performed since the mid-1960s was undertaken, namely the Mustard procedure or the Senning procedure.
- 75** Both of these operations employ the same principle. Deoxygenated blood returning from the body is diverted so that it flows to the left ventricle (instead of the right), then to the lungs. Similarly, oxygenated blood returning from the lungs is diverted so that it flows to the right ventricle and then to the aorta. Thus instead of the left ventricle pumping blood to the body, the right ventricle continues to do this work and the left ventricle continues to pump blood to the lungs. Since the operation was first designed,

it has been questioned as to whether the right ventricle was capable of sustaining the demands of pumping at a higher pressure than if it were providing blood flow to the lungs. The operation is very effective and enables children to lead normal lives but in the longer term, complications have been reported, mostly during late adolescence or early adult life. Therefore considerable efforts were made during the 1980s to perfect the more logical Arterial Switch operation.

- 76** During the 1980s there were some isolated reports of Arterial Switch operations being done in the United Kingdom but virtually all centres continued to rely on the Mustard and Senning procedures. Meanwhile, considerable advances in the Arterial Switch technique were made in a few centres in the United States and in Europe and Australia. Towards the end of the 1980s a few centres in the UK were obtaining good or satisfactory results by using the Switch procedure and by the early 1990s the operation had become well established in most of the major centres. By the mid-1990s it was expected that all major centres would have been performing the Arterial Switch operation instead of the Mustard or the Senning procedure with a reasonable expectation of good results. It was recognised that the major technical problem with the Switch procedure continued to be related to the difficulty of relocating the coronary arteries. Surgeons began to appreciate that if the coronary artery anatomy was particularly difficult, it was advisable to ask for help, if at all possible, from one of the few surgeons with a wide experience of dealing with the problem. Great reliance was ordinarily placed on the paediatric cardiologist to recognise that a coronary abnormality might be present in an individual case.
- 77** Associated additional abnormalities create more work for the surgeon and consequently complicate the technical procedure. Each of the additional abnormalities must be repaired in addition to the Arterial Switch being carried out. There is one notable exception. Some children with TGA also have a VSD together with pulmonary stenosis. If the VSD is high in the ventricular septum and just below both great arteries it is often more convenient to perform the so-called Rastelli operation. In this procedure a patch is placed on the defect in such a way that flow from the left ventricle is diverted through the VSD and into the aorta. This process necessitates closing the connection between the left ventricle and the pulmonary artery. Then a valved conduit is placed between the right ventricle and the pulmonary artery.
- 78** Most patients who have survived the Arterial Switch operation have an uncomplicated course but it is essential that they are kept under regular review and are assessed by echocardiography for evidence of any of the later complications. Some of these patients need further operations or cardiac catheter interventions in order to remedy problems such as narrowing of the pulmonary arteries or very occasionally significant leaking of the aortic valve. Although there is the expectation that children undergoing the Arterial Switch operation are likely to have better long-term results than those with the Mustard or Senning operation, not many patients have had a sufficiently long post-operative period in order to be able to confirm that belief.

## Total Anomalous Pulmonary Venous Drainage (TAPVD)

Figure 9: Total Anomalous Pulmonary Venous Drainage



### The problem

**79** TAPVD is rare, comprising around 1% of all congenital heart abnormalities. A successful operation can usually ensure uncomplicated survival, whereas 80% to 90% of babies with TAPVD die before their first birthday if they are not treated surgically. All of the pulmonary veins draining blood from the lungs should normally be connected to the left atrium. In TAPVD they drain instead into the right atrium, or more commonly into one of the veins from the body which eventually drains into the right atrium. The diagram (Figure 9) demonstrates the different possible sites to which the pulmonary veins commonly drain. It is essential that the hole in the wall between the atriums, normally present in the fetus, remains open in the newborn baby so that blood returning from the lungs can flow from the right to the left atrium and then to the body. Much of the blood returning from the lungs to the right heart is again pumped to the lungs together with blood returning from the body. The increased flow causes the right ventricle to become volume loaded and also causes lung congestion. If the inter-atrial hole is too small, then the flow to the right ventricle and the lungs is even greater, with consequently worsening congestion. It is more usual for right to left atrial flow to be adequate in which case there is still volume-overload of the right

ventricle together with lung congestion, but there is sufficient oxygenated blood flowing to the body. The pulmonary veins most commonly connect to one of the veins from the upper part of the body and this is usually associated with the fewest severe emergency problems. When the pulmonary veins connect to one of the veins draining the lower part of the body, the blood often has to flow through the liver before it reaches the main lower vein joining the right atrium. The passage of blood, by going through the liver, or even through a more tortuous route, is considerably slowed down, and the pulmonary venous drainage is essentially obstructed, causing severe congestion of the lungs. Babies will then often present within hours after birth with severe breathlessness and cyanosis, and resuscitation may be difficult.

### Diagnosis

**80** Newborn babies with TAPVD present with severe breathlessness and cyanosis and are often confused with those who more commonly have a primary lung problem, known as 'respiratory distress syndrome'. The diagnosis of TAPVD by echocardiography can be extremely difficult, and was even more so in the mid-1980s when colour-flow mapping was not available. The diagnosis depends on showing that the pulmonary veins are not connected to the left atrium, and also being able to visualise their connection to an abnormal site. Even when colour-flow mapping is used, it may be difficult to identify the flow in the pulmonary veins. Cardiologists, despite being meticulous in searching for the confirmation or rejection of the diagnosis of TAPVD, may remain uncertain of its presence. The baby with either TAPVD or with respiratory distress syndrome is usually so ill that there is reluctance to undertake cardiac catheterisation because of the considerable risk.

### Management

**81** Most babies with TAPVD are very ill when the diagnosis is made. Normal pre-operative supporting measures are undertaken while arrangements are being made for corrective surgery. Pre-operative measures might include the admission to the ICU and support on a ventilator. The operation is a major procedure using an open-heart technique but the majority of the operation takes place outside the heart, the only intra-cardiac element being the connection of the pulmonary veins to the left atrium. In the mid-1980s the operative risk was significantly higher than it became in the early and mid-1990s. The better results were due largely to improvements in early diagnosis as well as in pre-operative intensive care, surgical techniques and post-operative management. The most difficult cases have always been those in whom the pulmonary veins tended to be obstructed in some part of their course.

**82** After successful repair it is unusual to have significant longer-term problems. Occasionally the pulmonary veins become obstructed at or near the surgical connection to the left atrium and re-operation becomes necessary. Most babies proceed to lead trouble-free, uncomplicated and normal lives.

## The Fontan procedure

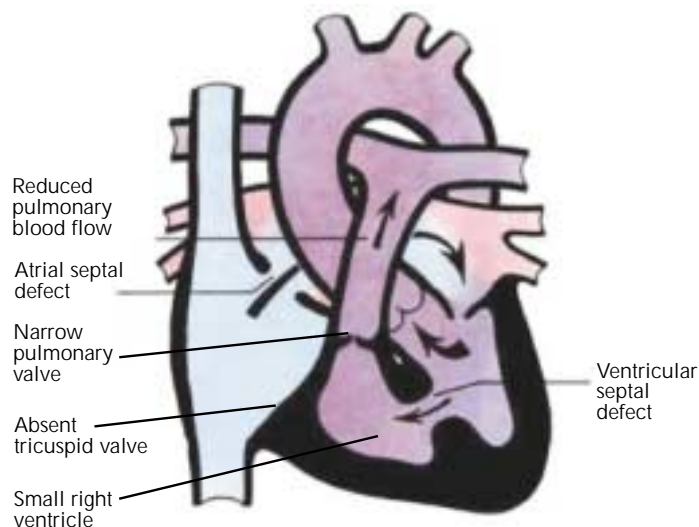
**83** Thus far, the second half of this chapter has focused on the diagnosis and management of a number of specific abnormalities. This section takes a different perspective, and considers one important procedure, the Fontan procedure, which may be used to help children who present with a range of heart abnormalities.

### The problem

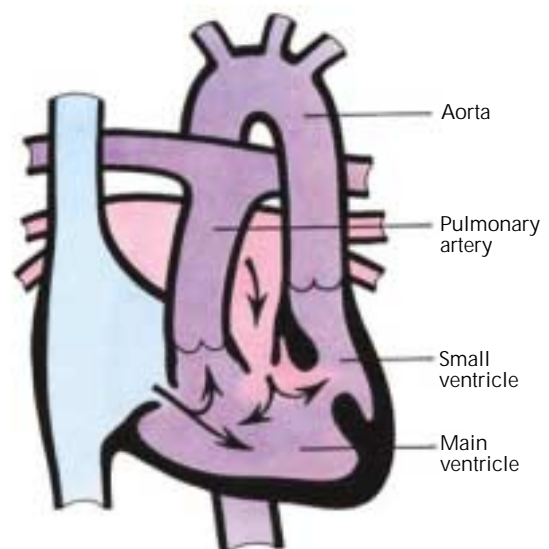
**84** There is a group of patients who have only one effective ventricle instead of two. The commoner abnormalities in this group are one of the following:

- A single ventricle pumps blood into both great arteries (the aorta and pulmonary artery).
- Two ventricles are present but one is too small to perform its normal function.
- The connections between the atriums and ventricles are unsuitable for an operation that would separate the ventricles into two effective chambers that would then pump blood into the appropriate great arteries.

**Figure 10: Tricuspid atresia**



**Figure 11: Double inlet ventricle**



**85** For illustrative purposes, diagrams of two examples are shown above, namely tricuspid atresia and double inlet ventricle.

- In the normal heart the tricuspid valve opens to allow blood to flow from the right atrium to the right ventricle. In tricuspid atresia, the valve fails to develop. Consequently, all the deoxygenated blood that enters the right atrium must flow through the hole that is normally present in the wall between the two atriums in the fetus and newborn baby. Blood flows into the left atrium, then the left ventricle and

then into the aorta. In other words, deoxygenated blood flows into the aorta, and causes the baby to be cyanosed (blue). The baby needs a series of medical and surgical procedures in order for it to have adequate blood flow to the lungs and consequently to survive and grow.

- In double inlet ventricle all the blood from both atriums flows into an effectively common ventricle and then out to both great arteries. The overall result is a considerable increased flow of blood to the lungs. The effects on the baby are similar to those described for a VSD (see [paras 44–46](#)).
- There are complicated forms of AVSD in which it is technically not possible to separate the two ventricles surgically so that each can function independently. The baby has all the features already described for CAVSD (see [para 49](#)) but there is a structural problem in relation to the atrio-ventricular valves such that separation into two valves is not technically possible.
- In hypoplastic<sup>13</sup> left or right ventricle there is a very small ventricle that is incapable of functioning independently in order to pump blood into either the aorta or the pulmonary artery respectively.

## Diagnosis

- 86** In all of the congenital heart abnormalities described earlier, the importance of a careful and complete diagnosis has been repeatedly emphasised. The same principles apply to the diagnosis and assessment of abnormalities in which there is only one effective ventricle. Demands are therefore made on all of the diagnostic skills of the cardiologist. Careful echocardiographic assessment is essential in planning the initial procedure. When necessary, additional cardiac catheterisation is carried out.

## Management

- 87** All of these conditions usually require at least one preliminary operation. The overall aim is that eventually the child will have the type of operation that was first performed in 1968 by Francis Fontan in Bordeaux. He connected the right atrium directly to the pulmonary artery in a patient with tricuspid atresia. Thus instead of the blood being pumped by the right ventricle into the pulmonary artery, it flowed there passively from the right atrium. The operation ensures that the ventricle pumps blood to the aorta and to all of its branches and that the blood returning from the body in the main veins is all diverted to the pulmonary arteries. Blood returning from the lungs flows normally into the left atrium and then into the effectively single ventricle which again pumps the blood to the body.
- 88** The Fontan operation itself, or one of its modifications, does not usually present major technical difficulties. Its success depends on the careful preliminary preparation of the patient by means of one or more palliative operations. The first surgical procedure is usually undertaken either in the newborn period or in the first few months of life.

Depending on the underlying problem, it may be a shunt operation in order to increase the pulmonary blood flow, or it may involve banding of the pulmonary artery in order to decrease the flow. In some cases a more complicated operation may be undertaken in order to re-route blood flow into the aorta and pulmonary arteries; this is known as the 'Damas-Kay-Stansel procedure'. Then since the late 1980s, most patients between the ages of 4 months and 1 year have had a further operation in which the superior vena cava (the main vein draining the upper part of the body) is connected directly to the pulmonary artery. It achieves blood flow from the upper part of the body going directly to the lungs and in that sense is essentially halfway towards the Fontan operation.

- 89** The cardiologist and the surgeon need to plan all stages of the timing and the overall management together, always bearing in mind that the ultimate goal will be the Fontan procedure. Throughout the period of management of the child it is important to recognise the importance of assessing the sizes of the pulmonary arteries and judging whether the resistance to blood flow through the lungs has remained normal. It is uncommon for the Fontan procedure to be undertaken in a child below the age of around 3 years.
- 90** A few weeks or months before the proposed date of the Fontan operation, detailed investigations are undertaken, including cardiac catheterisation and angiocardiology (see [para 20](#)). The suitability of the patient for the operation is determined by the detailed assessment of the function of the effective ventricle and of the structure and function of the pulmonary blood vessels. The chief guiding principle is that the resistance to blood flow through the lungs should not be higher than normal, because if it is, there will be a back-pressure effect in the main veins draining the body, with potentially serious consequences. The pressures and blood flow in the pulmonary arteries are measured and the resistance to flow is calculated. It is also necessary to visualise the pulmonary arteries and their branches and to ensure that there are no areas of narrowing that might cause some increase in the resistance to flow. At the time it might be advisable for the cardiologist to use interventional catheter techniques, i.e. balloon dilatation,<sup>14</sup> in order to enlarge any narrowed areas. It is also important that the function of the ventricle is shown to be adequate and that the presence and severity of any valve leaks within the heart are demonstrated.
- 91** The Fontan operation or one of its modifications is an open-heart procedure. The technical problems relate largely to the underlying abnormality and the nature of any preliminary operations that may have been performed during earlier years. During the 1980s the 'classical' Fontan operation was generally performed. It consists of making a direct connection between the right atrium and the pulmonary artery. Because the pressure in the right atrium is then higher than normal, it becomes distended over the years and blood tends to swirl around in the chamber without moving forward efficiently into the pulmonary artery. Blood flow becomes sluggish and there is a tendency for small clots to form. When the clots advance into the pulmonary arteries,

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<sup>14</sup> Balloon dilatation – a specially designed cardiac catheter is passed into the narrow portion of the pulmonary artery. A balloon, incorporated into the catheter, is inflated under pressure to a pre-determined diameter. The balloon is then deflated and together with the catheter is removed

they may block the smaller vessels. This, in turn, increases the resistance to blood flow into the pulmonary arteries with a consequent further increase in the right atrial pressure. The other effect of the right atrial distension is to make the heart vulnerable to rhythm disturbances with consequent deterioration of the function of the heart.

- 92** During the early 1990s several different strategies or modifications were introduced, some of which were used in combination:
- One was to create a more tube-like connection between the right atrium and the pulmonary artery by channelling the main veins more directly to the connection.
  - Another was to make a small hole (about 5 mm in diameter) in the wall between the two atriums. This allowed blood to flow from right to left atrium and tended to reduce the right atrial pressure but had the disadvantage of making the child slightly cyanosed.
  - In some centres anticoagulant drugs have been given routinely in all patients in order to reduce the incidence and risk of clots forming in the right atrium and pulmonary arteries.
- 93** Overall, the results depend largely on the pre-operative factors that were described above. Early post-operative problems after the Fontan procedure are relatively common and do not necessarily depend on the pre-operative findings. They relate to the higher pressure in the main veins draining the body and the back-pressure effect and congestion of many of the organs. The heart itself needs to adjust to a set of unusual circumstances and often requires drug support for several days post-operatively. Careful management of fluid intake and fluid balance is often critical. Despite the most meticulous care it is not uncommon for children to accumulate fluid in the space surrounding the lungs (pleural effusions), and chest drains are often necessary for many days or even for weeks after the operation. The absorption of food from the gut may be inefficient for a period of time and this, too, requires careful attention. Occasionally the kidneys function inefficiently and may require support.
- 94** All the above post-operative problems usually resolve within a period of a few weeks and the child may lead a full and comfortable life for many years. The main noticeable problem is a lack of stamina compared with other children but participation in short bursts of vigorous activity is usually achieved. In the longer term, especially in association with the 'classical' Fontan operation, rhythm disturbances and fluid accumulation become significant problems in many of these patients as they go through late adolescence or early adult life. It is hoped that the longer-term effects of the modified operations and the associated medical treatment will be more favourable.