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Paediatric Cardiac Surgery Inquiry

Paper: "An evaluative commentary on systems for review and audit at the United Bristol Hospitals NHS Trust 1984 to 1998"
by Kieran Walshe and Nigel Offen

I confirm that the paper gives a good review of the development of medical audit in the United Bristol Healthcare NHS Trust. With the benefit of hindsight, and in the light of subsequent events, I accept that there could have been a greater involvement of the Trust Board in the medical audit outcomes, although how we could have achieved that in practice in the climate of the time is difficult to envisage. As with other governance issues, clinical audit took time to develop and become an accepted part of clinical practice, and was then carried into the overview of Trust Boards through the development of clinical governance.

As I wrote in my statement of 27 October, 1999, "...it was the firm view that the Trust Board was not an arbiter of clinical opinions. It was accepted that there was a professional machinery for dealing with clinical matters, including the involvement of the Royal Colleges". I understood this to be a widely held view at that time.

Formal clinical audit was in its infancy at the time, and we felt that the UBHT was in the vanguard of its introduction. The paper by Walshe and Offen concludes that "UBHT's arrangements for review and audit were less good than those at many other NHS trusts". However, the authors give no evidence to substantiate their claim and I question whether "our knowledge of and involvement in medical and clinical audit at the time" carries sufficient scientific rigour to make the conclusion.

I emphasise that, with the benefit of hindsight, I accept the criticism of the medical audit process at that time, and that I welcome the introduction of "clinical governance"; it is only the comparative position of UBHT that I question.



Brian Pickering
31 August 2000

Dr John Roylance
**Response to Report by Kieran Walshe and Nigel Offen to the "Evaluative
Commentary on Systems for Review and Audit at United Bristol Hospitals'
NHS Trust from 1984 to 1995"**

The comments below relate to successive paragraphs in the report and will be numbered according to the original paragraphs.

Paragraph 5

It is unhelpful to combine under one heading the varieties of audit, quality assurance, quality improvement and review activities. This leads to confusion when clarity is required. It has always been the practice, certainly in teaching hospitals and probably throughout the Health Service, for consultants to review the quality of their care and the outcomes achieved. In addition Bristol, in keeping with all teaching hospitals, provided each year a substantial volume of original articles which were submitted to the medical literature. These articles predominantly related to the quality of care and the expected outcome. Medical audit and subsequently clinical audit, were different in two ways. First, it was anticipated that ultimately it would provide a continuous review of the whole spectrum of care rather than investigate particular topics. Secondly, it was intended that standards of care and of outcome would be agreed, against which current practice could be compared. It was and is essential that these standards be created before inexperienced and lay minds could safely judge the quality of care.

Paragraph 6

In the days of the United Bristol Hospitals, the forerunner of UBHT, there was held monthly a so called clinical staff meeting, which reviewed all mortalities and studied each month a particular topic, or occasionally several topics. Dr Roylance was secretary to this meeting in the mid 1960s. Typical of the topics discussed was the subject of phlebothrombosis and pulmonary embolism. As a result of a full review, changes were made to patient care. Subsequent monitoring demonstrated a reduced incidence of both phlebothrombosis and pulmonary embolism. As specialisation and sub specialisation within the practice of healthcare progressed, detailed reviews of patient care were undertaken within each speciality group. The clinical staff meeting evolved into a forum for post graduate education and continued education. Detailed monitoring and review of patient care has always formed part of the infrastructure for education and research which have always constituted a major part of the responsibility of the teaching hospital. It should however be borne in mind that there is a distinction between "Review" and that which is now known as "Clinical Audit".

Paragraph 7

It is to be regretted that the authors of this document have found only limited evidence of review activities. Their failure to find the evidence does not constitute evidence that these activities did not take place. The reality is that all consultants and their junior staff, in all specialities, regularly and consistently reviewed the quality of their care.

Paragraph 8

It must be repeated that although very little of the evidence presented to the Inquiry relates to systems for review, it is quite improper to conclude from this that that is positive evidence that such systems did not exist.

Paragraph 10

The District Audit Committee, established in December 1990, met the requirements of the Regional Health Authority in its terms of reference and constitution. No decision was made to devolve to directorates responsibility for medical audit and the ringfenced resources for audit. The clinical directorates pre-existed the introduction of medical audit as part of the implementation of the general management function and the involvement of medical staff in management. The funds for medical audit were allocated directly from regions through the Regional Medical Officer to the medical staff. District management was not directly involved in this allocation but had the responsibility to support the initiative with such management action as was required. The funds were allocated on the basis of consultant numbers. In practice, of course, no cash actually reached the consultants, only an authority to commit funds. The money was processed through the Finance Department which recorded the precise expenditure committed under this ringfenced financial authority.

Paragraph 11

It needs to be re-emphasised that the funding was allocated directly to consultants, not to directorates. The consultants, of course, were managerially within clinical directorates, but management took no direct part in the distribution and allocation of these funds. The manner in which the resources were used was on the basis of agreement between the Regional Medical Officer and the consultant staff.

Paragraph 12

The data on how audit resources were used would lie within the Finance Department records which were communicated, at the time, to the Regional Finance Department.

Paragraph 13

The formal monitoring and reporting on the use of audit monies were provided by the Finance Department and should still be available.

Paragraph 15

Throughout the five years from the introduction of the concept of medical audit, the two major initiatives were to develop the extensive patient care monitoring that already existed into the more formal form of proposed medical audit and to move towards a continuous monitoring of all patient care against agreed standards. The agreed strategy, underpinning these moves, was generated at regional level and required Districts and subsequently Trusts, to ensure this change was implemented in a manner which retained confidentiality to the speciality groups, with no involvement of management in the actual audit results. Management's role was confined to facilitating audit by ensuring the appropriate infrastructure was created. The review by the SWRHA Regional Audit Team in early 1994 formed the basis of detailed discussion

between the Regional Audit Team and the District representatives. All the matters discussed resulted in a mutual agreement on a way forward.

Paragraph 18

The changes which took place in 1996 were a natural development and only possible because of the successful evolution of clinical audit during the previous five years.

Paragraph 19

It is important to note that Dr Trevor Thomas was also a member of the Regional Audit Committee which reinforced the communications between that Committee and the District and subsequently Trust.

Paragraph 20

The Medical Audit Committee was established in accordance with the regional recommendations. It exercised its authority through the Medical Committee and was seen as responsible for the introduction and monitoring of medical audit. The Chairman of the Committee was responsible for reporting to the District General Manager and subsequently the Chief Executive, any managerial action that was required. This separation was in order to reinforce the message that medical audit was a matter for consultants and not for managers. It was widely understood that this separation was a necessary pre-requisite for the effective introduction of audit. The Regional Audit Committee allocated audit monies directly to consultants and this was overseen by the Audit Committee. No occasion arose when direct sanctions or powers of the Audit Committee were found in any way wanting. The Audit Committee fulfilled a major role in the development of clinical audit and this was strongly supported by the Chairman of the Medical Committee and the District General Manager, later the Chief Executive.

Paragraph 22

At the outset medical audit was conceptualised as wholly a professional concern to be developed as part of continuing medical education and teaching and to form a better infrastructure for clinical research. Only by adopting such a stance was it possible to develop audit at the speed that was achieved. It has facilitated the current thinking on healthcare quality and improvement with the multi-professional collaboration, openness and teamwork. The Chairman of the Medical Committee and the Chief Executive separately and together had worked very hard towards the day when outcome standards could be incorporated in workload contracts.

Paragraph 23

It is quite untrue to suggest that between 1990 and 1995, UBHT management played very little role in the leadership or development of clinical audit. The Chairman of the Medical Committee and the Chief Nursing Adviser in particular combined with the Chief Executive facilitated, encouraged and reassured all staff in the development of audit. This was done by personal contact, individual and group discussions, but not by issuing process documents which would, at the time, have been counterproductive.

Paragraph 26

It was clearly understood at the time that in a very large District/Trust effective clinical audit with continuing monitoring of all care against agreed standards, would require a sophisticated computerised database. No appropriate software was available commercially or within the NHS. The Trust's computer experts therefore collaborated energetically with the Regional Computer Centre to develop such software. It is not unusual for the early development to be not initially successful, but adequate systems are only developed on the basis of early practical experience. There is no doubt that the efforts made during those years to develop suitable computer software has underwritten the effective development of clinical audit. The development of the role of Audit Assistants, continued in Bristol as it did in other Districts and Trusts. The Audit Assistants in Bristol met regularly as a group and their Chairman attended the monthly meetings, together with the District Advisers of other professions allied to medicine, with the Chief Executive and Executive Directors. The suggestion that a management structure based on directorates separates and isolates staff is quite unfounded. There was the very closest of collaboration and communication between directorates and between staff of similar speciality from within each directorate.

Paragraph 28

As an adequate computerised record system was an essential prerequisite to clinical audit, it is unacceptable to suggest that the cost of developing such a system was other than money well spent. The decision to expend this money was supported by a consensus of advice from within the District and from the Regional Health Authority. To provide extra money for Audit Assistants when there was no way of functioning without an adequate information system would clearly have been money wasted.

Paragraph 29

As examples of good practice emerged these were used to inform and encourage other specialities. It is inevitable that when a single initiative is introduced in a large organisation the speed of progress of its constituent parts varies across the organisation.

Paragraph 30

There was a growing use of more explicit and systematic approaches to the selection of topics for audit in 1993 and indeed earlier. Reflecting sometime afterwards on a rapidly developing initiative has unfortunately given rise to misunderstandings. Defined standards were not available in those years and I suspect few robust standards exist today.

Paragraph 31

During the period under discussion, there was no defined body of knowledge or group of experts well versed in established clinical audit. Such expertise developed from within academic environments found in teaching hospitals. As clinical audit became better developed and better understood than Bristol, as with other parts of the Health Service, instituted effective teaching programmes.

Paragraph 33

Underlying the whole of the introduction of clinical audit was a genuine understanding that the precipitate involvement of management and the breaking of confidentiality regarding results would have seriously impaired the development of audit. The Chairman of the Audit Committee himself saw that the release of audit information would prevent his Committee achieving the development of audit within the District and Trust. He was, in no way, restricted in raising matters of concern either in the process of audit or regarding the results of audit. He could require of the Chief Executive, such management action as he deemed appropriate or he could raise issues of a professional nature within the forum of the Medical Committee. The fundamentally important issue was that it was for the Audit Committee to determine when action was necessary and at that time proactive monitoring and action by managers was proscribed for the reasons stated.

Paragraph 37

Reporting by doctors to the Medical Committee was part of the mainstream mechanism for managing the Trust. The Chairman of the Medical Committee attended Health Authority meetings and was subsequently made Medical Director of the Trust Board. The Audit Committee was thus part of the advisory infrastructure supporting the Medical Director's responsibility to management. It must be emphasised that the Medical Committee formed part of the communication system and was in no way separated from central management.

Paragraph 42

Dr Charles Shaw was invited by the UBHT Medical Audit Committee to become a member illustrating their intention to remain very closely related to the Regional Medical Audit machinery and to inform themselves of such expertise as was at that time available. The SWRHA report was discussed in detail as noted in paragraph 15 and a number of misunderstandings were corrected. For example, the directorate structure was a natural consequence of the implementation of the Griffiths' report in a very large organisation. The audit responsibility and funds were not allocated to the directorates but to the consultants themselves. As a result of these discussions agreement was reached with the Regional Audit Group and the foundations were laid for the reorganisation which took place in 1995/96.

Paragraph 43

The relationships which were developed with the Bristol and District Health Authority, far from limiting the use of medical audit, in practice facilitated these discussions with, at the time, every expectation that standards when they merged would be included within contracts.

Paragraph 44

I totally reject the judgement that UBHT's arrangements for review and audit in the early 1990s were less good than those in many other NHS Trusts. It may well have been that UBHT's arrangements were different to other Centres for a number of reasons, not least of which was its size but it was the view in the Southwest that UBHT

was leading the Southwest in the evolution of clinical audit. Some Trusts had not implemented the general management function and had not delegated decision making to operational level. Other Trusts were small and such delegation did not present an issue. It was natural in both to have a single central audit function but there is good evidence that this was not accompanied by a real commitment of the medical staff to the processes which were instituted. It is true that teaching hospitals did seem to be slow to respond to the development of medical and clinical audit because the culture of audit and the exercise of review were already in existence. It was the need to establish better systems which was a precursor to abandoning the existing approach and it should be remembered that the introduction of audit was initially to encourage review and not as a tool to monitor performance.

Paragraph 45

The decision to invest initial resources in computer systems was supported by all at the time. It can be argued that by doing so the overall development of suitable systems was expedited. The responsibility for and the funds to support audit, were not allocated to directorates, they were allocated to consultants. The fact that the consultants were grouped into directorates is irrelevant and not the major obstacle that it appears to be when seen from afar. The Clinical Directors were involved in audit as doctors, but not as managers. This has clearly led to some confusion and misunderstanding on the part of distant observers.

Paragraphs 46 and 47

The re-emphasis of the disadvantages of the delegation of decision making to operational level is clearly at variance with the recommendations of the Griffiths' report which the District General Manager was appointed specifically to implement. There are many views about centralised and decentralised management structures and many Districts implemented the Griffiths' report only in name. For example, district management teams were renamed district management groups, the District Administrator in many cases was retitled District General Manager and the management and culture continued unchanged. The recommendations of the Griffiths' report have major managerial advantages and enable the involvement of all carers in the management process.

Paragraph 48

UBHT developed a group of staff with special skills in audit and quality improvement and very much learnt as the process evolved. There was no pre-existing group of such staff and they had to be developed throughout the Health Service. The resources within teaching hospitals were clearly an advantage to those groups in the identification and development of such audit staff.

Paragraph 49

The comments in this paragraph may well be true. As Bristol at the time had a strong and shared vision and values, consistent and stable clinical and managerial leadership, good inter-professional relationships and well established clinical managerial arrangements, it is no surprise that the development of clinical audit was effective.

Paragraphs 50 and 51

The conjecture that the management at Bristol was dysfunctional is rejected, both from the evidence provided and from personal experience. Clinical audit during the period in question, was far too primitive and underdeveloped throughout the Health Service to have any possible bearing on the subject of the inquiry. Not only were standards not established at that time to allow the inexpert to have a valid opinion, the volume of cases treated within paediatric cardiac surgery were so small that valid statistical comparisons were not possible. It was for this reason that the cases were summated nationally in an attempt to produce some indication of the overall success. There is inevitably a spread of results across units each individually with relatively small throughputs. Recent reports in the media, for example make the claim that mortality in the Bristol Children's Hospital are now less than half the National average. The development of validated risk stratification of patients and the summation of care provided across the country, may in the future allow valid monitoring of care. Until then, Trust Boards and Health Authorities will have to rely upon advice from within the speciality.

Considerations of medical and of clinical audit must be placed within the contemporary circumstances. The concept of clinical governance by health service management first appeared in 1995. Until then, the clearly understood responsibilities of management were to provide an environment in which consultants could exercise their professional skills independent of others. The Royal Colleges were responsible for determining when doctors had reached the stage of being capable of exercising that independence. Management could only intervene when advised by experts that such action was necessary.


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DR JOHN ROYLANCE

24 Oct 00
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DATED

An evaluative commentary on systems for review and audit at the United Bristol Hospitals NHS Trust from 1984 to 1995: additional comments

Kieran Walshe and Nigel Offen

Introduction

1. These additional comments have been prepared by Kieran Walshe and Nigel Offen, the authors of an expert commentary prepared for the Bristol Royal Infirmary Inquiry on the systems for review and audit at the United Bristol Healthcare NHS Trust (UBHT) from 1984 to 1995¹. They are intended to provide clarification and further comment on some issues raised by interested parties in their written responses to the commentary². Those written responses are, along with the evaluative commentary and the wider evidence on which it is based, in the public domain. We are very grateful to those parties for their thoughtful and constructive responses, which stand in their own right as submissions to the Inquiry. Many of the issues raised by their responses concern matters of interpretation or opinion, and do not need to be addressed specifically in these additional comments.

Scope of the evaluative commentary

2. It should be noted that the evaluative commentary was based on a review of documents selected and provided by the Inquiry's legal team, and not on a review of all written and oral evidence presented to the Inquiry. We focused especially on the contemporaneous documentary evidence from the time period under review, which we believe provides the most reliable and objective information available.
3. It should also be noted that the primary purpose of the evaluative commentary was not to summarise all the available evidence on audit and review at UBHT but to set this evidence in the context of the wider development of medical and clinical audit in the NHS over this period.

Hindsight, fairness and balance

4. In reviewing the available evidence, we strove to avoid making errors of hindsight. We tried to judge the systems for review and audit at UBHT by the standards of the time, not those of the present day. We also endeavoured to put aside what we knew about the primary events which the Inquiry was established to investigate, in order that such

¹ Walshe K, Offen N. An evaluative commentary on systems for review and audit at the United Bristol Hospitals NHS Trust from 1984 to 1995. Bristol: Bristol Royal Infirmary Inquiry, 2000.

² Comments from Mr B Pickering, Mr J D Wisheart, Dr J Roylance, Dr T Thomas and Mr J P Dhasmana have been received.

information would not influence our assessment. We believe we were successful in doing so, and that our commentary is fair and balanced. It makes some important criticisms of UBHT and also of the Bristol and District Health Authority (BDHA) and the South Western Regional Health Authority (SWRHA) but we would suggest those criticisms are amply supported by the evidence.

5. It should be noted that where our commentary references research undertaken into the development of audit in the NHS, it does so in order to set the wider context referred to above, and every effort is made to compare UBHT with other similar trusts at the time.

Matters of fact

6. We noted the lack of information about many specialties, including paediatric cardiology and paediatric cardiac surgery in the annual audit reports from 1990 to 1995, and the apparent lack of action to follow up such failures to provide information. We stand corrected that there is – in one year, 1990 – mention of paediatric cardiology in the annual audit report, but we reiterate that the general absence of evidence of the progress of audit is striking. There is no direct evidence, in annual audit reports or in other sources, that the audit committee treated such a consistent and continuing failure to provide information on the progress of audit with the seriousness that it deserved. Rather, it seems evident from the reports that clinical directorates or specialties were allowed to submit or not submit information as they wished.
7. We did not suggest that there was no audit being undertaken in paediatric cardiac surgery over the period under review, and a number of responses provided a helpful summary of those activities. However, this confirms the view expressed in our commentary that those activities were not documented in a way that would allow others – either at the time or in retrospect – to assess their effectiveness.

Interpretation and overall conclusions

8. It should, perhaps be reiterated that our commentary suggests that the systems for audit and review at UBHT were relatively poor (in the bottom quartile of NHS trusts) in the early 1990s, and that the Trust's relative position declined between 1990 and 1995 largely because other NHS trusts made greater progress. The four main failings which we identified were:
 - a) The lack of leadership for medical and clinical audit on the part of the audit committee, which had few formal powers and little apparent influence, but which was clearly placed in that position by the Trust rather than choosing it for itself. Nevertheless, those who led medical and clinical audit over this time must accept some responsibility for its shortcomings.
 - b) The absence of a central audit function in the Trust, which made setting a strategic direction, monitoring progress and following up areas where audit was slow to develop almost impossible. This is illustrated by the lack of reporting on paediatric cardiology and paediatric cardiac surgery, but is equally true in other specialties.

- c) The lack of proper control and accountability for monies for medical and clinical audit, which amounted to over £1 million between 1990 and 1995, which means it cannot even be said with any certainty that the funds were used for audit, let alone that they were well used.
 - d) The fact that evidence was available that UBHT's audit programme was a "low outlier" in how it was organised and structured and how resources were used from 1990 onwards, but that neither the Trust nor other organisations acted on that evidence until 1995.
9. We argued that, while some praiseworthy and worthwhile audit activities took place within UBHT over the period which we reviewed, the systems for review and audit which were the main focus of our commentary were deficient.

KW/NO – 9/11/2000.