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OPENING BY MR LANGSTAFF

MR LANGSTAFF: Professor Kennedy, Mavis Maclean, Rebecca Howard, Professor Sir Brian Jarman, ladies and gentlemen. The Chairman has already described who I am and my task at this Inquiry. It is my role to give independent legal advice to the Inquiry, and to present the evidence. In this I have the great advantage of being assisted by two other counsel: Eleanor Grey and Alan Maclean.

You may not hear quite so much from them as you do from me during the course of this Inquiry, but they are in no sense silent partners. It is essential in an Inquiry such as this that the work of analysing, presenting and examining the evidence is shared between the three of us, so no-one should read any particular significance into the fact that Miss Grey or Mr Maclean

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1 asks questions of a witness rather than me, or vice  
2 versa.

3 Let me give you an overview of what I hope to  
4 achieve within the next hour or so. It is to explain  
5 where this Inquiry starts from, how it came into being,  
6 and in particular, what it proposes to do and the  
7 processes by which it will do it.

8 In doing this, I shall develop four main themes.  
9 These are, first, that this Inquiry starts its  
10 investigation afresh. Secondly, that the Inquiry will  
11 be comprehensive and inclusive. Thirdly, it is a very  
12 public process and fourthly, the Inquiry's analysis of  
13 data will be careful and cautious.

14 The first theme needs to be emphasised at the  
15 outset and it is this: we start this Inquiry with  
16 a clean sheet. When conclusions of fact come to be  
17 drawn and recommendations made of future advantage for  
18 the National Health Service, the panel will do so on the  
19 basis of the material which has been presented as part  
20 of this Inquiry. We do not start with a case to be  
21 accepted or rejected. We do not begin with any  
22 conclusions. Conclusions may be where we end up, but  
23 they never make a good starting place. Preconceptions  
24 have no place in this Inquiry. If it is to inquire  
25 fairly and rigorously, it must assume nothing and be

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1 prepared to question even that which seems most obvious.

2 Chairman, as a barrister yourself, you will know  
3 that counsel are often accused of repetition. However,  
4 repetition is one of the best ways of ensuring that  
5 a message is heard and understood. I hope, therefore,  
6 that I shall be forgiven for repeating, perhaps in  
7 a number of different ways during the course of this  
8 opening, that this Inquiry does not begin with a view or  
9 a bias which it seeks to justify. As part of the legal  
10 team, I do not present a case; I am not here to  
11 prosecute any surgeon or cardiologist or any other  
12 health professional, any more than I am to put a case  
13 for them. We have both the luxury and the  
14 responsibility of taking no side, and of having merely

15 a determination to present the evidence and to question  
16 it in a way which we hope will enable the panel to get  
17 to the bottom of things.

18 As if to emphasise that this is not a trial, you  
19 will notice that this is not a courtroom. The Inquiry  
20 has gone out of its way to organise the rooms and  
21 facilities to allow as many as possible to follow the  
22 proceedings without being intimidated by the  
23 surroundings.

24 Why the Inquiry? In one sense, it is easy to say  
25 why we are here. The Secretary of State for Health made  
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1 a statement to Parliament on 18th June 1998. He  
2 provided the terms of reference which are to inquire  
3 into the management of care of children receiving  
4 complex cardiac surgical services at the Bristol Royal  
5 Infirmary between 1984 and 1995, and relevant related  
6 issues; to make findings as to the adequacy of the  
7 services provided; to establish what action was taken,  
8 both within and outside the hospital, to deal with  
9 concerns raised about the surgery, and to identify any  
10 failure to take appropriate action promptly; to reach  
11 conclusions from these events and to make  
12 recommendations which could help to secure high quality  
13 care across the NHS.

14 Two observations: first, this is no usual  
15 Inquiry. It is not a case of a single incident with  
16 tragic results. If a ferry sinks, if an airliner  
17 crashes, if a tube station or an oil rig goes on fire,  
18 then there is an incident to inquire into. Secondly, in  
19 any such case, you can be confident from the beginning  
20 of the Inquiry that something has gone badly wrong.

21 But this is not a case of a single incident. We  
22 are asked to examine a process. Cardiac surgical  
23 services were provided to many children of many  
24 different ages over a 12 year period. All those  
25 children required treatment; they were ill. The

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1 survival of any one child cannot, on its own, show that  
2 the care given to others was adequate. The tragedy of  
3 any child's death -- and I use the word "tragedy"  
4 deliberately, because I defy anyone to maintain that the  
5 death of a child is not a tragedy, however unlikely it  
6 is to have happened. The tragedy of any child's death  
7 cannot on its own demonstrate that the services provided  
8 were inadequate.

9 One of the focuses which has emerged from the  
10 witness statements which have been submitted to the  
11 Inquiry since it opened last October has been a concern  
12 expressed by many parents about the quality of care  
13 their child or children had at Bristol. Some who were  
14 content in the belief that doctors had tried their best  
15 for their son or daughter, have watched the TV reports  
16 and have read the papers, and have come to question  
17 whether that belief was justified. I hope that the  
18 evidence that we shall produce will enable those parents  
19 to know, if for nothing else, for their own peace of

20 mind, whether there was anything they might reasonably  
21 have done which could have secured a better outcome.  
22 I said at the outset that we have no answers. The  
23 first question may, however, seem startling. Bear in  
24 mind that an Inquiry such as this must start without  
25 preconceptions if it is to do its job properly, with  
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1 integrity, and if it is to carry conviction. The first  
2 question is whether there was indeed a problem with the  
3 treatment provided in Bristol. Did the care provided at  
4 Bristol, taken either overall or individually, match the  
5 standards of care provided elsewhere in the UK?  
6 There may be those who think that imposing that  
7 basic question was Bristol in fact significantly  
8 different from any other hospital carrying out cardiac  
9 surgery on children, that we are merely paying lip  
10 service to the need to appear unbiased and open in  
11 approach? This is not so. If my first theme is that at  
12 this stage of the Inquiry there are no answers, merely  
13 questions, the second theme must be to emphasise the  
14 comprehensive nature of the Inquiry upon which we are  
15 engaged.  
16 At the General Medical Council, I will call it the  
17 GMC for short, 29 deaths were examined in detail,  
18 a series of 53 cases was studied. Two operations -- two  
19 operations alone -- were central: the arterial switch to  
20 repair the transposition of the great arteries, and the  
21 operation to repair the atrial ventricular septal  
22 defect, AVSD for short. The time-frame was much more  
23 limited than the breadth of this Inquiry, which is far  
24 greater. By contrast with the GMC, we will draw  
25 statistical conclusions from over 2,000 cases of  
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1 surgery, both open heart surgery and closed heart  
2 surgery.  
3 I say over 2,000: the Trust has been unable to  
4 tell us from its own records the precise number of such  
5 cases, but once the necessary cross-checking has been  
6 done to ensure there is no duplication, we shall be able  
7 to supply it. We shall deal with a range of  
8 procedures. We shall consider surgery over 12 years.  
9 Every case, to a greater or lesser extent, will form  
10 part of that consideration. We shall look at all  
11 paediatric cardiac surgery and at all outcomes, not only  
12 death but also morbidity such as brain damage. Let me  
13 lay to rest once and for all that this Inquiry is into  
14 the death of 29 babies. If it were, it might imply that  
15 the death of any other baby were of lesser importance.  
16 It might, moreover, suggest that where a child survived,  
17 but left let us suppose brain-damaged or with renal  
18 problems, that that is not to be taken into account.  
19 Because of the way the Inquiry will examine the data  
20 which it has obtained, I can assure the parent of every  
21 child who had heart surgery since 1984 that their  
22 child's case will take a part in the evidence upon which  
23 the Inquiry will base its conclusions. Some cases may  
24 have more immediate prominence. Some parents, for

25 instance, whose children's treatment raises issues  
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1 representative of many, will be asked to give oral  
2 evidence. However, prominence must not be confused with  
3 importance and the fact that, inevitably, many will not  
4 give evidence orally does not mean in any way that they  
5 are being passed over and forgotten.  
6 Over half a million pages of clinical records have  
7 been obtained. Not only has the Inquiry managed to  
8 obtain those clinical records, but has been active in  
9 a number of other fairly unseen ways since last  
10 October. The Inquiry has powers given by Act of  
11 Parliament to require documents to be provided to it by  
12 order of the Chairman, and require evidence to be given  
13 and further, to require that evidence will be given on  
14 oath, as indeed it usually will be. Documents have come  
15 into the Inquiry's offices in London and latterly in  
16 Bristol from a number of different sources. We have had  
17 them from the Department of Health; from the  
18 cardiothoracic register of the United Kingdom; from  
19 a number of parents; from the private papers of the  
20 clinical professionals involved; from various regulatory  
21 bodies from the United Bristol Healthcare Trust and from  
22 several others.

23 As at this morning, those of you who have had the  
24 luxury of having a printed copy of what I am to say in  
25 advance will need to make some alteration here, because  
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1 I can bring you up to the minute. As at this morning,  
2 a total of 28,720 documents other than clinical records  
3 have been provided, indexed and scanned into an  
4 electronic database. Many of those documents consist of  
5 10 or more pages. Of the medical records, we have  
6 3,136. As I have said, more than half a million pages.  
7 At one stage in the process, we estimated that if  
8 one person on his own were to read every page at  
9 a reasonable rate, allowing two minutes for an A4 sheet  
10 of paper, it would take him over 20 years of working  
11 time to read each document just once. That is why  
12 a considerable team has had to be recruited to assist  
13 the Inquiry.

14 So how precisely have the team coped since last  
15 October in uncovering documents, requiring evidence and  
16 analysis and how can we go about a task which is beyond  
17 a reasonable time-scale for any one person? The answer  
18 is, of course, that not all the documents are relevant,  
19 and that of those which are, the degree of relevance  
20 varies from minimal to very considerable. Every  
21 document has been read by a legally qualified member of  
22 the Inquiry team. Unless obviously irrelevant it has  
23 been re-read by a more senior lawyer checking for  
24 importance.

25 After this process of review and cross-check,  
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1 documents which may assist the Inquiry have been made

2 part of what we call a core bundle. This forms the  
3 essential data tool for the Inquiry, and it will be  
4 published in searchable form on a series of CDs.  
5 Let me deal for a moment with confidentiality of  
6 those documents, because it is a matter which I think  
7 concerns a number of people. Many of the documents  
8 contain confidential material, or material which was  
9 supplied under an assurance of confidentiality. The  
10 Inquiry undertook not to disclose details which tend to  
11 lead to the identification of a patient, a child, unless  
12 a parent or the patient consents.  
13 We regard this as vitally important. Accordingly,  
14 references which could have the result of identification  
15 are blacked out or redacted, of the documents which are  
16 copied. The database intended for presentation of  
17 documents on screen in this hearing chamber is also  
18 edited in the same way, and both the Chairman and I have  
19 a facility to check at the last moment, even, to ensure  
20 that there is no untoward reference, even if others  
21 missed it. May I say that much of the Inquiry team over  
22 the past fortnight has been checking and double-checking  
23 and subsequently checking again the document base to  
24 ensure that our promises on confidentiality have been  
25 and will be honoured. Thus, every effort has been taken  
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1 to ensure that unless a parent consents, a child cannot  
2 be identified. Redaction has proceeded on a next-door  
3 neighbour test: although parents are likely to know that  
4 the information relates to their child, would the  
5 material tend to identify the child to their next-door  
6 neighbour? If so, we have redacted it. If it becomes  
7 permissible to lift the redaction, then we may do so,  
8 but always respecting confidentiality and the parents'  
9 or patients' wishes as a prime concern.  
10 Let me return from confidentiality to a second  
11 theme: that the Inquiry intends to be comprehensive. It  
12 has received statements. Any formal statement received  
13 will be published. If, in that statement, anyone is  
14 referred to critically, that is, in a sense relevant to  
15 the Inquiry's issues and of sufficient importance, then  
16 before publication, it will be circulated to the person  
17 criticised for comment. Of course, although we do not  
18 expect it, if there should be any purely abusive or  
19 scandalous material which cannot take the Inquiry any  
20 further, that will be redacted. Statements will come  
21 from a range of sources. This is not just an Inquiry  
22 concerned with patients and surgeons. There is a much  
23 wider range of material to be examined. In particular,  
24 our terms of reference require us to go beyond the  
25 detail of the Bristol Royal Infirmary to the whole of  
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1 the National Health Service as a system, including the  
2 build-up to and the impact of the NHS reforms in 1991.  
3 The process of requesting formal statements has  
4 not been conducted randomly. Confidential  
5 questionnaires have been sent out to parents in response  
6 to their requests. 242, and there is a difference to

7 the figures because overnight we have had 8 more, have  
8 so far been returned. Of those, 156 said they were  
9 members of an action group. 107 identified the action  
10 group as the Bristol Heart Children Action Group; 36  
11 identified the action group as the Bristol Surgeons'  
12 Support Group. I should like, on behalf of the Inquiry,  
13 to thank all parents who have completed and returned  
14 such a questionnaire. The questionnaires have been  
15 extremely helpful to the Inquiry team, and it cannot  
16 have been easy to express their deeply held feelings to  
17 us on paper.

18 The answer to the questionnaires remains  
19 confidential. They are unseen by the panel. Everything  
20 the panel see is in the public domain. The answers to  
21 the questionnaires therefore form no part of the  
22 material upon which the panel decide whether they can  
23 make recommendations, and if so, what they will be.  
24 People who have sent in the questionnaires have been and  
25 may well be asked to provide written formal statements.

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1 Any statements submitted will be part of the evidence.  
2 Any formal statement, from whoever wishes to submit one,  
3 will be considered. Although we have a mass of evidence  
4 already, there is more to come. In particular, I would  
5 like to encourage everyone, for instance a member of  
6 staff at the Bristol hospitals, if there is anything  
7 they wish to say about what happened in Bristol, good,  
8 bad or indifferent from 1984 to 1985, to come forward  
9 and to speak to a member of the Inquiry staff. The  
10 press here today, particularly local reporters, can  
11 assist by reporting my plea for anyone who feels they  
12 have anything useful to add to the information to come  
13 forward and contact the Inquiry. The Inquiry means what  
14 it says about being comprehensive and inclusive. You  
15 already, I think, have realised that this Inquiry will  
16 be the widest ranging examination of the NHS ever  
17 conducted independently.

18 What about procedure? The procedure is not that  
19 of a trial. This is an Inquiry. Thus, as the Chairman  
20 explained last October, cross-examination will be  
21 limited. Eleanor Grey, Alan Maclean or I will examine  
22 the witness. After the first few witnesses have been  
23 heard, the written statement which has been published  
24 will be taken as read. There will be an opportunity for  
25 each witness to be re-examined by his or her

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1 representative to ensure they give a fair account of  
2 themselves; a short written statement summarising the  
3 effect and importance of the witness's evidence made  
4 overnight may be published the morning after the witness  
5 has completed his or her evidence. On application, the  
6 Chairman may allow that statement to be given orally.

7 The purpose of our questioning is to examine the  
8 evidence thoroughly. We would hope that it is fair but  
9 rigorous. What a witness says deserves to be treated  
10 seriously. Witnesses should remember that evidence  
11 which is not carefully examined, not looked at

12 thoroughly in its important respects, will carry less  
13 weight.

14 A third theme is the public nature of this  
15 Inquiry. It is unusual. No Inquiry has yet been so  
16 public. The daily transcript will be put on the  
17 Internet. After Easter, the proceedings will be  
18 transmitted live to Barnstaple, Truro and Cardiff. This  
19 is under controlled circumstances for the Inquiry, it  
20 will not be appearing on TV or radio. If anyone should  
21 attempt to use it in this way, sanctions will follow.  
22 When documents are referred to in the oral hearing, they  
23 will be part of the core bundle and they too will be  
24 made public. Because the Inquiry is taking evidence  
25 publicly on paper, not everyone will be asked to give  
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1 evidence orally; but those who are not called are not  
2 ignored. In many ways, their evidence may count for  
3 more. This is because we shall ask those to give  
4 evidence where we may need to amplify what they are  
5 saying; to put it in context or to challenge it. It  
6 may, for instance, be inconsistent with that which  
7 another witness has said. On the other hand, witnesses  
8 will not be called where their statement is  
9 self-explanatory and there is perhaps little that  
10 questioning could add. For the witness who is tempted  
11 to feel that his or her evidence has been treated as  
12 being of lesser value because he or she has not been  
13 called to sit in the central chair in the full glare of  
14 the cameras and bear public witness to what he or she  
15 has said, I would simply ask, is a statement likely to  
16 be regarded as of greater value if the evidence is  
17 publicly doubted, as may be the case with some  
18 witnesses, rather than accepted as obviously true?  
19 I would ask them, would they think that evidence which  
20 is full enough on paper so there is no need to ask  
21 anything to expand upon it orally, is not likely to  
22 carry more weight because it is seen to be full and  
23 frank in the first place.

24 We have endeavoured to select witnesses whose  
25 evidence covers a range of issues, which is broadly  
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1 representative of the evidence which we have received.  
2 Let me emphasise again, that no-one should feel that he  
3 or she is being treated adversely merely because her or  
4 his evidence has not been selected for oral scrutiny.  
5 Moreover, each week we will publish in advance the names  
6 of the witnesses whom we expect to call in the following  
7 week. Parents who are not called to give evidence in  
8 block 1 may find that they are being asked to give their  
9 evidence in block 3, or 5, or 6. For the parents'  
10 evidence runs seamlessly throughout the issues we have  
11 to consider. Each witness will be invited to see  
12 whichever of the three of us, Eleanor, Alan or myself,  
13 is going to ask them the questions when they do give  
14 evidence. They may, of course, not wish to avail  
15 themselves of this, but it may help to relieve some of  
16 the anxieties which are inevitable about the process of

17 being a witness, particularly on a stage as public as  
18 this.

19 May I say that of course, we are happy to see any  
20 witness with or without their representatives in advance  
21 of the evidence.

22 One category of witness perhaps deserves special  
23 mention, and that is experts. As the Chairman has just  
24 said, the Inquiry will establish a group of experts  
25 containing a number of experiments in each relevant area

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1 of expertise. The expert group will include experts in  
2 the following areas of expertise, first and perhaps most  
3 obviously: paediatric cardiac surgery. Paediatric  
4 cardiology, paediatric cardiac anaesthesia, paediatric  
5 intensive care, paediatric pathology, nursing, both  
6 paediatric care and intensive care, medical education  
7 and training, specialist surgical training, medical and  
8 clinical audit in relation to methodologies, regulation  
9 of the medical profession, NHS management and finance in  
10 the 1980s and 1990s, including the impact of the NHS  
11 reforms, and statistics and epidemiology.

12 The aim of the Inquiry's group approach is to move  
13 away from the model of expert evidence used in trials,  
14 where expert evidence is presented in an adversarial  
15 setting. As experts to the Inquiry, those in the group  
16 will be asked to give their opinion in the widest public  
17 interest, rather than in support of the case of one side  
18 or the case of the other. As Professor Kennedy has  
19 already made clear, there are no sides; there is no  
20 case.

21 The Inquiry is very mindful of the relative  
22 scarcity of expertise in a number of areas of interest  
23 to the Inquiry. We recognise that membership of the  
24 expert group may involve a considerable commitment of  
25 time and energy to the expert and to the institution

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1 where the expert works. Thus, to lighten the load on  
2 any one individual, a number of experts will be invited  
3 to serve in each area of expertise. Appointment to the  
4 group will be by invitation only. The Inquiry has  
5 sought and will continue to seek advice from experts as  
6 to those others whose expertise is well recognised, with  
7 a view to ensuring that the expert group first has  
8 sufficient numerical strength to ensure the Inquiry's  
9 demands are met with the minimum of inconvenience to any  
10 one group or institution, and secondly covers any  
11 principal difference of view or emphasis within a given  
12 specialty, and thirdly, is broadly based, both  
13 geographically or otherwise. I know the Chairman is  
14 always content to listen to suggestions for additions to  
15 the group, where it is considered that will be of  
16 assistance to the Inquiry.

17 The written opinions of the experts will be made  
18 public. They will be published on the Inquiry's web  
19 site. Although the Inquiry will not necessarily hear  
20 orally from each expert where views differ, it will seek  
21 to take advice and evidence where it seeks to reflect

22 fairly any divergence of opinion, and where it is  
23 important to explore it. The experts may be called to  
24 give oral evidence in addition to their oral and  
25 published reports. Where they are called to give  
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1 evidence, an expert may appear alone, or he may appear  
2 as part of a discussion where two or three experts who  
3 hold what are apparently different views will be invited  
4 to contribute. In the latter case, each will give  
5 evidence at the same time, moderated as it were by  
6 counsel, thus permitting an open panel-type discussion  
7 amongst the relevant experts.

8 The oral evidence which I have described, both  
9 from lay witnesses and from experts, will be taken in  
10 phases, in blocks. The Inquiry has two phases, and the  
11 oral evidence will be taken in the first phase, Phase I,  
12 of the Inquiry, in six blocks. If the first block  
13 parents will give evidence of their experience of and  
14 the treatment of their children at the BRI and the  
15 Bristol Children's Hospital. It is from their  
16 experience that everything else stems. They will  
17 feature in each of the other blocks of evidence as  
18 well. After setting the scene from their perspective,  
19 we shall move to block 2, to consider the national  
20 scene. Block 3 involves the local scene, the  
21 organisational structure, the staffing side. Block 4 is  
22 the nature of the services provided. Block 5 is their  
23 adequacy, and block 6 the concerns expressed about the  
24 services. Bear in mind that in the earlier blocks we  
25 shall be concentrating on structures, finances and  
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1 arrangements. Some witnesses may therefore give  
2 evidence in more than one of the blocks. For instance,  
3 many of you will know that Mr Wisheart, as Chairman of  
4 the Hospital Medical Committee, and later medical  
5 director of the United Bristol Healthcare Trust, had  
6 a central role to play in the administration of the  
7 Bristol hospitals. Accordingly, he will be asked to  
8 give evidence in block 3 about that aspect. He also  
9 will be asked to give evidence in the later blocks.

10 So there are two phases to the Inquiry: Phase I  
11 divided into the six blocks I have mentioned, and  
12 Phase II, where the wider issues raised by the Inquiry  
13 will be considered; conclusions drawn and  
14 recommendations made.

15 With such a mass of evidence, with so many  
16 witnesses giving evidence, and with the Inquiry being  
17 into a process rather than one single event, people may  
18 wonder when the Inquiry is going to finish. It will  
19 finish Phase I by Christmas. It has to. If the  
20 recommendations which the panel will make are to be made  
21 at a time when they will have any influence on the  
22 future of the NHS, then they must be made within  
23 a reasonable time-span. It is necessary for parents to  
24 be able to move forward; it is important for the  
25 Hospital Trust to move out of the shadows cast by the  
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1 past, so that it gives the service it can to the people  
2 of Bristol. No-one is served by delay.

3 Remember that the purpose of the oral evidence is  
4 to supplement the written evidence. Because much of the  
5 evidence is in writing, the Inquiry will be able to move  
6 more swiftly to its conclusions.

7 The timing of Phase II is driven by the same  
8 concerns. We will aim to start it even as Phase I draws  
9 to its completion, with a view to ending Phase II within  
10 the first half of next year.

11 How shall we manage the evidence? The Inquiry, as  
12 I have said, is not only unusual in being an Inquiry  
13 into a process, into a service delivered over several  
14 years, nor is it only the largest investigation into  
15 practices in the National Health Service for many years,  
16 indeed ever, it is also unique in the sense to which it  
17 will be accessible to any member of the public. I have  
18 emphasised already, it is going to be open,  
19 comprehensive and inclusive.

20 In front of you are two sets of screens, black and  
21 grey. On the ones which have a black support, you may  
22 see a little old grey-haired man who thinks he is the  
23 Inquiry's equivalent of Jeremy Paxman. That image,  
24 which will not always be of me, I hasten to add, will be  
25 transmitted after Easter from this hearing room to  
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1 Barnstaple, Truro and Cardiff; at the health centre in  
2 each. The Inquiry will place the evidence it has  
3 obtained in public libraries throughout the south west,  
4 and indeed South Wales. At the end of each day, the  
5 evidence, every question, every answer, will be placed  
6 on the Internet and we hope that this will inspire more  
7 people to come forward if they have anything useful to  
8 add or any comment to make. This Inquiry is a Public  
9 Inquiry and it takes the word "public" seriously.

10 The second screen, the grey one, is used for  
11 displaying documents to a witness for comment. I will  
12 show you how that works when I deal in a moment or two  
13 with the way the Inquiry will navigate through the sea  
14 of information available. If I can take that metaphor  
15 further, you, Chairman, as a barrister yourself, will  
16 know how lawyers love analogies, because they help to  
17 picture a process. In some respects, the Inquiry  
18 resembles some of the explorers of old setting out on  
19 a voyage of discovery. Like them, the Inquiry does not  
20 know how it will end up. It has, however, to start from  
21 somewhere, and it must be aware of currents flowing from  
22 different directions that may take it off course, and it  
23 must have a star to steer by.

24 How do we propose to make sense of the evidence  
25 which has come in, and which will accumulate, and  
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1 navigate our way through it?

2 Our starting place, perhaps, is matters of  
3 historical record. The Inquiry is into paediatric

4 surgical services. That covers children under 16. It  
5 also covers infants, that is, those under one year of  
6 age, including neonates, those up to 28 days of age. It  
7 is important to keep in mind the distinction between  
8 children over the age of one and under the age of one.  
9 The reason is this: in 1983 the then Secretary of State  
10 for Health designated a number of clinical services as  
11 supra-regional. They were those services which, in  
12 order to be clinically effective, or economically  
13 viable, needed to be provided by centres, each of which  
14 served a population significantly bigger than that of  
15 a single health service region. There were 14 regions  
16 in England and Wales. The advisory group, the  
17 Supra-regional Services Advisory Group -- you understand  
18 why I call that SRSAG -- designated nine hospitals for  
19 the provision of infant and neonatal cardiac surgery.  
20 They did that in 1983. Thereafter, until 1984, infant  
21 and neonatal cardiac surgery was a supra-regional  
22 service. The distinction between infants and neonates  
23 on the one hand and children over one on the other is  
24 that cardiac surgery provided to the latter group was  
25 not provided on a supra-regional basis.

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1           Supra-regional services received funding direct  
2 from what was then the DHSS. Designation as a centre  
3 thus had important financial consequences. Each centre  
4 was required to make a return each year to the  
5 Department, giving the numbers of operations conducted  
6 in any one year. In 1986 there was a review of the way  
7 in which the system was working. Can we have a look,  
8 please, at document 62, UBHT 62/401? Shall we try and  
9 amplify it so we can see? If we focus, please, on the  
10 second paragraph, can we have that highlighted in  
11 yellow? We can see there that in the report it records  
12 that the need was confirmed for a limited number of  
13 centres to perform a complex surgery, and there was  
14 a case for a possible reduction in the number of centres  
15 which were designated. The supra-regional centres are  
16 as follows ... can we scroll down, please? We can see  
17 that the hospitals are listed. If we go down to the  
18 bottom of what is now on the screen, we see the Bristol  
19 Children's Hospital and Royal Infirmary.

20           We then read this:

21           "The Bristol centre is one of the smallest centres  
22 in terms of throughput. The total number of operations  
23 on children aged under one year increased from 50 in  
24 1984 to 55 in 1985 .... It has, however, been seen as  
25 having a legitimate claim for development on

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1 geographical grounds and the consideration of this has  
2 included its proximity to the South Wales population."

3           May I add, for those of you who may be aware of  
4 some of the figures that have been bandied around, that  
5 the figure of 50 and 55 is a combined total of both open  
6 heart surgery and closed heart surgery.

7           As this document really demonstrates, the  
8 documents we have received have been scanned into an

9 electronic database. One of the advantages of the  
10 research which had been done by the staff of the  
11 Inquiry, the advantage of the electronic database, is  
12 that documents which may be far-removed in different  
13 files can be matched, displayed to you in a coherent  
14 manner, they can be highlighted, and indeed sometimes  
15 relatively indistinct old documents can be made, by the  
16 use of modern technology, to look rather better than  
17 they did originally.

18 Returning to the history of the supra-regional  
19 services, in 1992 the Secretary of State, the then  
20 Secretary of State, made an announcement which is to be  
21 found at document -- here we go to a different file --  
22 277/93. May we focus, please, on the centre of the  
23 page, under the heading "Neonatal and Infant Cardiac  
24 Surgery"? We see again the list of hospitals. Can we  
25 go down to paragraph 31? We can read there, some of it  
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1 is missing at the edge:  
2 "In its recommendations last year, the advisory  
3 group pointed out that there were effectively 10  
4 designated centres and that some activity was taking  
5 place in other units. This meant that the service must  
6 be considered for dedesignation. The government would,  
7 however, prefer in the interests of patients, that the  
8 service be rationalised into fewer designated units.  
9 Discussions are taking place with professional bodies,  
10 but unless these confer the prospect of early  
11 rationalisation, designation will have to be withdrawn."  
12 So what paragraph 31 suggests is that although  
13 patients benefit by having fewer rather than more  
14 specialist centres for cardiac surgery, because in fact  
15 more rather than fewer centres were actually performing  
16 the service, designation might have to be withdrawn.  
17 You may ask, why should this be, and there is an echo  
18 perhaps here of a letter which was written back in  
19 October 1986 -- may we look, please, at 278/432?  
20 Enlarge that. It is the second paragraph. Just reading  
21 from the bottom of that:

22 "Supra-regional arrangements apply only to England  
23 and the exclusion of Wales was made clear. Secondly  
24 funding arrangements: we have no powers to determine  
25 referral practices which remain a clinical  
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1 responsibility. HN(83)36 discourages health authorities  
2 from providing supra-regional services in units which  
3 are not designated as supra-regional centres", and this  
4 is the sting: "but this is not binding on clinicians."  
5 Referral practices therefore remain and remained  
6 a clinical responsibility. Did private professional  
7 decisions purportedly made in the best interests of  
8 patients, in fact harm patient care overall? No  
9 conclusions can be drawn at this stage. I must  
10 emphasise that, particularly on the basis of two  
11 documents which I have selected largely to impress you  
12 with the technology, but the issue is one for the  
13 Inquiry to consider.

14           A moment or two ago, I showed you a document which  
15 contained a summary of numbers reported for  
16 Supra-regional Services Advisory Group. You remember  
17 the 50/55 operations. You may have thought that those  
18 numbers were definitive. Sadly, this may not be the  
19 case. Again, as a result of the work which we have  
20 already done, I can tell you that there is some  
21 uncertainty about the accuracy of those figures. For  
22 instance, if one goes back to the Bristol Royal  
23 Infirmary and open heart surgery in 1984, some records  
24 suggest that four open heart operations were conducted  
25 that year; others have it as three. It seems no  
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1           definitive data was kept by the Bristol hospitals of the  
2 number of operations conducted. I hope I summarise our  
3 current information accurately and say a number of  
4 different systems, some on card index, some on computer,  
5 were kept for different periods by different  
6 individuals. At least one of those systems was  
7 unreliable, in part because no-one had sole  
8 responsibility for inputting information into it, and  
9 often medical staff did not enter information into the  
10 system which it was supposed to hold.

11           The information on one system, which was  
12 maintained in recent years by cardiac perfusionists was  
13 maintained for three years or so, and then the computer  
14 and the information stored within it was stolen from the  
15 Trust. I do not want to bore you with the further  
16 details, save to say that they are contained in a letter  
17 of 9th March 1999, only last week, from John Grey on  
18 behalf of the Trust to the Inquiry, which we shall put  
19 before you as part of the documentation. Indeed, if  
20 I can just add, it has taken the Trust some three months  
21 to identify all these relevant clinical records.

22           What, however, this indicates, is that there is  
23 a very great need for care in drawing conclusions too  
24 readily from data. Everybody here may already know that  
25 concerns were expressed by different people over  
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1           a number of years about paediatric heart surgery at  
2 Bristol. The suggestion is that other centres may be  
3 better, or better at least for some if not many  
4 operations to which congenital heart defects give rise.  
5 That is easy to say, but it is actually very difficult  
6 to discover whether there is any truth in it. In 1987  
7 a TV programme was screened in Wales as a result of the  
8 Children's Heart Circle for Wales criticising the  
9 Bristol Royal Infirmary paediatric cardiac surgical  
10 unit. That alleged, and I quote, that a "degree of  
11 concern has been expressed by independent well-informed  
12 sources about the standard of operations carried out at  
13 the receiving centre in Bristol. It has been suggested  
14 that this concern is widely held."

15           However, the author of those remarks was at pains  
16 to stress that such information -- and again I quote,  
17 "in no way represents hard evidence."

18           On that occasion, there was a response from two

19 cardiac surgeons: Mr Wisheart and Mr Dhasmana, and two  
20 cardiologists, Drs Joffe and Jordan, which asserted that  
21 the available figures showed that the allegations were  
22 totally false. They stated that the actual status of  
23 the facilities was better than most, and that the  
24 surgical results were at least equal to those achieved  
25 by other paediatric units elsewhere. Their figures were  
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1 used to defend surgical practice at Bristol. I quote  
2 that incident to show how in the past a non-specific  
3 allegation backed up by no figures was met by figures  
4 which in themselves were controversial. Neither  
5 approach is good enough for this Inquiry. We shall not  
6 be using figures as a weapon, rather seeking to  
7 understand what the best available figures may show us.  
8 With that introduction, let me spend a little time  
9 dealing with the whole question of statistics: figures  
10 may help to clarify the picture, but here I come to what  
11 is my fourth main theme: they cannot, in themselves,  
12 provide an answer. Figures must be approached with  
13 care. For a start, they are necessarily general. There  
14 may be much force in a complaint of a parent who  
15 observes that her child is not just a number, but an  
16 individual. We must not lose sight of the fact that  
17 each case is truly individual.  
18 On 7th August 1990, Dr Bolsin, a consultant  
19 anaesthetist, drew attention in a letter to Dr Roylance,  
20 who was then the District General Manager and  
21 prospective Chief Executive of the UBHT, to what he  
22 considered to be excessive mortality in paediatric  
23 cardiac surgery. There followed several years of  
24 professional disagreement about the outcome and quality  
25 of surgery at the Bristol Royal Infirmary. The  
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1 disagreement related at least in part to different  
2 interpretations of what the figures showed, and since  
3 then, various sets of figures have been looked at and  
4 interpreted by several others, both within the Bristol  
5 service and external to it.  
6 The panel will have to look at those figures and  
7 look at those interpretations, and ask, amongst other  
8 things, what those particular figures should have  
9 suggested to those who looked at them at the time. But  
10 how are we going to deal with the best figures  
11 available? What is the star by which we must steer?  
12 First, the Inquiry is not bound by the figures bandied  
13 around in the 1980s and 1990s in the Trust and outside  
14 it. Even though the GMC struck off one of the two  
15 cardiac surgeons who conducted open heart operations on  
16 children at Bristol, and censured the other, this  
17 Inquiry would lack integrity if it were not prepared to  
18 think the unthinkable: to contemplate that it may be  
19 possible, when all is said and done, that no valid  
20 conclusions can be drawn about Bristol. Of course, by  
21 contrast, the evidence which we uncover may indeed  
22 validly show that Bristol was the same as or different  
23 from other centres.

24                    This Inquiry has available to it much greater  
25                    resources than anybody else who has attempted to examine  
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1                    the figures thus far, and we intend to use those  
2                    resources to ensure that the figures are thoroughly  
3                    analysed. This week, we will publish our framework for  
4                    handling data. Let me outline the main elements of the  
5                    strategy here and now.  
6                    There is a range of data sources which is  
7                    available at both national and local level, which may be  
8                    relevant, first to show whether there is an apparent  
9                    difference between the performance of Bristol and that  
10                    of other centres in the UK, and secondly, whether the  
11                    difference is consistent or sporadic, and if so, to what  
12                    aspects of children's heart surgery it relates.  
13                    The first of the national sets is the Hospital  
14                    In-patient Enquiry (HIPE) which reported on a 10 per  
15                    cent sample of deaths and discharges of patients from  
16                    hospitals in England and Wales on a national basis until  
17                    1985. Regional health authorities established systems  
18                    of hospital activity analysis (HAA) similar to each  
19                    other, which reported administrative and clinical data  
20                    on all in-patients treated in NHS hospitals.  
21                    Eventually, the 10 per cent samples, or HIPE, were drawn  
22                    from those bases. Data was collected regionally but not  
23                    reported nationally between 1986 and 1988. Then, in  
24                    1989, following the recommendations of the Korner  
25                    committee, a national reporting system based on all  
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1                    reported episodes of care, not just 10 per cent of them,  
2                    was instituted.  
3                    Over the period affected by the Bristol Inquiry,  
4                    the data derived from patient administration systems  
5                    (PAS) were aggregated regionally and transmitted  
6                    nationally to an agency which analysed and reported the  
7                    data for the Department of Health as Hospital Episode  
8                    Statistics (HES). The coding of diagnostic information  
9                    used in these systems over the period we are concerned  
10                    with is based sequentially on the International  
11                    Classification of Diseases, 9th Revision 1975, and 10th  
12                    Revision 1992, the latter from 1995. The surgical  
13                    operation data was coded according to the Office of  
14                    Population Censuses and Surveys' Classification of  
15                    Surgical Observations, 3rd Revision (until 1985), and  
16                    4th revision from 1989. It became impossible to analyse  
17                    and record clinical data in progressively greater detail  
18                    and depth.  
19                    In respect of paediatric cardiac surgery, data was  
20                    sought independently of government from each hospital  
21                    performing such surgery throughout such period with  
22                    which the Inquiry is concerned, by the Society of  
23                    Cardiothoracic Surgeons. They prepared a register of  
24                    cardiothoracic surgery. Data from this source were used  
25                    extensively at the GMC hearings. The data which were  
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1 supplied voluntarily were not always complete, and there  
2 is a need to examine carefully the reliability of these  
3 returns.

4 There are key questions to be asked about data  
5 coverage, data quality, how the data were collected, how  
6 the data were validated, and indeed, the potential  
7 comparability of data sources. This task, to appraise  
8 the quality of the data, is the first task for the  
9 Inquiry to undertake if it is to have any proper  
10 assistance from the available data sources. It will be  
11 published before any new computations or new tables are  
12 produced, to help to ensure that any conclusions  
13 reached, if indeed they can be reached from the data,  
14 are sound and capable of standing up to scientific and  
15 public scrutiny.

16 May I please have slide SLD/1/1? Can it be turned  
17 around please? One of the great advantages of the  
18 system is that it allows us, as you see, to deal with  
19 things in landscape as in portrait style, but it may  
20 mean there is a moment or two of glitch.

21 I can summarise the process of statistical  
22 investigation in this way -- the first stage, which  
23 I have dealt with, is "Preliminary (but vital) critical  
24 overview" of the sources of data. Let me identify each  
25 of the next three stages before dealing with them in  
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1 detail. "Exploration", the second stage;  
2 "Confirmation", the third stage; "Explanation", the  
3 fourth stage. "Exploration" is to see whether the data  
4 suggests a difference in any and what respects between  
5 performance at Bristol and elsewhere. "Confirmation"  
6 examines whether the accuracy of the national  
7 performance figures and those from other centres can be  
8 confirmed; to see whether the Bristol performance can be  
9 calibrated against the results obtained on exploration  
10 of the data; and to make a judgment as to the degree of  
11 bias in the results -- "bias" here, of course, I am  
12 using in the technical sense.

13 The third, "Explanation", looks to see to what  
14 extent explanation offered as to any apparent and  
15 confirmed difference between Bristol and other centres  
16 may be consistent or inconsistent with the data.

17 Going back to the second of those, exploration is  
18 going to be a very considerable undertaking, and it  
19 involves two aspects: first of all, there is an exercise  
20 to look at the clinical record of every single child who  
21 had surgery at Bristol; to capture information about  
22 each child's diagnosis, the surgical procedure performed  
23 and the outcome. Secondly, it involves independent  
24 analysis of the national data to see what they can tell  
25 us about comparative performance. Although the Inquiry  
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1 will be conducting its own analysis from the records  
2 themselves, the results will, where necessary, be  
3 cross-checked against existing local records.

4 There are several local records, and sadly, none  
5 were complete. They were the surgeons logs, the

6 operating theatre registers, the patient administration  
7 system (PAS), a cardiologist's card index system which  
8 was maintained from 1984 to 1988; the South Western  
9 Congenital Heart Register maintained by Dr Jordan until  
10 1993; and the Patient Analysis and Tracing System  
11 installed in 1992. Those will be cross-checked against  
12 other incomplete national sources, for instance, there  
13 may be some information to be gained from the National  
14 Confidential Enquiry into Peri-operative Deaths. You  
15 understand why I call that "NCE". In 1989 it conducted  
16 a particular survey of paediatric cardiac surgery, and  
17 you also have the Working Party report, of which  
18 I showed you a brief extract on the screen earlier.

19 We intend to deal orally with the conclusions  
20 which expert statisticians reach in relation to the  
21 data. Since this is an Inquiry not a trial, we are able  
22 to deal with the issue by having two or three experts  
23 engage in public discussions with the limitations of the  
24 various data sources. Rather than the process of one  
25 expert at a time giving evidence independently

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1 cross-examined by a barrister on the basis of a lawyer's  
2 possibly limited understanding of expert issues, we  
3 anticipate a panel or group discussion, moderated as it  
4 were by me, and the experts should be able to determine  
5 whether the evidence suggests that Bristol has  
6 consistently or sporadically outlying performance, and  
7 hence whether the data raises further questions, and if  
8 so, what those questions are.

9 Because of the comprehensive nature of this  
10 Inquiry, its determination to draw conclusions justified  
11 by the best available evidence, we cannot begin with any  
12 assumptions as to what those answers are going to be.  
13 Although, for our part, the legal team has looked at the  
14 various analyses produced by others throughout the  
15 history of this matter, it would be wrong to begin with  
16 any one of them. We are, in reality, in a better  
17 position to establish the facts if they can be  
18 established, than those who produced those studies.

19 In summary, I repeat the fourth theme of my  
20 opening: the data, when it is analysed, may establish  
21 a difference between Bristol and other surgical centres,  
22 either comprehensively or in particular respects. If it  
23 shows this, it will lead us to ask what might be the  
24 reasons for the difference, but it cannot, on its own,  
25 establish what are those reasons. The most the data can

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1 demonstrate is an association between factors. They do  
2 not permit a conclusion about causation.

3 Terms of reference as wide as they are, the fact  
4 that the Inquiry is looking at a process rather than  
5 a series of events, rather than an individual tragedy,  
6 the inadvisability of drawing conclusions from available  
7 data without private, detailed and public discussion,  
8 the sheer mass of documentary and statement material and  
9 the comprehensive nature of the Inquiry, may lead anyone  
10 to wonder how sense can be made of it all. If

11 unreliable statistics are the currents which may pull in  
12 the wrong direction, what is the star by which to  
13 steer?

14 This is where the Issues List comes in -- an  
15 issues list which I am pleased to say appears to have  
16 been well-received. The Issues List is of course  
17 inclusive. It provides a focus, but it must be  
18 remembered that not all of the issues which are listed  
19 in that list are of necessarily equal weight, nor will  
20 they necessarily receive equal treatment.

21 The Issues List is not of purely intellectual and  
22 analytical significance. To demonstrate how it works,  
23 let me take a human example. First, let me, I think,  
24 remove the slide from the screen and have it blank,  
25 thank you.

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1 Let me take a human example. Suppose a baby is  
2 born some time between 1984 and 1995, so it is some time  
3 ago, and, say, somewhere in North Devon. Suppose that  
4 the baby, unknown to her parents, has a congenital heart  
5 defect. I will follow her through from birth to the  
6 outcome of treatment at Bristol hospitals, and comment  
7 on the issues as I go.

8 At first the baby may not thrive. She may be off  
9 her food. She may show tinges of blueness, a peripheral  
10 pulse may be absent. The parents take the baby to their  
11 GP or a clinic, a doctor, perhaps, or paediatrician,  
12 notices the problems at the maternity hospital. Since  
13 the quality of outcome depends in many cases on the  
14 speed and quality of referral, the Inquiry has to  
15 examine that. It is issue E1.

16 "The arrangements and services available to manage  
17 the transfer of sick children from referring hospitals  
18 to the Bristol Royal Infirmary."

19 The local hospital perhaps it is, after referral  
20 from the GP, refers the child to a cardiologist from  
21 Bristol. This will be the first occasion when the  
22 parents come into contact with Bristol. The  
23 paediatrician chooses Bristol, but he might, arguably,  
24 have chosen Southampton, Birmingham, or even London.  
25 Why? On what basis? It is issues D2 to D5. I need not

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1 perhaps set them out: D2 is the judgment or impression  
2 formed by referring paediatricians or other clinicians  
3 of the paediatric cardiac surgical services provided by  
4 the BRI. D4 is the factors influencing clinicians, in  
5 deciding to refer children to the BRI rather than to  
6 other centres performing paediatric cardiac surgery.

7 So our baby is referred for investigation and  
8 opinion. That may be by outreach at a clinic organised  
9 by Bristol but not at Bristol; for example, it is in the  
10 West Country. The process of assessment has to be  
11 looked at. The scope of the services provided is  
12 examined under issue B: was such a service readily  
13 available or not? Issue B looks at the BRI and its  
14 Paediatric Cardiac Surgery Unit, the management,  
15 structure, organisation and staffing of the Paediatric

16 Cardiac Surgical Unit. Much may bear on the speed of  
17 the referral: whether the baby is referred as quickly as  
18 it might be elsewhere is issue C8, the adequacy of the  
19 assessment comes generally under issue E, the  
20 pre-operative management of cases.

21 Suppose that the little girl in my example is  
22 seriously unwell and has to be admitted urgently to  
23 a Bristol hospital. What arrangements are there  
24 available to transfer her from the referring hospital to  
25 Bristol? If, for instance, she has difficulty in  
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1 breathing and may be in heart failure, does a paediatric  
2 team transfer her, or is she in an ordinary ambulance?  
3 If so, are there adverse consequences for her.

4 One of the questions is whether it is better for  
5 cardiac surgery to be available at a larger number of  
6 district hospitals to ensure immediacy of treatment and  
7 to avoid the adverse consequences of transfer and the  
8 time it takes; or, conversely, whether it is better to  
9 concentrate it in fewer centres of regional, or fewer  
10 still of national excellence, to ensure that surgeons,  
11 cardiologists, intensivists, anaesthetists, are familiar  
12 through repetition with almost any unusual variant of  
13 congenital heart disease. That is where issue A comes  
14 in: the regional and national context.

15 Our baby arrives in Bristol: is it at the Bristol  
16 Children's Hospital, or is it the Bristol Royal  
17 Infirmary? At the former, it is set up solely for  
18 children, but children undergoing different surgery,  
19 perhaps wards with cancer and heart patients mixed, some  
20 babies, some near adolescents. The latter is an adult  
21 hospital: is it suitable for children? So we find  
22 ourselves looking at issue H, the split site, as well as  
23 issue E, pre-operative care.

24 Soon after admission, the little girl is likely to  
25 have an echocardiogram, or possibly an angiogram. In  
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1 1988, as a matter of fact history, facilities for both  
2 were much improved at the Bristol Children's Hospital,  
3 as they were for catheterisation. The possible impact  
4 of this is to be borne in mind when looking at review  
5 cases of medical audit, issue M, and when drawing  
6 lessons from the data considered as part of issue C,  
7 the nature and outcome of the services provided.

8 The results of the baby's investigations have to  
9 be considered before any surgery is undertaken. The  
10 decision has to be made as to whether to treat the child  
11 by closed or by open heart surgery; it may be, for  
12 instance, that palliative procedure can be carried out  
13 now, to be followed at a later stage by corrective  
14 surgery. The Inquiry will seek to establish how those  
15 discussions were taken, by whom and what the process  
16 was. Who was it who took ultimate responsibility? What  
17 were the parents told?

18 Moreover, unless surgery is so urgent that it  
19 cannot wait, it has to be fitted in at some time. As to  
20 timing, delays may have occurred in the surgery of

21 babies. Did this harm them? Were other delays caused  
22 by what is euphemistically called "shortage of beds"?  
23 That is a phrase suggestive of the inability to afford  
24 a metal bedstead and mattress, but in reality is often  
25 a question of the availability of sufficient trained and  
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1 paid staff. Does this mean that although everyone knows  
2 the little girl should ideally be operated on between 9  
3 months and 12 months of age, she may in fact have to  
4 wait until 14 to 15 months to fit in? On the other  
5 hand, did the availability of finance play a part? Did  
6 the fact that surgery for the under ones was paid for  
7 directly out of the national pot mean that surgery may  
8 have been brought forward when it might better have been  
9 delayed? These are all part of issue E, specifically,  
10 E6 to 9, and again, I shall not bore you with reciting  
11 the actual issues.

12 As to information given to parents, for instance,  
13 whether there may be legitimate grounds for debate as to  
14 the best procedure in the interests of the child, are  
15 the parents of the little girl in my example told?  
16 Suppose that the cardiologist and surgeons know that  
17 they can perform a procedure which may give her life for  
18 some 10 or 20 years, which is of much lower risk than  
19 a procedure which, if it succeeds, will probably give  
20 life for 60 or 70 years? But which, if it fails, will  
21 lead to speedy death. Whose decision is it to perform  
22 such an operation? To what extent are the parents asked  
23 for their views?

24 We are looking here not only at issue E, but also  
25 at issue L, L being informed consent. Moreover, when  
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1 the parents are told of the risk of the operation, are  
2 they told the risk the surgeon has experienced or is it  
3 the risk which the unit has experienced, or is it the  
4 last reported national record, or is it from  
5 a textbook?

6 Returning to our baby, explanations will be given  
7 to the parents of our child about the condition, the  
8 need for surgery and the risks, but not just about  
9 surgery; also in relation to the continuing care of the  
10 child. If surgery is to be delayed, it may be of great  
11 importance to the parents to know what they should best  
12 do to watch their child and to protect her and to  
13 strengthen the baby for later operation.

14 Again, issue E, in particular E11 and E15, and E15  
15 I just need to quote. You will understand how it fits  
16 in: liaison of staff with parents and the participation  
17 of parents in the assessment and care of their child.

18 Eventually, let us suppose that the baby goes for  
19 open heart surgery. The conduct of this is issue F.  
20 Many factors may go to make the operation on the child  
21 successful or the reverse. The British Paediatric  
22 Cardiac Association will tell the Inquiry that to look  
23 just at the role of the surgeon, the skills of whom are  
24 an obvious factor, issue F1, is to take too simplistic  
25 an approach. Systems failure is very important and the

1 role of others deserves emphasis too. So we shall look  
2 also at the skills of those other than surgeons  
3 assisting at the operation, and we shall look at the way  
4 they work as a team.

5 The reliability of the pre-operative assessments  
6 with which they begin are one factor, as are the less  
7 obvious ones, such as the design and performance of  
8 equipment, the hours of work, the familiarity with the  
9 work and the effect that this may have on how long the  
10 procedure takes. Timing might be critical: for  
11 instance, the amount of time spent on by-pass, or the  
12 cross-clamping times.

13 So far as one can tell, were operations carried  
14 out at Bristol in the same manner as they were elsewhere  
15 at the same time? Issue F.

16 Suppose the baby spends a long time in theatre.  
17 What about her parents? How have they found what is  
18 undoubtedly an anxious time? Issue I: treatment of  
19 families. Were there adequate facilities to help them  
20 and to help them to help their child? Suppose that the  
21 little girl in my example comes through the operation.  
22 What now? She goes to ward 5 in the Bristol Royal  
23 Infirmary, into intensive care where adults and babies  
24 are cared for together in a single ward. It has often  
25 been said that the hours following difficult surgery may

1 be critical to survival. Our issue G looks at this.

2 The baby's parents will want to know how far the  
3 ICU, the Intensive Care Unit, meets or met any published  
4 standards. Bear in mind, standards have changed over  
5 the period with which we are concerned.

6 Issues overlap here, as they do elsewhere. The  
7 split site, which is issue H, may have an impact, for  
8 the care may be provided to the baby in the Bristol  
9 Royal Infirmary, where I have for the purposes of this  
10 journey placed her. As I say, there she will be in  
11 a ward which will have adults undergoing intensive care  
12 and the Association of Paediatric Anaesthetists will  
13 tell the Inquiry that having just one site is a matter  
14 of importance because of the availability of facilities,  
15 clinicians and infrastructure and the Inquiry will have  
16 to consider to what extent its absence, the fact there  
17 was not just one site, makes a difference to our baby.

18 Intensive care may demand very different things  
19 from those nursing adults to those who nurse children.  
20 How is the mix arranged to avoid potential disadvantage?

21 At a later stage the baby may be taken from the  
22 BRI for intensive care at the Children's Hospital. That  
23 involves a transfer, with any attendant risks. The  
24 surgeons are no longer on hand for urgent consultation.  
25 But paediatric expertise may be more readily available.

1 Sadly, let us suppose, that some days after the  
2 operation, our baby loses the fight for life. Issues I,

3 the treatment of families, including the bereaved, and  
4 issue G, post-mortems and inquests, are raised, and the  
5 Inquiry will want to consider carefully, particularly in  
6 view of recent events, whether appropriate information  
7 is given to her parents first about what may have caused  
8 her death (issue J), and second, whether consent, if it  
9 is required by law, was properly and sensitively sought  
10 for the post-mortem and for the retention of tissue or  
11 organs of the body, and if it was not required, whether  
12 proper and adequate information about that matter was  
13 given to parents in an appropriate fashion.

14 Finally, was the death of the child reviewed  
15 internally by the clinical staff to see if any lessons  
16 could be learned? Was it placed in context, such that  
17 the clinical staff had a proper appreciation of their  
18 level of success or failure, reviewed in a manner which  
19 might help to aid performance for the future?

20 Perhaps, more particularly, if in a happier  
21 example, the child survived but had almost died, was  
22 there any attempt to learn from the near miss, so that  
23 the same risks were never taken again?

24 The journey of the child that I have described  
25 takes place in a particular setting. To understand it  
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1 and the factors at play this Inquiry needs to set it  
2 into context. That obviously includes the organisation  
3 of the Bristol Royal Infirmary, physical, managerial,  
4 administrative. It involves the relations between  
5 personnel; the role of outside bodies from the Royal  
6 Colleges to the GMC, and, indeed, the Department of  
7 Health itself. If, for instance, available reports  
8 indicated that Bristol was a significantly poor  
9 performer of paediatric services to the under ones,  
10 should something have been said about it? Was there  
11 a role here for the professional bodies?

12 In the hypothetical journey that I have described,  
13 I appreciate that I have said, really, very little about  
14 the last issues in the Issues List, issues M and N, the  
15 review of cases, medical and clinical audit and the  
16 expression of concerns. That is because these issues  
17 arise not so much out of the treatment of any individual  
18 baby, they arise out of the history of the service as  
19 a whole, and that is perhaps so well known that I need  
20 not recite it in detail.

21 I have, I think, for completeness, to touch on it  
22 a little, and some aspects of that history may be known  
23 to many from sources such as Private Eye. Others I have  
24 already touched on when I referred to the December  
25 agreement there had been between Dr Bolsin and others,  
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1 and Mr Wisheart and others about the lessons to be  
2 learned from available data. It is unnecessary in this  
3 option to examine the rights and wrongs of that  
4 disagreement. Firstly, the Inquiry does not and cannot  
5 begin with conclusions. My present purpose is simply to  
6 record that it happened as a matter of history. It is  
7 also a matter of history that the concerns which

8 Dr Bolsin had were expressed both within the local  
9 service, in particular to senior colleagues, and outside  
10 it to the Royal College of Surgeons, and that they came  
11 to the attention of the South West Regional Health  
12 Authority and to the Department of Health. Those  
13 concerns were based at least in part on the figures  
14 Dr Bolsin saw.

15 Matters came to a head in 1995, the final year of  
16 our terms of reference. That was the year in which  
17 Mr Dhasmana performed an arterial switch operation which  
18 provoked particular controversy. The child died in the  
19 operating theatre. Following that, complex neonatal and  
20 infant cardiac surgery was suspended, pending the  
21 appointment of Mr Ash Pawade in the May of that year as  
22 a specialist paediatric cardiac surgeon. Since then,  
23 media programmes, Despatches, Panorama in particular,  
24 have raised criticisms of the paediatric cardiac  
25 surgeons in Bristol. The GMC has heard and considered  
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1 charges against Mr Wisheart, Mr Dhasmana and Dr Roylance  
2 and a number of legal actions have been taken by parents  
3 against the Trust.

4 The GMC proceedings attracted considerable public  
5 interest. They were monitored closely by the parents on  
6 whose children the surgeons operated.

7 On 1st June 1998, the BBC aired a programme on  
8 Panorama about the events in Bristol of the doctors  
9 involved and that focused on the unsuccessful switch  
10 operation I have mentioned. The allegations made in the  
11 programme were whether those operations proceeded  
12 without the opposition of Dr Bolsin of the surgical unit  
13 the night before the operation and without the knowledge  
14 of the child's parents, and very shortly, on 18th June  
15 1998, Frank Dobson, Secretary of State for Health,  
16 announced to Parliament that an Inquiry would be  
17 established to enquire into the management of children's  
18 heart surgery at the BRI and to reach conclusions and  
19 make recommendations to secure high quality care across  
20 the whole NHS.

21 That is our task.

22 In conclusion, then, I hope I will be forgiven for  
23 yet again repeating and emphasising my four main themes:  
24 first, this Inquiry starts with a clean slate. It has  
25 many questions to ask, but as yet no answers. It has to  
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1 be open. The Inquiry is just that: an inquisitorial  
2 process, not a trial. There is no case to win or lose,  
3 there are no sides and accordingly the procedures will  
4 not be those of a court of trial.

5 Secondly, the Inquiry is comprehensive. It will  
6 and must look at a mass of evidence and do so afresh.  
7 Third, it is a Public Inquiry. It will be the most  
8 accessible Public Inquiry yet, through video links, the  
9 Internet, the publication of formal evidence as it is  
10 received for our consideration and in consequence, much  
11 of it will be in writing. (4) in so far as the figures  
12 are concerned, we must proceed with caution, remembering

13 that if, after careful expert consideration, they do  
14 demonstrate a difference between Bristol and other  
15 centres, they still do not answer why that difference  
16 exists.

17 If I had to select a fifth theme, to reflect the  
18 issues that will act as our star, our point of  
19 reference, it is perhaps this: to focus, to the  
20 exclusion of other concerns, on that which the surgeons  
21 did will be to select only a part, albeit a dramatic and  
22 obvious part, of the whole story. Whether an operation  
23 succeeds or not may well depend on many other less  
24 visible but nonetheless real factors. One of the  
25 purposes in sketching through the hypothetical case  
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1 history is to emphasise that pre-operative care,  
2 post-operative care, organisational structures,  
3 financial and human constraints and the communication of  
4 information in an effective and sensitive way, are all  
5 likely to have an outcome, an impact, on the outcome of  
6 surgery. Also, to focus solely on the surgeon's role at  
7 operation in Bristol, or anywhere else, prevents our  
8 seeing the wider context and implications.

9 Finally, let me remind you that the first block of  
10 evidence in Phase I is that from parents. As with all  
11 other witnesses, they will be encouraged to tell their  
12 story as they see it. It is their story that the  
13 Inquiry wants to hear on its way to reaching  
14 conclusions.

15 It is of course our duty to test recollections and  
16 the view expressed, for instance, if they are  
17 inconsistent or not borne out by documentary evidence,  
18 and equally, it is our duty to put questions which  
19 others will wish to hear the witness deal with, whenever  
20 this will further the Inquiry's interests.

21 Counsel, in opening the case, often tell a court  
22 or a jury what they are going to hear, and they put  
23 together a picture they wish to paint before the first  
24 brushstroke of the evidence is ever applied. Here there  
25 is no case, as I have said a hundred times, and it is  
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1 better that the witnesses tell their own story than that  
2 I give you my version of it in advance. The evidence  
3 should come from them, not from me.

4 Having set out the procedure which the Inquiry  
5 will adopt, may I simply say that block 1 begins  
6 fittingly, you may think, with some parents telling  
7 their individual stories. However much we may talk of  
8 systems or audit, or self-regulation of the profession,  
9 or statistics, it should never be forgotten that it is  
10 the care of individual human lives that is the centre of  
11 our concern.

12 Today we will hear from Mrs Clarke. It will be  
13 probably at about half past 1, I suspect. Tomorrow we  
14 shall hear from Mr Wagstaff, whose child survived  
15 surgery, and Mr Parsons, whose child did not. May  
16 I hope that, however you perceive their answers to me,  
17 you accept it as their personal perspective. And please

18 remember that it cannot be easy to give evidence so  
19 publicly about matters which are inevitably deeply  
20 personal.  
21 Ladies and gentlemen, members of the panel, thank  
22 you.