

**Response of the Department of Health
to the Written Submission of the BHCAG**

The written submission of the BHCAG in many places does not truly reflect and indeed misrepresents the evidence that was put before the inquiry.

In the circumstances it is not our intention to respond to each of the allegations made. However, some further comment is necessary on the four main areas of the submission which directly affect the Department of Health and its witnesses.

These are :

- (a) Bristol was wrongly designated in the first place.
- (b) The Department of Health failed to monitor Bristol, adequately or at all, once it had been designated. Thereafter it applied the "wrong burden of proof" when considering Bristol. It is further alleged that the SRSAG should have dedesignated Bristol.
- (c) The lack of responsibility of the SRSAG.
- (d) The failure to respond to concerns about Bristol.

Allegation A : Bristol was wrongly designated in the first place

Chapter K 2.3.6

The only conclusion here is that Bristol was designated solely because of its location. Its throughput was minimal and there was no evidence that the quality of its work was good enough to justify designation.

Halliday Day 13
033

16 Q. Would it follow from that a unit such as Bristol, doing the small numbers that it was in 1983/84, was unlikely to grow very significantly over the next few years? A. If there was no other factors, but with assurances from the Royal College that they were going to do what they could to strengthen that unit, then there was every prospect that there would be a change in the referral pattern. Q. So what you are saying is really, "Well, if the Advisory Group were looking at this as a matter of their own experience and the criteria, Bristol would not qualify, except on geography, and geography depends upon the quality being maintained and improved; we are assured by the Royal College of Surgeons that they are going to do their best to make sure that happens". Is that it. A. that is essentially it."

Response

The evidence shows that Bristol was :

- i. designated by using input and expert advice from clinicians and the Royal Colleges
- ii. at the point of and prior to designation there was no expressed concern about quality or outcome at Bristol
- iii. there was, however, concern about referral rates. This was taken into account at the point of designation and was subsequently reviewed and monitored by Dr Halliday and by those on the SRSAG.

It is true that an important reason for designation of the centre at Bristol was geography. It was considered important for the welfare of parents and their families that a geographical spread be maintained.

However, there was no expressed concern about the quality of care provided at Bristol. Although it was acknowledged that there were low referral rates prior to designation of the unit the Royal Colleges assured the group that they would attend to the referral issue.

There was therefore never any need for the SRSAG to be concerned about Bristol except in relation to low referral rates.

Had the Colleges not supported the unit it is most unlikely that it would have been designated.

Accordingly there was no reason not to designate Bristol.

Allegation B : The Department of Health failed to monitor Bristol adequately, or at all, once it had been designated. Thereafter it applied the “wrong burden of proof” when considering Bristol. It is further alleged that the SRSAG should have dedesignated Bristol.

Chapter K 2.2.7

Post designation the SRSAG insisted on being given positive evidence that Bristol was failing before the status was reviewed. Pre-designation the SRSAG required no evidence that the quality of its care was satisfactory. Insofar as they did have evidence, the low throughput and concerns of Professor Henderson suggested that it was not satisfactory.

Halliday Day 89

0122

15 A.I was not aware that Professor Henderson was expressing concerns that I needed to take note of. Q. If he was saying that Bristol was bottom of the league, did you know precisely what that might imply? A. You have to take into account that here was a Professor of Cardiac Medicine in Wales who was expressing views which were contrary to the policy of the Royal College of Physicians and which undermined the credibility

of his views to begin with. He was alleging that one of the units was at the bottom of the league, but one of the units has to be at the bottom of the league, they cannot all be at the top. A league table is exactly that, some at the top, some in the middle and some at the bottom. But I was reassured because every single visit by anybody appointed to visit Bristol, be it on behalf of the Welsh Office or the Royal College of Physicians or by working groups set up at the request of the Department of Health, all gave Bristol a clean bill of health, all the colleges had knowledge as a result of their training visits and none of them gave any indication there were any problems in Bristol. So against all of these informed opinions by leading experts, we had a Professor of Medicine who had expressed views which suggested that one unit was at the bottom of the league and that also did not agree with the Royal Colleges' policies. Q. Let me be clear about this, you had those concerns expressed to you by the Chief Medical Officer of Wales? A. I think you must put it in context: we did not have a formal meeting. Professor Crompton was not coming to me to say "I have a major concern here that I need you to address", because had he done so we would have arranged a formal meeting, we would have had agendas, we would have taken minutes, we would have considered future action. There was nothing like that at all. He came to see me and it was -- the kind of meeting we had many times before and on this occasion he expressed the views that Professor Henderson had allegedly made.

Professor Crompton in evidence commented on Day 21 at 0028 that :

"But again, I had no evidence in support of that view. That made it slightly difficult for me to go to another Department of State without evidence to say that there may be something not quite as good as it might be.."

and at 0032

"I was reflecting what Professor Henderson was saying to me. You remember that I also had information from the Gwent consultants which was contrary to that. In the absence of factual data, my case was fairly weak.."

Response

- i. There was no available evidence in 1987 that quality at Bristol was a concern. Although concern was expressed by Professor Henderson in 1987 (relayed by Professor Crompton to Dr Halliday), this was without detail. He simply alleged that Bristol was at the bottom of the league. The context of his concern was not put in any formal meeting.
- ii. Of itself, being at the bottom of the league would not be a cause for concern, although it was noted by Dr Halliday.
- iii. All other sources indicated that there was no concern about outcome at Bristol. This was admitted by Professor Crompton.

- iv. The cardiac surgeons, collectively supported by the cardiologists, argued for continued designation of the service and that the service should include Bristol.
- v. Clearly evidence would have been required in order to dedesignate the unit at Bristol.

Chapter K 2.7.2

Another striking point is that, as with other managing bodies, the SRSAG imposed a high burden of proof on those who sought to persuade them that Bristol requires investigation.

Chapter L 2.9.2 (burden of proof)

The attitude was typified by Sir Michael Carlisle who said that the SRSAG committee would have needed hard evidence to de-designate Bristol and was not prepared to “jump to conclusions ...”(day 15, page 83, lines 24 and 25)

Halliday Day 89

0124

11 A. I am sorry, the only concerns I had heard about Bristol was that the referral rates were low and there was a reluctance of clinicians to refer -- apparently there was a reluctance of clinicians to refer to Bristol. I was never able to ascertain why that was so. No one ever questioned the outcome in Bristol; no one was questioning the clinical standards there. All of the reports we had, and we had many of them, not only reports but reports of visits, all gave Bristol a clean bill of health and then we have one individual who the only evidence I get is that he alleges it is at the bottom of a league table and no detail is provided□

0125 □

A. I am sorry, but you receive information, you do not necessarily take action, but you do not dismiss it; you retain the information and if something else comes along to complement what you have just been told then you might well take action. In terms of what Professor Crompton had told me, I had no justification for taking action. What was I expected to do? I could not go to the Royal College and say "A Professor Henderson in Wales is alleging there is something wrong in Bristol". It would be irresponsible of me to ask the College to investigate on that basis. If, however, I was presented with some evidence, some data to suggest there was something wrong then, yes, I could do something."

Carlisle Day 15

0082

Q. Suppose those discussions had resulted in the views expressed to Dr Halliday that he picked up, that Bristol was not up to the mark surgically; it was below par and had remained so for some years: again, hypothesis. If that had come through, do you think the Supra Regional Services Advisory Group would have done something about it? A. If it had been reported to the Supra Regional Services Advisory Group, I am sure it

would have referred the matter in the first instance as an enquiry to Sir Terence English to say, "Is there substance in this?" Possibly to others as well. I do not think one would jump to conclusions. One would want a pretty speedy response to that sort of enquiry. I have no doubt if that evidence were forthcoming, steps would have been taken to discontinue that service in that unit.

Response

There was never any "persuasion to investigate" the unit at Bristol, the question of whether there was ever a "high burden of proof" or otherwise was not therefore tested.

Information was received by Dr Halliday and considered in the context of other information that was available and had been passed on by clinicians and the Royal Colleges. The concern raised by Professor Henderson (via Professor Crompton) was the only one that was ever raised. It was not acted upon for the reasons articulated by Dr Halliday.

Sir Michael Carlisle, the chairman of the group, was clear that no concerns were ever raised during Group meetings about quality at Bristol. Present at these meetings were representatives of the Royal Colleges and experts in paediatric cardiac surgery, who had been chosen because of their expertise.

In any event, Sir Michael Carlisle made it clear that had there been any evidence investigation and discussion would have ensued forthwith. He himself, being non-medically qualified, would not have "jumped to conclusions" without referring the matter "in the first instance" to the head of the Royal College and "possibly others as well".

Therefore a procedure was in place which provided both an avenue of communication and a means by which to investigate and analyse any information that was forthcoming. The final result, if verified, would have been dedesignation of the unit.

Accordingly the suggestion that there was in any sense a burden of proof is misguided and unfounded.

Chapter K 2.5.1

Despite the ideals of excellence that underlay designation, those responsible for administering the system wholly failed to provide the monitoring necessary to ensure that the designated departments met quality criteria of any kind. Dr Halliday conceded (day 13, page 41, line 21 "We collected activity data. I cannot be absolutely certain how much mortality data we get. We got activity data.")

Chapter L 1.2.1

For a variety of reasons there was no proper information about outcomes for the whole of the period from 1984 to 1995. This was true throughout the National Health Service and meant that such bodies as the Royal Colleges and the Department of Health acted largely in ignorance of quality of care being provided.

Carlisle Day 15

019

Q. I think the first and the last. Let me put it this way: the layman might say, and I really put it to you for comment, how can it be said that there are continually improving levels of patient care with outcomes which compare favourably on the one hand, and how can it be claimed that the quality of service is constantly monitored when the fact is that the Supra Regional Services Advisory Group did not have satisfactory data to deal with the quality of the service provided? A. There is evidence, when you look nationally and internationally, about some of the excellent work that the Supra Regional Services Advisory Group have done: heart transplantation, liver transplantation, there were cases, I am old enough to remember, when people were flown across the Atlantic for operations, and I think there is enough evidence to support that statement. What there is not is the hard aggregated data throughout the whole of the services. There is sufficient evidence, I think, for that claim to be realistic. The quality of service being constantly monitored and approved sought, just because we did not have the hard data in terms of numbers that we were striving to achieve, did not mean that quality was ignored. The visits made by the Medical Secretary and the Administrative Secretary on a regular basis to these units, discussions were held with not only consultant surgeons but nursing staff, managers and others in those units, so there was a very heavy reliance on the feed-back from those meetings. We also had the Royal College of Surgeons where these centres, like many others, are used as training experiences for more junior doctors. They are supervised by the Royal College of Surgeons, and it is my experience there is a very strong set of information that passes, perhaps informally, at that level. There was every effort made to monitor the service, and improve it. What we did not have was the hard evidence, the hard data, to which I have alluded earlier.

Carlisle Day 15

0082

Q. Suppose those discussions had resulted in the views expressed to Dr Halliday that he picked up, that Bristol was not up to the mark surgically; it was below par and had remained so for some years: again, hypothesis. If that had come through, do you think the Supra Regional Services Advisory Group would have done something about it? A. If it had been reported to the Supra Regional Services Advisory Group, I am sure it would have referred the matter in the first instance as an enquiry to Sir Terence English to say, "Is there substance in this?" Possibly to others as well. I do not think one would jump to conclusions. One would want a pretty speedy response to that sort of enquiry. I have no doubt if that evidence were forthcoming, steps would have been taken to discontinue that service in that unit.

Response

Although the systems at that time were not as sophisticated as the audit systems that are in place today, nevertheless the SRSAG was kept apprised of the units by, *inter alia*, :

- i. visits made to the units

- ii. discussions with Consultant Surgeons, managers and nursing staff at the units
- iii. input from the Royal Colleges, and from those members of the group who were representatives of the Royal Colleges
- iv. attending conferences in the UK and in other parts of the world
- v. informal avenues of communication

However, no clinical standards were in existence which would have enabled the SRSAG to analyse effectively the outcome statistics at Bristol.

Chapter K 1.4

The body overseeing designation wrongly failed to de-designate once it became clear that there were continuing and justified concerns about many aspects of paediatric cardiac surgery at Bristol.

Response

It is emphatically denied that there were continuing concerns, as detailed above. Monitoring and visits took place and there were no expressed concern about outcome or quality other than the relayed conversation of Professor Henderson. The only other concerns related to referral rates.

No one has given evidence to the effect that there were “clear” concerns. Professor Crompton admitted that the concerns were not backed up by evidence, and indeed were contrary to the prevailing view.

Allegation C : Lack of responsibility of the SRSAG.

Chapter L 1.2.4

Key factors in the failure to respond to warnings were :-

A lack of any clear sense of responsibility in these organisations (the Department of Health, the Regional Health Authority, SRSAG, the Royal Colleges) which might have been in a position to act.

Response

The inquiry has revealed confusion within the SRSAG which was previously not known to the Department of Health. This is referred to and elaborated upon in the oral submission of the Department of Health.

Chapter L 1.2.4.2

Application of an excessive burden of proof which meant that administrators reacted tardily (if at all) to the evidence that they were given.

In response to the hypothetical situation put by Mr Langstaff that reports came back from units

to the effect that the Bristol was not performing, Dr Halliday replied

- i. that Secretariat (himself and Steve Owen) would have put in a paper to the Advisory Group expressing concern about a particular unit.
- ii. Dr Halliday understood that this would in effect be a recommendation to the Chairman that he invite the President of the appropriate college to set up a Working Group to review this situation.

There was no application of any “burden of proof”. The proposition was never tested as the situation never arose.

Chapter L 2.7.12

The irony of this passage (Sir Alan Langlands day 65, page 28 lines 22 ff) is that although Sir Alan said that he wanted to avoid saying that nobody was responsible, that is the clear effect of his comments.

Response

This misinterpretation of the evidence is rejected.

The Department of Health accepts that it is responsible and accountable for any failings of the systems that were in place during the period covered by the inquiry.

Ultimate responsibility rests with the Department of Health and the Secretary of State.

This is, however, in the context of delegated responsibility for the treatment of individual patients.

The sheer scale of the NHS necessitates that powers have to be delegated downwards which means that a system of accountability are established. Whilst the Department of Health (or the NHS executive which is an integral part of it) has many avenues of influence it does not directly manage patient services.

Sir Alan Langlands commented on Day 65 at 059

“in that complex situation which exists, not just in the NHS but in every health system, it seems to be that the key thing is to ensure that the roles and responsibilities of individuals, the roles and responsibilities of statutory bodies, the roles and responsibilities of the Department of Health and the NHS Executive, are adequately defined, so that everyone can see the distinctive contribution that each of these players should make to ensuring that we have a system that is risk-free as possible”.

It is therefore against this standard and this background that the Department’s responsibilities must be judged and assessed.

However, nothing can detract from the shared responsibility for clinical outcomes. Sir Alan was keen in the same piece of evidence to emphasise that :

- i. individuals are responsible and accountable
- ii. the Department of Health must be accountable for the systems that were in place

It is in this context that Sir Graham Hart was keen to emphasise the “shared responsibility for clinical outcomes”

Allegation D : Failed to respond to concerns about Bristol

Although it is accepted, without qualification, that there were systemic failings at no time prior to July 1994 (this is a correction to our written submission where it says July 1995) were departmental officials in possession of facts that would have alerted them to the concerns that were apparent (i.e. when Dr Doyle was contacted by Dr Bolsin).

It now appears that several people had fragmentary concerns about the situation at Bristol but failed to communicate them in a way which would enable anyone within the Department to assemble the fragments and take that action needed to be taken. There were many avenues with which concern could have been brought to the attention of the Department, including, but not limited to :

- i. contacting the chairmen of the SRSAG
- ii. contacting any Departmental official or Regional Health Authority official
- iii. contacting Health Ministers
- iv. or the Chief Medical Officer directly

Chapter L 2.8.8

Even where a problem was acknowledged, it was often played down to the point of misrepresentation. Hence, Ms Hawkins commented to Dr Halliday’s reassurances (day 56, page 85, line 24 ff) : -

“Dr Halliday told us that he understood that the problem with Bristol was the throughput of numbers and that all he heard about the quality of outcome was that Bristol was not the best until, that is -- leave aside the events of 1991/92.

Did the Department ever express a concern to you about the throughput of cases in neonatal and infant category?

To my knowledge no.

Did they ever express the view that they had heard in the corridor or through the back door that however good or bad the results might appear on paper to be, their view was that Bristol was not one of the best?

I can say no because if they had, I would have had sleepless nights”

Response

The suggestion that there was any misrepresentation is rejected. The evidence of Dr Halliday is not inconsistent with that of Ms Hawkins.

Chapter L 2.4.2

Ms Hawkins had been told that paediatric cardiac surgery at Bristol was poor and therefore wrote to Dr John Roylance on November 20 1991 (letter ref. UBHT 38/430). Roylance's reply, largely drafted by Mr Wisheart (UBHT 0038 0430 and UBHT 0036 0432) suggested that the problem was contracting not quality, which Hawkins described in evidence as "a clever sidestep".

Response

This is completely inaccurate. At no time did Ms Hawkins ever receive any information to the effect that there was any concern about paediatric cardiac surgery. This is confirmed in her second statement and in her oral evidence.

The letter (UBHT 38/430) refers to cardiac surgery. The reply deals with waiting lists. There was no reference at any time to paediatric cardiac surgery.

Chapter L 2.5.8

The tenor of their evidence was that the magazine was trivial and of no consequence; most said (without any expression of regret) that they had been quite unaware of what was written and (by implication) had they been aware of it, they would have ignored whatever was published in a magazine with the reputation of Private Eye.

Response

Allegations were made in three editions of Private Eye in 1992. It is true that those in the department (Sir Kenneth Calman for example) who did read it were not pre-disposed to accept its accuracy.

Sir Kenneth drew attention to statistics in one of the articles which were incomplete and did not make sense

In any event, the concerns were investigated by Alistair Mason (the RMO), who made inquiries of colleagues who reassured him that they were unaware that there was any concern at Bristol

Sir Kenneth was clear that had Dr Hammond approached him he would have certainly taken follow up action

If the intention of the author, who is himself a clinician, was to bring the content of the articles to the attention of the Department of Health it was, in our submission, a serious misjudgment to

use this avenue.

23 February 2000

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