A Report on the Bristol Histopathology Inquiry

by a member of the public

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1. PREFACE

The purpose of this report is to provide a patient and public perspective of the events surrounding the Inquiry and to review whether patient safety has been a priority before and during the Inquiry.

The report also comments on the start of the Review of the Future of Pathology Services for Bristol, North Somerset and South Gloucestershire.

I am the author of the report, a member of the public who has used Bristol histopathology services. I became involved patient advocacy in 2005, have attended scientific training for advocates in the United States of America and Europe, and have played a full and active part in local NHS service reorganisations. My family lives in the area served by Bristol's Histopathology Service.

The Report of the Inquiry Panel commissioned by University Hospitals Bristol NHS Foundation Trust to inquire into some serious allegations of misdiagnosis against the Trust is due to be made public, in full, in December 2010.

The questions raised in this report are those that many local people expect the Inquiry Panel's report to answer. We will see whether it meets our expectations.

I have listed below the organisations of which I am a member. However I am the sole author of this report. It is not written on behalf of any of them and none of them have contributed to it.

Mrs Daphne Havercroft November 2010

University Hospitals Bristol NHS Foundation Trust
The Patients Association
South Gloucestershire Local Involvement Network (LINk)
Independent Cancer Patients' Voice (ICPV)
Breakthrough Breast Cancer Campaigns and Advocacy Network
National Cancer Research Institute (NCRI) Breast Clinical Studies Group
NCRI Consumer Liaison Group
National Breast Cancer Coalition (United States)
BUST (Breast Cancer Unit Support Trust)
Lay Reference Group, Bristol, North Somerset, South Gloucestershire Review of Pathology Services

2. INTRODUCTION

2.1. What is Pathology?

According to the Royal College of Pathologists (RCPath), some of the main achievements of pathology are:

- developing vaccines against major infectious diseases such as smallpox, diphtheria, polio influenza and meningitis
- enabling safe blood transfusion
- managing the immune system for successful organ transplants;
- monitoring drug treatment
- establishing a tissue diagnosis and a prognosis in tumours and inflammatory diseases
- pinpointing the genetic causes of disease.

http://www.rcpath.org/index.asp?PageID=19

2.2. RCPath has produced a Public Benefit Statement that says 70-80% of all healthcare decisions affecting diagnosis and treatment involve pathology.

http://www.rcpath.org/resources/pdf/Public_benefit_statement_v3.pdf

There are various pathology disciplines including clinical biochemistry, haematology, immunology, microbiology, genetics, forensics, paediatric and cellular pathology (including histopathology)

2.3. The Bristol Histopathology Inquiry concerns paediatric pathology and adult histopathology services in the specialisms of breast, lung, gynaecology and skin. Histopathology is the study of disease in tissue.

3. BACKGROUND

3.1. In June 2009, Dr Phil Hammond, local GP and journalist, published a report in his fortnightly "MD" column in Private Eye Magazine concerning allegations of 15 cases of misdiagnosis in breast, skin and lung histopathology by University Hospitals Bristol NHS Foundation Trust (UHBristol). Some of the allegations went back to 2000.

3.2. The allegations were not simply about differences in interpretation of malignant or benign conditions. Some allegations concerned benign conditions that were diagnosed as malignancies and vice versa.

3.3. Further allegations of gynaecological misdiagnosis against UHBristol were publicised by the local news programme BBC Points West and by Dr Hammond later in June 2009.

3.4. Dr Hammond reported that the concerns about some adult histopathology specialities were raised by clinicians who worked at North Bristol NHS Trust (NBT). However, he was subsequently contacted by a former paediatric consultant of UHBristol concerning allegations of serious errors in respect of paediatric pathology going back to 2001, the time of the BRI Heart Inquiry and the Alder Hey Organs Retention Inquiry.

3.5. When the allegations of the 15 cases were made public, UHBristol acted quickly to establish

two audits and an inquiry. It amended the case number to 26 only after I requested that the gynaecological allegations reported by the BBC and Dr Hammond be included in the Inquiry.

3.6. Since the Inquiry Panel was convened in 2009, there have been at least three further allegations of misdiagnosis, in addition to the 26 original cases.

a. A breast biopsy specimen cancer diagnosed as grade 1 cancer by UHBristol; and the same specimen diagnosed as grade 3 cancer by three NBT pathologists specialising in breast disease. Grade 3 has very different implications for patient care to grade 1.

b. A tuberculosis missed by UHBristol.

c. A patient diagnosed with malignant mesothelioma by UHBristol. NBT reviewed the case shortly before the patient was scheduled for chemotherapy and diagnosed a benign condition. Consequently the patient was saved from having unnecessary chemotherapy.

None of these allegations has been publicly refuted by UHBristol. Therefore I assume that the Trust accepts these errors were made.

3.7. In a letter to the Chair of the Joint Health Scrutiny Committee dated 15th April 2010, Mr Robert Woolley, then Acting Chief Executive of UHBristol, admitted that two of the 26 cases of concern had been misdiagnoses leading to patient harm. The Trust admitted liability and financial settlement was reached.

3.8. This report refers to three timelines:

Timeline A - University Hospitals Bristol Paediatric Pathology Concerns Timeline, produced by Mr Richard Spicer, a Paediatric Surgeon who worked for the Trust until 2008.

Timeline B - Bristol Histopathology Timeline, produced by Mrs Daphne Havercroft

Timeline C - Timeline produced by Deborah Lee, former Co-Director of Commissioning, NHS Bristol

All three timelines are appended to this report and can also be found on Dr Hammond's website where **Timeline B** contains links to supporting documentation

http://drphilhammond.com/blog/category/bristol-path-inquiry/

4. EVENTS PRIOR TO THE INQUIRY

4.1. The 15 allegations reported to Dr Hammond were contained in a letter dated June 2007 from a clinician to Dr Martin Morse, Medical Director of NBT. However Dr Morse had been aware of concerns since at least 2004, when he was copied on a letter from NBT clinicians to UHBristol histopathologists raising concerns about the quality of lung histopathology reporting.

4.2. Also copied on the 2004 letter were Dr Jonathan Sheffield, Medical Director of UHBristol until 1st October 2010, and Mrs Ruth Brunt, now Chief Executive of NBT.

4.3. Members of the public may wonder why NBT doctors saw UHBristol's histopathology reports. In 1997, it was decided that all Bristol's thoracic surgery should be centralised at UHBristol. Therefore when NBT lung physicians required patients to undergo lung biopsies, they would and still do refer them to UHBristol's BRI (Bristol Royal Infirmary) for surgery. The biopsy would be

reported by UHBristol histopathologists and the patient seen for follow up at NBT. It was during follow up that NBT clinicians saw some diagnoses they disagreed with.

4.4. During later years, the NHS planned, and in some cases, implemented other service centralisations in Bristol, under the Bristol Health Services Plan (BHSP), now called the Healthy Futures Programme. Among the members of the Healthy Futures Programme Board are the Chief Executives of the Primary Care Trusts of Bristol, North Somerset and South Gloucestershire (known as BNSSG), UHBristol, NBT, Weston Area Health NHS Trust, Avon and Wiltshire Mental Health Partnership NHS Trust and the Great Western Ambulance Service NHS Trust.

4.5. One of the service changes planned by BNSSG was the centralisation of Bristol's breast surgery at St Michael's Hospital, managed by UHBristol. In 2007, UHBristol's breast surgery was transferred from the Bristol Royal Infirmary (BRI) to St Michael's Hospital. It was planned to transfer NBT's breast surgery, based at Frenchay Hospital, to St Michael's in 2008.

4.6. The planned transfer of Frenchay's breast surgery did not occur due to concerns raised by patients that there was lack of evidence that breast services would improve. They believed that the move could be detrimental to the NBT service. The NBT clinicians also had concerns that they would be unable to maintain the quality of their service.

4.7. The controversy culminated in a hearing on 15th October 2007 at the Joint Health Scrutiny Committee in Bristol Council House, attended by NHS managers, breast clinicians, patients and members of the public. Patients had discovered, under the Freedom of Information Act, that the transfer of breast surgery to St Michael's Hospital was a trade off between UHBristol's Head & Neck Cancer Surgery and NBT's Breast Surgery, to balance the finances between the two Trusts. UHBristol's Head & Neck surgery would go to NBT, NBT's breast surgery to UHBristol. There was no evidence that the changes would deliver measurable benefits for patients, or that the consequences of detaching surgery from the rest of the Breast and Head & Neck services, including histopathology, had been considered.

4.8. At the 15th October meeting, patients and members of the public heard NBT clinicians tell the members of the Joint Health Scrutiny Committee that the “issue of the pathology services” had to be resolved. All attendees - councillors, NHS managers (including Deborah Lee, NHS Bristol's Acting Chief Executive), clinicians, patients and members of the public also heard a clinician express the view that “some aspects of UBHT's pathology are not up to standard”. The clinician also stated that concerns had been previously raised about histopathology and a strategic review of the service in Bristol was discussed six years ago, but no actions were taken.
(UHBristol was formerly called UBHT, before it achieved Foundation Trust status in June 2008.)

4.9. At the end of 2007, the transfer of NBT's breast surgery to St Michael's was halted. In 2008 BNSSG instigated a review of all breast services. Patients and the public assumed that the senior NHS managers in attendance at the 15th October meeting would have investigated the concerns raised about UHBristol's pathology, especially as it is now known that Dr Martin Morse, present at that meeting, had been in possession of the letter containing specific details of the 15 allegations four months earlier, in June 2007. However the concerns were not investigated.

4.10. Timeline B shows that no action was taken by senior NHS managers present at the 15th October meeting to investigate and respond to the clinicians about their concerns. It was not until the allegations were escalated to the Avon, Somerset and Wiltshire Cancer Services (ASWCS) Network in July 2008, by NBT's Clinical Lead for Patient Safety, who is also an Associate Medical Director, that senior managers acted.

4.11. Despite NHS Bristol knowing about clinicians' concerns since at least October 2007, they were not entered onto its risk register until March 2009, 17 months later.

4.12. The actions taken after July 2008 were ineffective, as evidenced by **Timeline C**, compiled by Deborah Lee, NHS Bristol's former Director of Commissioning, who was present at the October 2007 Joint Health Scrutiny Meeting in her temporary capacity as Acting Chief Executive of Bristol PCT (as NHS Bristol was formerly known). It was only exposure by Dr Hammond in June 2009 that prompted an official investigation.

4.13. As stated in 4.1, concerns about UHBristol's histopathology had been raised in writing in 2004. They were raised in public three years later in 2007, in the presence of Ms Lee. Yet there is no evidence that any action was taken to formally investigate the allegations and protect patient safety, pending the outcome of any formal investigation.

5. COMMENCEMENT OF THE INQUIRY

5.1. UHBristol instigated an Inquiry on 19th June 2009 following the publicising of the 15 misdiagnosis allegations. Its Medical Director, Dr Jonathan Sheffield publicly declared that there was no evidence to confirm a serious error rate. He said the review was necessary to reassure patients and the public.

http://www.uhbristol.nhs.uk/university-hospitals-bristol-nhs-foundation-trust-launch-independent-pathology-review-0

5.2. UHBristol appointed an Inquiry Panel and also commissioned an audit of 3,500 cases for one year, 2007, to establish whether there was a "significant error rate".

5.3. Initially, the Inquiry only included the 15 cases, which did not include the gynaecological allegations or the paediatric cases. It seems that UHBristol only included these cases subsequently, when prompted to do so by public exposure of the gynaecological and paediatric misdiagnosis allegations. Yet Dr Sheffield and other senior people in UHBristol were aware of the existence of these allegations long before they were exposed by Private Eye and the BBC.

5.4. Further evidence that indicates a reluctance to acknowledge the existence of the Gynaecological allegations and include them in the Inquiry is provided in **Timeline B,** 26th June 2009 entry:

"In your letter of 22 June 2009 to Jonathan Sheffield, you talk about gynaecological cases which were misdiagnosed and you ask for a review of these individual cases. I have been unable to establish what you refer to in this instance".

(Extract of letter from Ms Deborah Evans, Chief Executive, NHS Bristol, to Mrs Havercroft 26th June 2009)

5.5. A Freedom of Information response from NHS South West shows that on 22nd September 2008, Ms Evans was briefed by her Director of Commissioning, Deborah Lee about an email issued to ASWCS Director Mary Barnes dated 22nd July 2008 that included reference to gynaecological allegations.

Will the Inquiry Panel's report comment on Ms Evans' claim that she did not know what Gynaecological allegations were being referred to nine months after her Director of Commissioning briefed her about them?

5.6. Eventually UHBristol confirmed that 26 cases would be reviewed.

http://www.uhbristol.nhs.uk/histopathology-review-june-2009

5.7. Dr Hammond also reported allegations that UHBristol histopathologists had performed substandard work for the Bristol Coroner. This was not included in the Inquiry Terms of Reference, for reasons that have not been explained.

5.8. UHBristol and the Inquiry Panel ignored established problem solving methodology in their approach. Firstly define the problem, then solve it, then investigate the circumstances that led to the problem so that it is not repeated.

5.9. UHBristol and the Panel launched an investigation into the circumstances leading to a problem that they had not defined. The truth about the alleged misdiagnoses should have been independently and impartially established quickly and thoroughly. Only then should an independent inquiry panel been established.

6. CONDUCT OF THE INQUIRY - The Inquiry Panel

6.1. UHBristol commissioned what it referred to as an “Independent Review Group” chaired by a barrister, Miss Jane Mishcon. I refer to this group as “The Inquiry Panel” throughout the report.

http://www.uhbristol.nhs.uk/histopathology-review-june-2009

I regard the Panel's “independence” credentials as questionable for the following reasons:

6.1.1. It has never been made public how the Panel was selected and how the members' independence was tested.

6.1.2. The Panel was commissioned and paid for by UHBristol, the organisation under investigation. By contrast, the Oxford Paediatric Cardiac Inquiry, whose report was published in July 2010, was commissioned by the Strategic Health Authority, not the Trust under investigation.

6.1.3. The Oxford Inquiry Panel comprised a statistician and representatives from the Care Quality Commission. The Bristol Inquiry would have benefited from such membership, but had neither.

6.1.4. According to UHBristol's website, Mr Michael Summers is “Patient Representative” on the Panel. He is described as the Vice Chairman of the Patients' Association. However it appears that Mr Summers stepped down from this role early in 2010, before many of the inquiry witnesses gave evidence. UHBristol did not inform the public that Mr Summers has had no connection with the Patients Association for most of the inquiry period. It has never been made clear exactly what constituency of patients he represented.

6.1.5. The clinical representation on the Panel comprises a former President of the Royal College of Pathologists and an Oncologist. The Bristol medical professionals who believe errors have been made, and had to face affected patients and their families, are physicians and surgeons. Yet neither profession was represented on the Panel.

6.1.6. The Oxford Inquiry Panel included nurses. They are well placed to understand the psychological and emotional consequences for patients and their families of diagnostic errors. The Bristol Panel would have benefited from a nurse member, but the profession was not represented.

6.1.7. The Terms of Reference of the Inquiry were developed by UHBristol and the Panel,

without any external consultation with local patient and public stakeholders to ensure that they had confidence in them.

6.1.8. The conduct of Strategic Health Authority (SHA) NHS South West, the BNSSG Primary Care Trusts, particularly NHS Bristol, Lead Commissioner for UHBristol, and ASWCS (the Avon, Somerset and Wiltshire Cancer Services Network), in response to the allegations, is a matter of public interest, yet is not within the Inquiry's published terms of reference.

6.1.9. The Inquiry was conducted privately, witnesses gave evidence voluntarily and were not required to do so under oath. This raises concerns about bias in the conduct of the Inquiry as well as possible bias in the evidence of some witnesses.

6.1.10. It appears that the Panel and UHBristol decided not to inform the people (patients and/or families) who are the subject of the 24 allegations of misdiagnosis, the 2 confirmed misdiagnoses and the recent cases (see section 3.6) of the existence of the Inquiry, to enable them to give evidence. No effort appears to have been made to enlist the help of the media to publicise the inquiry to give patients and families the opportunity to give evidence to the Panel. And it appears that the "patient representative" on the Panel did nothing to ensure that patients and their families were informed of the Inquiry and invited to meet the Panel.

6.1.11. Despite Bristol being the centre of the damage to children that led to the Bristol Heart Inquiry in 2001, there appears to have been no attempt to externally audit the paediatric cases, which are additional to the 26 adult cases, and invite parents to give evidence to the Inquiry Panel. Therefore I draw the conclusion that UHBristol accepts that very serious errors were made in paediatric pathology, yet is not prepared to be held to account to families to explain why they occurred.

6.1.12. The official reason given for the lack of notification to patients and families appears to be "patient confidentiality". Readers of this report can judge for themselves whether this is a credible reason, or whether avoidance of possible litigation is more plausible.

"We will enable patients to rate services and clinical departments according to the quality of care they received, and we will require hospitals to be open about mistakes and always tell patients if something has gone wrong" (*White Paper – Equity and Excellence – Liberating the NHS July 2010*)

6.1.13. "Miss Jane Mishcon: How much consideration have you and patients had to the fact that – something that struck us right at the beginning, forgive me, because I can't remember if we have talked about this with you before – that no concerns have been raised by any clinicians at UHBT or any of the surrounding Trusts that actually use the pathology services at the BRI."

(Extract from transcript of Histopathology Inquiry Panel interview with Mrs Havercroft 3rd June 2010)

6.1.14. Mr Richard Spicer, a former Paediatric Consultant of UHBristol raised concerns about his Trust's Histopathology Services during the period 2001 to 2008, after which he retired. His account of events is described in **Timeline A**. It shows that he was not the only UHBristol clinician to raise concerns. Mr Spicer gave evidence to the Inquiry Panel in January 2010. Yet six months later, Miss Mischon informed me that no concerns had been raised by clinicians at UHBT (now known as UHBristol).

6.1.15. There is further evidence in other sections of this report that casts doubt on the

Inquiry Panel's independence of UHBristol.

7. CONDUCT OF THE INQUIRY – AUDIT OF 3,500 CASES

7.1. UHBristol commissioned Source Biosciences to conduct an audit of 3,500 random cases from just one year, 2007. Concerns have been expressed in the media and by the public as to the apparent conflict of interest because the company has a contract with UHBristol to perform Her2 testing for breast cancer. These concerns have not received a satisfactory response from UHBristol or the Inquiry Panel.

7.2. "Mrs Havercroft - What are your thoughts on the question of the audit of the pathology samples and the 3,500 size?

Miss Jane Mishcon: I think it is difficult for us to express a view on that, only because it something that we're not party to, even though we have to deal with it"

(*Extract from transcript of Mrs Havercroft's interview with the Panel 26th November 2009*)

The Panel claimed to be independent of UHBristol, yet did not assure itself of the validity of the audit methodology **before** the Trust spent public money on it. The exact cost of the audit is unknown. It is included in "other" inquiry costs of £309,506 to the end of June 2010.

7.3. The 3,500 audit was commissioned by UHBristol in response to, in its words "allegations that there was a high error rate in the Bristol Histopathology Department". In fact the allegation was that some serious errors had been made that had harmed NBT patients in the areas of breast, skin, lung and gynaecological histopathology.

7.4. The 3,500 audit included GP specimens and large histopathology specialisms for which no concerns had been expressed, causing concern that the audit was designed to mask the true extent of errors in the areas of concern. I raised these concerns with the Panel in November 2009, but it allowed the audit to continue. This seems strange conduct by a Panel that claims to be independent of UHBristol.

7.5. Concerns were publicly raised as to why the 3,500 audit was performed for only one year, 2007, when alleged cases of misdiagnosis covered the period 2000 to 2010. The reason given by UHBristol was that 2007 was the **"most recent year prior to concerns being formalised by the North Bristol NHS Trust Medical Director, but was before the process changes in respiratory pathology agreed between the Trusts in August 2008**"

7.6. Since concerns had been expressed in a 2004 letter copied to NBT Medical Director, Dr Martin Morse and UHBristol Medical Director, Jonathan Sheffield, it is extraordinary that it took the pair four years to formalise the concerns between the Trusts. During that time and subsequently, it appears no action was taken to protect patients from any possible misdiagnoses.

Will the Inquiry Panel report on this apparent lack of concern by Trust Medical Directors to prioritise patient safety?

7.7. The process for reporting respiratory pathology between the Trusts did not change in 2008. The agreement that all NBT patients' respiratory pathology would be reported at NBT and not UHBristol was never implemented. Therefore in my opinion, the public has been misled because the main reason for choosing 2007 for the random audit collapses under scrutiny.

7.8. Although the agreement to change the process was made between Dr Jonathan Sheffield of UHBristol and Dr Martin Morse of NBT, Dr Morse's successor, Dr Chris Burton was in post when

UHBristol decided to proceed with an audit for 2007 only, on the basis of an agreement that had never been implemented. It appears that Dr Burton did not support the concerns of his own NBT clinicians and went along with this flawed methodology.

Will the Inquiry Panel's report comment on the validity of UHBristol choosing 2007 on the basis of misleading information presented to the public, the extent to which this was supported by by NBT's Chief Executive and Medical Director and the basis on which they supported it?

7.9. The fact that Dr Sheffield and Dr Morse had agreed to allow NBT report its own patients' respiratory pathology indicates tacit agreement between them that UHBristol's lung pathology reporting was not reliable. Yet the implications for the safety of UHBristol's own lung patients seem not to have concerned either of them, or Dr Morse's successor, Dr Burton.

Do they concern the Inquiry Panel?

7.10. UHBristol called the 3,500 audit a "random" audit. However, it stopped being "random" when the results did not suit the Trust:

"Sequentially, every fourth case was selected for the audit. During sampling an imbalance was discovered, with more selected specimens from one pathologist. Their specimens were therefore omitted from later stages of sampling, and sequential sampling continued until all pathologists had contributed approximately 550 cases to the audit. This sampling procedure ensures that the selected sample of specimens for review is representative of practice during 2007.

This assumes that, during 2007, each histopathologist reported the same number of cases, which is difficult to believe.

Will the Inquiry Panel comment on UHBristol changing the rules of its own audit part way through the process?

7.11. The goal of the 3,500 audit was to prove that the UHBristol's Histopathology Department had an error rate of no greater than 1-2%, on the basis of some unspecified literature that indicated a 1-2% error rate is usual. A note in the document describing the audit methodology says **"Liam Donaldson** (the former Chief Medical Officer of England) **says 1% of people suffer harm from medics so standard is 1%".**

7.12. The issue is not whether UHBristol's Histopathology Department had an error rate greater than 2% for 2007, but whether serious, avoidable misdiagnoses occurred in specialist areas during the period 2000 to the present that seriously harmed or had the potential to seriously harm patients.

7.13. The case of James Elwood demonstrates the danger of fixating on a perceived "normal" percentage. It can mask serious damage caused to patients.

http://cdnedge.bbc.co.uk/1/hi/health/788250.stm

Dr Elwood's error rate was close to what is claimed to be an expected error rate, yet he removed himself from the GMC register and it was accepted by the NHS that he had seriously harmed some patients.

Will the Inquiry Panel's report comment on why UHBristol spent public money on an audit that was not fit for the purpose of ascertaining whether serious and avoidable errors have been made in the reporting of breast, lung, skin and gynaecological histopathology?

8. CONDUCT OF THE INQUIRY – THE 26 CASES

8.1. As noted in 5.3, the Inquiry was originally set up to investigate only the 15 cases in the 2007 letter to Dr Martin Morse. It seems likely that, despite some UHBristol Board Members being fully aware of gynaecological and paediatric allegations, they would not have been included in the Inquiry unless they had been exposed in Private Eye.

8.2. The paediatric cases are not included in the 26 cases. No reason has been given.

Will the Inquiry Panel's report offer an explanation?

8.3. The 26 cases were identified by NBT from correspondence. It is not clear why NBT did not simply ask the clinicians who raised the concerns to identify the cases.

Is it clear to the Inquiry Panel and will it share that information in its report?

8.4. The audit of the 26 cases was conducted by Source Biosciences, concerns about a potential conflict of interest having been mentioned in 7.1.

8.5. It seems that the clinicians who raised concerns were excluded by NBT's current Medical Director, Dr Chris Burton, and UHBristol's former Medical Director, Dr Jonathan Sheffield, from participation in validating the cases for review and confirming that all the slides and reports sent for audit to Source Biosciences were complete.

In June 2010, the Inquiry Panel appeared disinterested when made aware of public concerns about the conduct of the review of the 26 cases. Will its report show a similar lack of interest?

8.6. In a joint response to a Freedom of Information Request, Drs Burton and Sheffield said that many of the 26 cases had already had an external review of the histopathology as part of the usual process for resolving cases where there is a difference of local opinion.

8.7. It has never been made clear why the two Medical Directors felt that public money should be spent on a further external review and why they regarded the cases as unresolved when they had already been through a review process specifically to resolve differences of opinion.

8.8. The slides sent to Source Biosciences were extracted by UHBristol staff without independent, external review of the process to ensure that all the slides and reports relevant to each case were sent to the reviewers.

8.9. As noted in 6.1.10, none of the patients and families whose cases are part of the Inquiry were informed about it. Although two families became aware when contacted by the Sunday Telegraph.

http://www.telegraph.co.uk/health/healthnews/7575095/Inquiry-into-fears-of-botched-cancer-diagnoses.html

http://www.telegraph.co.uk/health/healthnews/7969543/Hospital-at-centre-of-cancer-misdiagnosis-scandals-makes-secret-payouts-to-patients.html

An Independent Inquiry Panel would have raised similar concerns to the ones above about management of the audit of the 26 cases. Will the Inquiry Panel express concerns in its report?

9. CONDUCT OF THE INQUIRY - VERITA

9.1. Management of the Inquiry was performed by UHBristol's legal department until early 2010 when Verita, a company that performs investigations, was appointed.

9.2. Verita has conducted some high profile public sector investigations, including the Baby P and Michael Stone cases, and would, on the face of it, seem to have been a logical choice to manage the Bristol Inquiry. However, there are some matters of public interest and concern in relation to Verita's independence and possible conflicts of interest that have not been addressed:

9.2.1. As noted in 6.1.8, the Terms of Reference of the Inquiry do not include the response of the Strategic Health Authority, NHS South West, to the allegations of misdiagnosis, yet this is a matter or public interest.

9.2.2. Verita supplies services to investigate Mental Health Homicides for NHS South West. Exceptionally Verita has been awarded this work under a single tender arrangement.

9.2.3. During 2010, Verita was appointed, under a single tender contract, by the Department of Health, to conduct an Inquiry ordered by the Secretary of State for Health into the circumstances leading to the dismissal of John Watkinson, former Chief Executive of the Royal Cornwall Hospitals Trust, with particular focus on the part played by the Strategic Health Authority and its Chief Executive, Sir Ian Carruthers, OBE.

9.2.4. Verita, the Department of Health and the Strategic Health Authority did not publicly declare Verita's existing commercial relationship, under a single tender arrangement, with the SHA whose conduct it investigated in relation to the John Watkinson dismissal. The Department of Health's Procurement Policy states that single tender procurement should only be used in exceptional circumstances.

9.2.5. UHBristol procured Verita's services to manage the Bristol Histopathology Inquiry, also under a single tender process. The Trust's Standing Financial Instructions say that ordering above £25,000 without competitive tendering is forbidden unless the budget holder believes there is an exceptional case for doing so. The cost to the Trust of Verita's services for the period January 2010 to 30th June 2010 was £113,500, averaging over £18,000 per month.

9.2.6. Is Verita the only company in the UK that is capable of conducting public sector inquiries?

Will the Inquiry Panel's report explain why UHBristol did not go out to tender to procure services to manage its Histopathology Inquiry?

9.3. Miss Jane Mishcon, Chair of the Histopathology Inquiry, is a junior at Hailsham Chambers. Hailsham and Verita collaborated on a seminar in March 2010 on NHS Investigations. The slide set is available here:

http://www.hailshamchambers.com/events-content/investigations--reviews-and-inquiries-in-the-nhs--walking-the-tightrope---a-seminar-by-hailsham-chambers-and-verita.asp

It includes a section called “Saving Time, Money and Reputations” The presentation says nothing about protecting patient safety. The word “patient” is not mentioned at all.

9.4. According to its e-newsletter dated May 2010, Verita claims to have played a crucial role in one of the inquiries into failings in patient care at Mid Staffordshire NHS Foundation Trust. It says that it contacted patient and user groups to encourage them to take part, and supported witnesses.

Verita appears to have taken no action to prompt the Panel and UHBristol to contact patient and user groups to encourage them to contribute to the Bristol Histopathology Inquiry.

10. CONDUCT AND CULTURE OF NHS ORGANISATIONS IN THE SOUTH WEST

10.1. **Timelines A, B** and **C** provide a clear picture of the timeliness and adequacy of the actions taken by NHS South West, NHS Bristol, and ASWCS, as well as NBT and UHBristol.

The timelines show what happened. The Inquiry Panel's report ought to tell us what should have happened. We wait to see whether it does.

10.2. As noted in point 4.8 and **Timeline B**, NHS Bristol was aware of clinicians' concerns at least since October 2007. Therefore why did it not act upon them?

10.3. The histopathology allegations emerged when pathologists in one Trust saw some reports of pathologists in another Trust and did not like what they saw. Therefore why did the SHA, ASWCS and NHS Bristol not ensure that consistent, safe and high quality standards of pathology reporting were implemented by UHBristol and NBT before centralising clinical services?

Has the Inquiry Panel asked this question and will it provide the answer in its report?

10.4. Even when the concerns were raised in public in October 2007, NHS Bristol, NHS South West, ASWCS, NBT and UHBristol carried on trying to centralise services without stopping, getting pathology support right and then resuming. It seems that, in the haste to reconfigure services to meet reconfiguration target dates, pathology was trampled underfoot.

10.5. NHS Bath & North East Somerset (BaNES), supported by ASWCS and NHS Bristol, commenced a review of Gynaecological Cancer Services in September 2008. Their intention was to centralise Bristol and Bath's Gynaecological Cancer Surgery at either the Royal United Hospital, Bath, or St Michael's Hospital, Bristol. Patient and Public members of the review were not told about the Gynaecological misdiagnosis allegations against UHBristol, despite UH Bristol, ASWCS and NHS Bristol knowing about them. They were expected to participate in making a decision as to whether St Michael's or the Royal United Hospital was the preferred location for centralisation, despite the NHS withholding information material to the decision making process.

Does the Inquiry Panel believe this conduct towards patients and the public was acceptable?

10.6. Provider Trusts have an AIMS (Adverse Incident Management System) form for the registration and investigation of adverse incidents. It is a matter of public interest to know whether AIMS forms were raised by UHBristol for the paediatric cases and UHBristol and NBT for the 24 cases of alleged misdiagnosis, the 2 cases of confirmed misdiagnosis and the 3 most recent cases (see 3.6).

We wait to see whether the Inquiry Panel investigated and reported on this.

10.7. NHS organisations have processes for raising Serious Untoward Incidents (SUIs). They are registered on a system called STEIS (Strategic Executive Information System) and monitored to closure by Primary Care Trusts and Strategic Health Authorities. It is a matter of public interest to know whether SUIs were raised for the 26 cases of alleged misdiagnosis, the paediatric cases and the 3 most recent cases (see 3.6).

We wait to see whether the Inquiry Panel has investigated and reported on this.

10.8. NHS Bristol, as Lead Commissioner for UHBristol and responsible for commissioning safe, high quality services on behalf of the local community, knew about clinicans' concerns since at least 2007, yet **Timelines B** and **C** show that was unwilling and/or unable to hold UHBristol and NBT to account to agree to investigate the allegations, four years after after they were raised by NBT clinicians.

The Inquiry Panel is aware of the timelines. We await its comments on the contents.

10.9. The slide set presented in the Verita/Hailsham Chambers Seminar, referred to in section 9.3, says that the Commissioners should set the scope of the investigation and draft clear terms of reference for inquiries. Inappropriately, NHS Bristol left it to UHBristol to do this. However, it would have been equally inappropriate for NHS Bristol to set the scope and terms of reference due to the questions about the adequacy of its performance in commissioning safe histopathology services and its response when it became aware of concerns.

We look forward to seeing the Inquiry Panel's opinion as to why the NHS Foundation Trust, the subject of the allegations, seems to have had excessive freedom to set its own Terms of Reference and control the case audits.

10.10. Information that has emerged during a review of pathology services instigated in June 2010 by BNSSG shows that **"In commissioning the Review of Pathology Services it was recognised that the information held for commissioning and monitoring performance and quality of pathology services was inadequate."** (*NHS North Somerset Freedom of Information Response September 2010*)
and:

"There is little or no pathology commissioning expertise in PCTs due to;

- **the 'bundled' nature of pathology as a support service to specialty level commissioning. As such there has never been a perceived need to understand pathology.**

- **the lack of national performance management standards requiring commissioners to have a focus on pathology, in the same way as radiology and endoscopy have historically had."**

(NHS South Gloucestershire Pathology Commissioning Paper, November 2010)

Will the Panel report on the inadequate monitoring of pathology performance and quality by BNSSG and whether it regards that as a contributing to Bristol's Pathology Problems?

10.11. In a letter dated 30th July 2010, NHS South West informed me that **"Information on the current quality and safety baseline of pathology services is not held at regional level though NHS organisations responsible for commissioning and providing pathology services should hold such information"**

10.12. NHS South West has informed me that Primary Care Trusts are accountable for the commissioning and delivery of services within their locality and that it is the role of the Strategic Health Authorities to hold Primary Care Trusts to account.

10.13. As the organisation to whom the BNSSG PCTs are accountable for commissioning, NHS South West must be gravely disappointed that they have admitted they have little or no pathology

commissioning expertise and have not perceived that they need to understand pathology.

Will the Inquiry Panel comment on the failure of BNSSG to meet the expectations of the SHA in respect of accountability for holding current quality and safety baseline information for commissioning pathology services?

Will the Inquiry Panel comment on why the SHA appears not to have tested its assumption that BNSSG should collect and hold data to enable it to commission safe, high quality pathology services?

10.14. The Royal College of Pathologists says that **" 70-80% of all healthcare decisions affecting diagnosis and treatment involve pathology."** Therefore it is extraordinary that BNSSG PCTs believed they had no need to understand pathology and develop the expertise to ensure that they commissioned safe, high quality services. I wonder if this state of affairs is replicated around the country, or whether it is unique to BNSSG and NHS South West?

Will the Inquiry Panel comment on this?

10.15. BNSSG also says that "Pathology services are subject to regular CPA (Clinical Pathology Accreditation) inspections and this information is used to inform service improvements within the provider organisations". This is true, but diagnostic accuracy is not within the scope of CPA.

10.16. NHS Bristol, as Lead PCT for Commissioning UHBristol services has, by the NHS's own admission, no pathology commissioning expertise and inadequate information to monitor performance and quality of Pathology services. NHS Bristol has known of clinicians' concerns about UHBristol's histopathology since at least October 2007. As NHS Bristol had no data with which to assess UHBristol's pathology performance and quickly decide whether patient safety was being compromised, it seems negligent of it to have taken no action in 2007 to establish whether the clinicians' concerns were justified.

The Inquiry Panel should have investigated why NHS Bristol took no effective action. We wait to see whether it has done so.

10.17. Warning signs of inconsistencies in the Avon, Somerset and Wiltshire Cancer Services (ASWCS) Network were there for the Network Board and BNSSG to see in the The National Cancer Peer Review Report for 2006, which said this of said this of the ASWCS Network Pathology Group:

"there are tensions within the group, and little agreement around the future centralisation and development of pathology services within the Network".

"Diagnostic reviews in which there is a significant change in diagnosis are not being appropriately discussed with the primary reporting consultant (despite the agreed Network protocol)"

"There is underutilisation of expert diagnostic resources within the Network (e.g. cardiothoracic, Gynaecology)."

10.18. The National Cancer Peer Review Report also contained this warning about UBHT's (now UHBristol) Cancer Pathology Services:

"Overall, there is no evidence of a clear vision for the development of Cancer Services within this locality. The UBHT Cancer steering group needs to provide a strong voice and vision for cancer services within the Trust/locality, supported by stronger engagement and support from commissioners."

“There appeared to be poor preparation for the peer review process, both in respect to documented evidence and the arrangements for the review visit.”

“The histopathology department is supporting a large and expanding number of cancer MDTS.”

“Effective planning and commissioning of pathology services within Bristol are key to the future of this service. The review team were concerned that, currently, the department does not hold CPA accreditation”

“Concerns
• No CPA accreditation. Investment in staff and facilities to achieve this is essential.
• Planning blight whilst awaiting future direction of Bristol acute healthcare and its effects on Pathology services.”

It seems these warnings were ignored and cancer services were reconfigured in Bristol without resolution of the concerns raised by the National Cancer Peer Review Team. Will the Inquiry Panel comment on this?

10.19. In June 2008, UHBristol's Chair, Dr John Savage, was copied on a letter exposing the gynaecological allegations and allegations of substandard work performed for the Coroner by pathologists employed by UHBristol. As a non-executive Board member, Dr Savage is responsible for ensuring the Board acts in the best interests of the public and is fully accountable to it. Yet there appears to be no evidence that he took any action to do this on receipt of the letter.

10.20. UHBristol achieved Foundation Trust status on 1st June 2008, shortly before its Chair, Dr John Savage, received the letter concerning the allegations. He did not inform Monitor, the Foundation Trust regulator of the allegations until 1st June 2009, in a routine telephone conversation, nine days before Dr Hammond exposed the allegations in Private Eye.

Will the Inquiry Panel report on whether the actions of UHBristol's Chair were timely and appropriate when he became aware of the allegations of misdiagnosis?

10.21. NHS Bristol, NHS South Gloucestershire and NHS North Somerset (comprising BNSSG), NHS South West, UHBristol and NBT all have this standing agenda item for their Board Meetings:

“Resolution. That representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest (section (2) Public Bodies (Admission to Meetings) Act 1960)”

I surmise that the contents of these confidential minutes, kept secret from the public, contain information about how the above organisations, individually and collectively decided to deal with the histopathology allegations. Whether this information is consistent with the information provided to the public is a matter of public interest and is certainly not prejudicial to it. Rather, it is prejudical to the public interest not to know what was discussed in these closed sessions in respect of the histopathology allegations.

Will the Inquiry Panel's report comment on whether significant matters of public interest are hidden in secret NHS Board Meeting Minutes?

11. ACTIONS OF DOCTORS

11.1. In the years since Professor Stephen Bolsin exposed the concerns that led to the BRI Heart Inquiry, it has not become any easier for clinicians to speak out about serious concerns of patient safety. However, some Bristol clinicians have been brave enough to raise concerns through proper channels and give evidence to the Inquiry Panel. Patients and the public should be grateful that they are prepared to protect patients by doing so. They are in the good company of Professor Bolsin, a champion of patient safety.

Will the Inquiry Panel's report recognise the important contribution to patient safety and pathology quality made by those who had the courage to speak out about their concerns?

11.2. Unfortunately we do not know how many doctors have concerns about UHBristol's histopathology and have remained silent about them.

11.3. According to the BBC, Dr Gabriel Scally currently Director of Public Health for NHS South West commented on the James Elwood case (7.13) that **"It does raise a number of serious questions about doctors' responsibilities when concerns are raised about their work."**

11.4. Among the duties of a doctor registered with the General Medical Council (GMC) are:

"Make the care of your patient your first concern."

"Be honest and open and act with integrity."

"Act without delay if you have good reason to believe that you or colleague may be putting patients at risk."

11.5. The GMC duties of Doctors in management positions, such as Medical Directors are contained in the GMC Document "Management for Doctors – Guidance for Doctors"

http://www.gmc-uk.org/guidance/ethical_guidance/management_for_doctors.asp

The following guidance is particularly relevant to the events leading to the Bristol Histopathology Inquiry:

"You continue to have a duty of care for the safety and well being of patients when you work as a manager"

" It is crucial that clinical performance is managed at the local level. This is an essential feature of a GMC-approved working environment. You must make sure that effective systems are in place to give early warning of any failure, or potential failure, in clinical performance, and that such failures are addressed quickly and effectively".

"You should make sure that adequate systems are in place for investigating complaints promptly, fairly and thoroughly and that all staff, regardless of grade or seniority, are aware of reporting and complaints procedures and can seek advice, report an incident or make a complaint when necessary".

"**Management involves making judgements about competing demands on available resources. If managerial concerns conflict with your primary duty to the extent that you are concerned for the safety or well-being of your patients, you should declare the conflict, seek colleagues' advice, and raise your concerns formally with senior management and external professional bodies as appropriate".**

"Concerns about patient safety or the conduct, health or performance of staff can come from a number of sources, such as patients' complaints, colleagues' concerns, critical incident reports and clinical audit. If you receive such information you have a duty to act on it promptly and professionally. You can do this by investigating and resolving concerns locally or by referring serious or repeated incidents or complaints to senior management or regulatory authorities".

If you are responsible for investigating incidents or complaints you should make sure that:

- **appropriate adverse event and critical incident reports are made within the organisation and to other bodies, such as the National Patient Safety Agency**
- **you have a working knowledge of the relevant law and procedures under which investigations and related proceedings are conducted**
- **patients who make a complaint receive a prompt, open, constructive and honest response**
- **clinical staff understand their duty to be open and honest about such events with both patients and managers**
- **all other staff are encouraged to raise genuine concerns they have about the safety of patients, including any risks that may be posed by colleagues**
- **staff members who raise concerns are protected from unwarranted criticism or actions**
- **systems are in place to ensure that incidents, concerns and complaints are investigated promptly and fully**
- **the person or people being investigated are treated fairly**
- **patients who suffer harm receive an explanation and, where appropriate, an apology**
- **recommendations that arise from investigations are implemented or referred to senior management"**

Has the Inquiry Panel investigated whether the responses of doctors whose work was the subject of concerns were appropriate and put patient safety first, in accordance with their duties as doctors registered with the GMC?

Has the Inquiry Panel investigated whether the conduct of former UHBristol Chief Executive Dr Graham Rich, former UHBristol Medical Director Dr Jonathan Sheffield, former NBT Medical Director Dr Martin Morse and current NBT Medical Director, Dr Chris Burton, has met the standards required by the GMC?

12. ROLE OF MDTs (Multidisciplinary Teams)

12.1. UHBristol has countered claims that diagnostic errors have been made by some of its histopathologists by claiming that diagnoses are made at MDT (Multidisciplinary Team) Meetings.

12.2. It is clear from the Royal College of Pathologists' Document "Quality Assurance in

Histopathology and Cytopathology Reporting Practice February 2009" that sometimes a diagnosis may be refined or amended at MDT meetings. However the expectation set by the following statements is that histopathology diagnoses are made before MDT meetings and presented to the team for discussion. There should be protocols in place, and followed, that enable pathologists to review and discuss differences of opinion before MDT meetings.

http://www.rcpath.org/resources/pdf/g082_qahistoreporting_feb09.pdf

12.2.1 **"**Informal case discussions with colleagues within a department. This is often useful to confirm or explore difficult differential diagnoses. Departments should encourage individuals to have a low threshold for engagement in this practice to ensure constructive dialogue ***and to avoid the exposure of any difference of opinion at later stages in the diagnostic pathway"***

12.2.2 "All pathologists should be aware of the limits of their expertise and should be encouraged (and not inhibited) by local, Network and national policies to ensure that their diagnostic reports are as complete and accurate as possible, guiding patient care in an optimal fashion"

12.2.3 "Pathologists should be encouraged to record the involvement of colleagues (with their agreement) in the production of a diagnostic report".

12.2.4 "At all stages, it must be absolutely clear who is taking responsibility for the content and accuracy of the report and for communicating the report to clinicians. This is indicated by the report signatory in whose name the report is electronically authorised. If a range of opinions is expressed in the report, either a clear conclusion should be offered or the process whereby a conclusion could be reached should be described"

12.2.5 When diagnostic reports are produced for NHS Trusts by external organisations such as Source Biosciences, who takes responsibility for the content and accuracy of the report and the presentation of it at MDT meetings, since Source Biosciences histopathologists do not attend?

Has the Inquiry Panel asked this question?

12.2.6 "Pathologists should work with service provider organisations, Cancer Networks and service commissioners to ensure that the agreed quality assurance processes are appropriately resourced as part of clinical care pathways".

12.3. The Royal College of Pathologist's document "The Role of the Lead Pathologist in the Multidisciplinary Team Meeting" says:

"Where pathology reporting standards are agreed across a Cancer Network, usually through the relevant NSSG (Network Site Specific Group - example Gynaecological NSSG), **the lead pathologist should take responsibility for implementing these standards. In order to facilitate this, the lead pathologist should either attend NSSG meetings or have direct communication with the pathologist(s) who does attend the meetings"**

12.3.1 One of the Inquiry Panel's members is a Professor of Pathology. Therefore its report should show whether it has investigated to what extent these Royal College of Pathologists Guidelines have been followed by the Avon, Somerset and Wiltshire Cancer Services Network and the BNSSG Commissioners, who sit on the Cancer Network's Board.

12.3.2 The guidance says that Cancer Peer Review Standards require "that each MDT should agree standards for pathology reporting, without specifying how this should be

achieved. The lead pathologist is clearly best placed to agree these standards with their clinical colleagues."

The Inquiry Panel should have investigated with MDT clinical leads and lead pathologists whether agreed standards were in place for reporting and whether the standards have been implemented and followed. We wait to see whether it has done so.

The Inquiry Panel should have investigated what MDT Leads knew about the pathology misdiagnosis allegations and what they did to try to resolve them. Its report will show whether it has.

12.4. In March 2010, Bristol's Gynaecological Cancer MDT Lead appeared before South Gloucestershire and Bristol Health Scrutiny Committees to speak in support of transferring Gynaecological Cancer Surgery from Bath to UHBristol's St Michael's Hospital, despite the allegations of misdiagnoses against UHBristol's Gynaecological Histopathology Service.

12.5. He told the Health Scrutiny Committees that the external review of cases had concurred with his pathologist's findings. This was three months before Miss Jane Mishcon informed me that "we don't know the results of the independent review".

When I raised concerns about this conduct with Miss Mishcon, because it seemed to me to compromise the integrity of the Inquiry, she did not reply and, when pressed for a response, appeared unconcerned, regarding it as a matter for UHBristol.

13. ACTIONS OF REGULATORS

13.1. The Care Quality Commission (CQC) was informed of the allegations of misdiagnosis on 9th June 2009 by Deborah Evans, Chief Executive of NHS Bristol.

13.2. The CQC decided not to conduct its own inquiry pending the outcome of the UHBristol Histopathology Inquiry.

13.3. Monitor, the Foundation Trust Regulator was informed of the allegations by Dr John Savage, Chair of the Board, UHBristol, in a routine telephone conversation on 1st June 2009.

13.4. I have made both CQC and Monitor aware of allegations that have been made since the Inquiry Panel convened (section 3.6). I have seen no evidence that either regulator has taken action to protect patients, despite UHBristol apparently accepting that errors were made as it has not refuted them.

14. ACTIONS OF THE ROYAL COLLEGE OF PATHOLOGISTS (RCPath)

14.1. RCPath was quoted as follows in the Bristol Evening Post 20th June 2009:

"A spokeswoman for the Royal College of Pathologists said: "Experience has demonstrated that allegations of poor performance can arise for many reasons, sometimes including personal conflicts between individuals"

"Histopathology reports represent professional opinions, not measurements, and we have occasionally seen cases where genuine and understandable differences of opinion on difficult cases have been misrepresented as 'errors'."

14.2. It seems inappropriate and unhelpful for RCPath to have publicly speculated on the UHBristol problems. A thorough, independent, external investigation was required to identify the exact problem, not speculation.

14.3. UHBristol's website says that it and NBT had been working together since since 2008 to establish the basis for a joint review into Histopathology services by the Royal College of Pathologists. Therefore it is clear that RCPath must have known about the concerns since at least 2008.

14.4. RCPath is not a regulator. It has charitable status. Its Public Benefit statement says:

"The College's mission is to promote excellence in the practice of pathology and to be responsible for maintaining standards through training, assessments, examinations and professional development, to the benefit of the public."

14.5. RCPath has guidance for Healthcare Organisations on dealing with concerns about performance in pathology.

http://www.rcpath.org/resources/pdf/concernsreperformanceinpathologyfeb06.pdf

It can carry out a review if invited to do so by Healthcare Organisations.

14.6. Given RCPath's stated commitment to patient benefits and the fact that the majority of its members are doctors, and therefore subject to GMC guidelines and duties, it seems strange that it appeared unable to influence the UHBristol and NBT Medical Directors to order a formal review of the serious concerns.

One of the Inquiry Panel members, Professor Sir James Underwood, was President of RCPath from 2002-2005. We wait to see what the Inquiry Panel says about the adequacy of the communication between RCPath, UHBristol and NBT to investigate and resolve the misdiagnosis concerns in the interests of patients.

15. ACTIONS OF THE GMC

15.1. The GMC has been provided with documentation relevant to the Inquiry, including copies of **Timelines A, B** and **C.**

15.2. So far the GMC has been publicly silent as to whether its members involved in the events surrounding the Inquiry have fulfilled their GMC duties of making the care of patients their first concern, by acting without delay to investigate concerns that patients may have been put at risk.

16. BNSSG REVIEW OF PATHOLOGY SERVICES

16.1. It is clear that a review of BNSSG commissioned Histopathology Services is required to ensure safe, high quality service for the clinicians and patients who use them.

16.2. The Healthy Futures Programme Board instigated a review of all Pathology Services, including histopathology, in June 2010, to implement the recommendations of the Carter Review of Pathology.

http://www.pathologists.org.uk/publications-page/Carter%20Report-The%20Report.pdf

http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Healthcare/Pathology/DH_075531

16.3. The Healthy Futures Programme Board's approach to local patient and public involvement has been controversial because it excluded local people from involvement in developing the process for local patient and public involvement. Six months after the Review was instigated, it has emerged that seventeen local groups that may have an interest in the Review have not been contacted.

16.4. The Review has also been controversial because some lay people regard timescales set for agreeing the configuration of pathology, including histopathology services, as unrealistic. The original target date was October 2010, then December 2010 and is now February 2011. This is still regarded as unrealistic by some, due to the fact that there is much work to do to develop a safe, high quality service that will deliver measurable benefits to local people.

16.5. As the Inquiry Panel's report is not yet published, February 2011 does not give enough time for local people to review the report to decide whether they regard the conduct of the Inquiry as satisfactory and comment on the extent to which the outcome of the report and its recommendations should be taken into consideration in the Pathology Review.

16.6. The Healthy Futures Programme Board is led by NHS Bristol and chaired by its Chief Executive, Deborah Evans (see Sections 5.4 and 5.5). This report exposes the PCT's role in the events that led to an Inquiry that should not have been necessary if the concerns had been properly investigated by senior managers when they first became aware of them. Therefore some BNSSG residents are not surprised that the Healthy Futures Programme Board seems overly keen to try to put the past behind it and expedite integration of UHBristol and NBT's histopathology services within an unrealistic timescale.

16.7. The Healthy Futures Programme Board does not appear to have learned lessons from the past in its haste to reconfigure Bristol's histopathology services. Reconfiguring clinical services without understanding the safety and quality of the pathology services that supported them led directly to the allegations of misdiagnosis because BNSSG did not ensure that all laboratories were working to the same consistent standards of quality and safety.

16.8. The Healthy Futures Programme Board seems set to repeat the mistakes of the past by rushing to integrate and centralise pathology services without understanding the current quality and safety service baselines for UHBristol and NBT. It had an opportunity to obtain this information when concerns were first raised, by engaging the Royal College of Pathologists to help to establish the performance of Bristol's histopathology services. It ignored this opportunity.

16.9. The conduct of the UHBristol 3,500 case audit for just 2007 will have provided no information on the quality of all Bristol's breast, lung, skin and gynaecological histopathology, nor any other specialisms.

16.10. The review of the 24 specific cases of alleged misdiagnosis and the 2 cases that UHBristol confirmed as misdiagnoses will not provide any information on the quality of the whole Bristol histopathology service in respect of breast, lung, skin and gynaecological histopathology, nor any other specialisms, because these are only cases where NBT clinicians identified concerns with UHBristol's histopathology reporting for NBT patients.

16.11. Local people with an interest in Pathology Services are committed to work with the Healthy Futures Programme Board to help to achieve a sustainable, safe, high quality histopathology service. However the Board should not dismiss or underestimate the serious damage that has been done to public trust in its member organisations and leaders by their handling of the events leading to the Histopathology Inquiry.

16.12. In a recent paper concerning changes to its own histopathology services, NBT has commented that It has been very difficult to recruit locums or indeed permanent consultants to Cellular Pathology in Bristol. This is consistent with a comment made at a meeting in August 2010 by UHBristol's former Head of Histopathology that **"there are currently a number of staff vacancies which are causing problems."**

16.13. By December 2010, at least three consultant histopathologists will have left Bristol, one from UHBristol and two from NBT. This attrition and the vacancy problems in Bristol's adult histopathology departments echo the difficulties described in Mr Richard Spicer's **Timeline A** whereby paediatric pathologists steered clear of Bristol due to the lack of management support and other issues.

Will the Inquiry Panel's report comment on why histopathology consultants are leaving and have left Bristol, why it is having difficulty filling histopathology vacancies and whether adult histopathology is set to follow a similar collapse to that of paediatric pathology, as described in Timeline A ?

16.14. The Healthy Futures Programme Board is advised to acknowledge that the conduct and outcome of the Inquiry may be regarded as unsatisfactory by the public, partly due to the restrictions on the Inquiry Panel's terms of reference. Also key witnesses may have withheld important information because they chose not to give evidence.

16.15. Any defensive and disrespectful behaviour by the Healthy Futures Programme Board towards any members of the public who may have issues with the outcome of the Inquiry, paid for by public money, will not help to achieve what everyone wants: - a safe, high quality, sustainable histopathology service for Bristol, North Somerset and South Gloucestershire. This is only possible if first class consultant histopathologists want to work here and are supported by Managers and Medical Directors.

"the arguments will be lost if the story is focussed on personalities and not the issues"
(Bristol Royal Infirmary Inquiry 2001)

17. CONCLUSIONS

17.1. The people of Bristol, North Somerset and South Gloucestershire have not forgotten the Bristol Heart Scandal and the courage of Professor Stephen Bolsin in exposing harm to patients. As a result of his actions to raise the profile of patient safety in the United Kingdom, he was unable to obtain work in the UK and now has a successful career in Australia.

"My earnest hope is that the Bristol Royal Infirmary Inquiry Report will lead to a genuine commitment on the part of the medical profession in the United Kingdom to implement policies to enable the monitoring of professional practice in all specialities." (*Professor Stephen Bolsin)*

17.2. The events leading to the Bristol Histopathology Inquiry show clearly that the medical profession in the United Kingdom has still not successfully implemented satisfactory monitoring of professional practice in pathology.

17.3. This report shows that the BNSSG Commissioners and the organisation responsible for their performance, NHS South West, do not collect data on pathology safety and quality to enable them to ensure that high quality pathology services are commissioned on behalf of the people they serve.

17.4. The report shows that the ASWCS Cancer Network has promoted centralisation of Cancer

Surgery, on behalf of the National Cancer Action Team, without due consideration of safe, high quality pathology services that are required to underpin them to deliver the improved outcomes for patients that are the stated purpose of centralisation.

17.5. It is clear that BNSSG Service reconfigurations have been planned and implemented over many years without an understanding of and proper planning for pathology. When misdiagnosis concerns were raised, BNSSG just carried on regardless.

17.6. The emergence of concerns about pathology is the obvious outcome of different working practices and performance standards between pathology laboratories in Bristol. Pathologists working in different laboratories in the city were able to see each other's routine reporting. This exposed differences in standards that the UHBristol and NBT Medical Directors failed to investigate and resolve.

17.7. These inconsistencies in standards of different laboratories could and should have been identified before the clinical services supported by them were reconfigured. BNSSG could have enlisted the assistance of RCPath to advise on standards of best practice before clinical services were moved, but did not do so.

17.8. NHS Bristol, Lead Commissioner for UHBristol, has known about the concerns since at least October 2007. As it performs this leading role on behalf of NHS South Gloucestershire and NHS North Somerset, as well as itself, it is unlikely, if it was discharging its duties properly, that it would not have informed those organisations of the concerns in 2007 and consulted with them on appropriate action.

17.9. NHS South West is responsible for the performance of NHS Bristol as Lead Commissioner for UH Bristol. Therefore it is unlikely, if there was an effective performance management process between NHS Bristol and the SHA, that NHS Bristol would not have informed the SHA in 2007 of the allegations that some histopathology standards at one of the South West's major teaching hospitals were unsatisfactory and informed the SHA of its plans to promptly investigate whether the allegations were founded.

17.10. Many of the questions I have raised in this report seem unlikely to be answered in the UHBristol appointed Inquiry Panel's report because they are outside the scope of its very narrow terms of reference**.**

17.11. If the Inquiry Panel's terms of reference have been expanded to cover some of these very important issues, it has not been made public.

17.12. I caution NHS organisations and the Inquiry Panel not to assume that the patients and the public are interested only in histopathology competency. They are also interested in whether senior NHS managers acted promptly and appropriately to protect patients and investigate concerns after they became aware of them and had no idea whether patients were being unnecessarily harmed.

17.13. Patients and the public also want to know whether Medical Directors and Doctors met their GMC obligations to make the care of patients their first concern.

17.14. If it is not to be regarded as merely an attempt to try to "save time, money and reputations" (*one of the topics of the Verita/Hailsham Chambers seminar March 2010 see section 9.3*), the Inquiry Panel's report must answer these key questions that should have been put to Senior Managers, including Medical Directors of the SHA, BNSSG, ASWCS, UHBristol and NBT concerning the allegations:

- **When did you first know about them?**

- **What did you do about them?**

- **How did you ensure that concern for patient safety was your top priority for all patients using NBT and UHBristol breast, skin, lung and gynaecological histopathology services and paediatric pathology services?**

17.15. If the Inquiry Panel's report does not answer these fundamental questions of public accountability and probity, I believe it will have seriously failed the people of Bristol, North Somerset and South Gloucestershire

"To err is human, to cover up is unforgivable, and to fail to learn is inexcusable."
(Professor Sir Liam Donaldson, former Chief Medical Officer of England, speaking at the launch of the World Alliance for Patient Safety in Washington DC on 27 October 2004)

18. HISTOPATHOLOGY TIMELINES

TIMELINE A - Paediatric Pathology Timeline

The Cast

GB Dr Graham Bayley, Clinical Director, Laboratory Medicine
NB Dr Nick Bishop, Medical Director
MM Dr Morgan Moorghen, Lead Clinician, Histopathology
GN Mr Graham Nix, Acting Chief Executive (afterHR)
MP Prof. Massimo Pignatelli, Head of Department of Histopathology
HR Mr Hugh Ross, Chief Executive
PR Mr Peter Richardson, General Manager, Laboratory Medicine
JS Dr Jonathan Sheffield, Medical Director (after NB)
LS Ms Lesley Salmon, General Manager , St. Michaels Hospital

The Narrative

10/7/01 Letter from Paediatric Surgeon to HR and NB warning them that actions taken by adult histopathologists and managers (notably PR) threatened to destroy the department of Paediatric Pathology.

16/7/01 Letter from Prof. of Paediatrics to HR and NB supporting above letter.

29/8/01 Letter from 8 senior clinicians in the Children's Hospital to HR expressing concern that the lack of expert paediatric pathology was threatening the standard of care for children.

8/10/02 Letter from Lead Clinician for Children's Surgery and Chairman of Division of Children's Services to GN and NB expressing extreme concern that decisions taken by adult managers had resulted in the collapse of Paediatric Pathology with potential severe adverse effects on patients.

8/1/02 Letter from paediatric surgeon to MP reiterating concerns about standards of care (particularly for children with tumours and Hirschsprung disease) since adult rather than specialist paediatric pathologists were providing histopathology services for children and also concerns that no moves were being made to rebuild the department and specialist paediatric technicians were being diverted to adult histopathology.

14/11/02 Letter from Clinical Director of Obstetrics and Gynaecology to NB ,GN,LS and MM expressing concern at the loss of paediatric pathology and the severe effects of this on neonatal, fetal medicine and genetics services. He lays the blame for the loss of service at the door of UBHT managers.

1/10/03 Letter from Professor of Paediatric Oncology to various managers , including GB expressing concern that there was no management support for paediatric pathology and that a detailed report of the Paediatric and Perinatal Pathology Working Group (which he chaired) had been ignored by the Medical Director and Executive Director.

24/2/04 Letter from Prof. of Paediatric Oncology to GB, MM, MP and PR reiterating above concerns.

19/5/04 Letter from recently appointed Paediatric Pathologist complaining about lack of support from adult pathologists and managers and the difficulty of having to work within an adult department rather than having a separate dedicated paediatric department , as previously existed.

This individual subsequently moved to another centre.

29/9/04 Letter from Consultant in Paediatric Intensive Care to MM highlighting the poor quality of Post Mortem services for children. This was particularly based on cases of children dying of cardiac disease and a decision was subsequently taken to send all such cases to London to a paediatric pathologist previously working in Bristol who had been forced to leave Bristol due to decisions taken by adult managers which adversely affected his working environment.

14/2/08 Letter from Prof of Paediatric Oncology to MP and JS highlighting the incompetence of adult managers in attempts to recruit paediatric pathologists. I quote “many of us have been disappointed to see how, over several years, the need for adult pathology development is seen as a competitive and (I regret to say) obstructive element in addressing paediatric pathology. In today’s NHS no one should feel the need to extinguish another person’s light just to help theirs shine brighter”.

TIMELINE B - Bristol Histopathology Timeline

What did they know?
When did they know about it?
What did they do about it?

The Cast

Mary Barnes Director, Avon, Somerset and Wiltshire Cancer Services Network (ASWCS)
Ruth Brunt Acting Chief Executive North Bristol NHS Trust (NBT), formerly Operations Director, NBT
Sir Ian Carruthers OBE, Chief Executive NHS South West
Murray Cochrane Associate Director of Strategic Services NHS South West
Mike Durkin Medical Director NHS South West
Deborah Evans Chief Executive NHS Bristol, a witness at the Bristol Royal Infirmary Heart Inquiry.
Deborah Lee UHB Director of Corporate Development (on secondment), formerly Co-Director of Commissioning, NHS Bristol, formerly a Governor of UHB, Acting Chief Executive NHS Bristol at the end of 2007
Rhona MacDonald Former Chief Executive NHS Bath & North East Somerset & former Chair of the Board, ASWCS
Lisa Manson Associate Director of Performance, NHS South West
Sonia Mills Former Chief Executive NBT, now Chief Executive NHS Oxfordshire
Andrew Millward Director of Communications and Corporate Services, NHS South West
Kieran Morgan Former Joint Director Public Health, NHS Bath & North East Somerset, a witness at the Bristol Royal Infirmary Heart Inquiry
Martin Morse Former Medical Director NBT
John Murdoch Lead Gynaecological Oncological Surgeon UHB
Geoff Pye Medical Director ASWCS
Graham Rich Former Chief Executive UHB
John Savage Chair of the Board UHB
Jonathan Sheffield Medical Director UHB
David Tappin Former Director of Strategic Development NBT, now performing the same role at NHS Bristol
Geoff Upton Strategic Service Change Manager NHS South West
Richard Weatherhead Chair of Bristol PCT

Statements in italics starting *“DL”* are taken from a response to a Freedom of Information Request that includes a timeline headed “UHB Pathology Issues” produced by Deborah Lee on 12th March 2009, covering the period 22nd July 2008 to 3rd March 2009 inclusive. Ms Lee's last entry of 3rd March 2009 says **“ DL admits defeat and escalates to Chief Executives”**.

http://drphilhammond.com/blog/wp-content/uploads/2010/09/Deborah-Lees-timeline1.pdf

31st August 2004

Letter sent by NBT Respiratory Physicians to a UBHT Consultant Thoracic Surgeon expressing serious concern about the quality of histopathology reporting of lung biopsy and resection specimens by UBHT Pathologists in respect of lung patients referred from NBT for surgical procedures at UBHT. The letter referred to a number of incorrect diagnoses and in 2 cases, serious adverse clinical effects.

Among the people copied on the letter were **Ruth Brunt, Martin Morse, Jonathan Sheffield.**

1st June 2007

A letter was sent to **Martin Morse** detailing 15 alleged errors in Histopathology at UBHT that had affected NBT lung, breast and skin patients. The allegations included malignancies incorrectly diagnosed as benign, and vice versa. **Jonathan Sheffield** received a similar letter in early **July 2007.**

15th October 2007

The Local Authority Joint Health Scrutiny Committee met to hear evidence from clinicians, NHS managers, patients and members of the public in respect of proposed changes to Bristol's breast care services. During the meeting, patients and members of the public heard from clinicians that **"the issue of the Pathology Services needs to be resolved"**

http://www.bristol.gov.uk/item/committeecontent/?ref=wa&code=wa048&year=2007&month=10&day=15&hour=13&minute=00 - click on minutes, top left

and that some aspects of pathology services at UBHT are **"not up to standard"**.

Among the NHS attendees at the meeting who heard clinicians express concerns about UHB's cancer pathology services were **Deborah Lee, David Tappin and Martin Morse. Deborah Lee** informed the meeting that **"all the issues raised could be resolved"**

According to a 2010 Freedom of Information Response from NHS Bristol **Deborah Lee** invited NBT to substantiate in writing and with detail the verbal allegations made at the Health Scrutiny Meeting. NBT did not provide any evidence in support of the allegations, despite **Martin Morse** having received details of 15 specific allegations over four months earlier, in **June 2007.**

It appears that **Deborah Lee** decided not follow up the concerns directly with the clinicians so that "all the issues raised could be resolved".

Martin Morse knew that one of his former NBT colleagues, the late Jane Hopes, was one of the patients affected by misdiagnosis. It seems likely that **David Tappin**, also a former colleague of Mrs Hopes would have known that her case was one of the misdiagnoses. Yet it appears that neither provided **Deborah Lee** with details of the specific allegations that had been formally raised with **Martin Morse. David Tappin** moved to NHS Bristol in **August 2008,** as one of **Deborah Lee's** fellow NHS Bristol Board Members.

26th February 2008

The ASWCS Breast Site Specific Group met. The notes of the meeting record that one of the members **"raised the issue over the quality of UBHT Pathology Services. He felt that a clear statement should be issued by UBHT either acknowledging or refuting these claims. He wasn't aware that this had happened. The group felt the current situation was divisive"**

See item 13 – Any other business.

http://89.234.34.107/avon/documents/website%5CSSGs%5CBreast%2FNotes%2026%20February%202008%2Epdf

April 2008

Reporting of cervical histopathology for UBHT patients was transferred to NBT following a Quality Assurance review in 2006 that identified that the correlation between cervical cytology reporting (all done at NBT) and subsequent biopsy reporting for UBHT patients (performed at UBHT), was significantly lower at UBHT than at NBT. It was stated to be the worst correlation in England. The Quality Assurance report concluded that, during the period studied, there was significant under grading of cervical cell changes in respect of loop biopsy specimens reported at UBHT. This would have increased the risk of gynaecological disease being under treated. The reviewers found no evidence that any patients were harmed. However, following the review, UBHT's cervical biopsy reporting was transferred to NBT. Other gynaecological histopathology reporting remained at UHBT, despite cervical biopsy reporting being regarded as one of the easier aspects of a gynaecological histopathology service.

15th June 2008

A letter was sent to **Graham Rich** for his urgent attention, copied to **John Savage** and **Sonia Mills**, referring to unresolved concerns about UBHT's histopathology services, including a range of diagnostic errors in reporting of gynaecological cases. It was stated that initially, the cases were drawn to the attention of the UHB Gynaecological Pathology lead and the UHB Lead in Gynaecological surgery, who is **John Murdoch**. Later cases were drawn to the attention of **Jonathan Sheffield** and **Martin Morse.** The letter also referred to allegations of substandard coroner's autopsies performed by UHB pathologists. The coroner's autopsies have not been included within the scope of the Inquiry for reasons which have never been publicly explained.

25th June 2008

A member of the public presented a paper to South Gloucestershire Health Scrutiny Select Committee containing questions relating to the clinical concerns about UBHT's histopathology services raised on **15th October 2007** and related this to public concerns about the ASWCS implementation of Cancer Surgery centralisation. **Mary Barnes** was asked by the Committee to respond to the letter.

22nd July 2008

DL *– Correspondence sent to* ***Mary Barnes****, Cancer Network Director from Dr Charlie Thomson,Renal Physician and Safer Patient Initiative Lead raising concerns about the quality of pathology services and citing examples of pathology errors that had led to unnecessary treatment and missed diagnosis of serious conditions in the areas of lung, breast and gynaecological cancer.*

Dr Tomson's letter stated that he believed that **Mary Barnes** had been made aware of the concerns. However, in a Freedom of Information response dated **16th July 2010**, signed by **Mary Barnes,** it was stated that she was not aware of the concerns before **22nd July 2008**, despite them

being raised at a Council meeting on **25th June 2008** in response to a paper she had produced.

Clinical members of **Mary Barnes**' Network had raised concerns publicly on **15th October 2007** and the concerns were referred to at the **26th February 2008** ASWCS Breast Site Specific Group Meeting.

It seems unlikely that **Mary Barnes**, ASWCS Director, and **Rhona MacDonald**, the ASWCS Board Chair, and whose Board Member colleague was **Deborah Lee**, would not have known that clinicians in their cancer network had expressed concerns about some aspects of UBHT's pathology safety long before **22nd July 2008.**

23rd July 2008

NBT's Medical Advisory Committee met. **Martin Morse** and **Sonia Mills** were attendance. The minutes record:

"Respiratory Histopathology

There continued to be serious cases of misdiagnosis by UHB histopathologists, despite there having been assurances that the problems had been overcome, and UHB continued to refuse to allow slides to be looked at by NBT histopathologists. Members discussed possible ways forward such as the consultant body reporting the matter to the Healthcare Commission".

8th August 2008

Letter from **Geoff Pye** to **Mike Durkin** informing him of Dr Tomson's letter regarding the pathology concerns and that Dr Tomson suggested that **"despite considerable efforts, these concerns have yet to be effectively addressed"**

22nd September 2008

DL *– **Geoff Pye** and **Mary Barnes** notified Deborah Lee, Director of Commissioning of correspondence from Dr Tomson.*

***DL** briefed (verbally) **Deborah Evans** and agreed action including letter to Network staff and Chair raising concerns over delay in reporting such a serious allegation to commissioners and brief to Strategic Health Authority.*

Dr Tomson's letter referred to the same concerns in respiratory and breast pathology that were formally detailed in the letter to **Martin Morse** dated **June 2007** and alluded to by clinicians in public, in the presence of **Deborah Lee** on **15th October 2007,** and which **Deborah Lee** chose not to pursue after receiving no response from **Martin Morse** to the request for specific details.

23rd September 2008

DL *– Detailed conversation with **Dr Jonathon** (sic) **Sheffield** who stated that he felt there was nothing in these allegations and that they were vexatious in nature. Discussion reached agreement that an external review of service would be undertaken to demonstrate to all that UHB services were safe and of appropriate quality and that the allegations were unfounded.*

NHS BaNES hosted a stakeholder event to start a review process for centralisation of Gynaecological Cancer Services for Bristol and Bath at either UHB or the Royal United Hospital, Bath. None of the public and patient stakeholders were informed that serious allegations of misdiagnosis had been made in respect of the UHB Bristol Gynaecological pathology service. They

only found out when the allegations were mentioned in the media, nine months later in **June 2009.**

24th September 2008

DL *-* ***Lisa Manson*** *briefed and agreed to involve* ***Mike Durkin*** *and seek his confirmation on whether a Royal College Review was considered sufficiently robust for the purpose.* ***MD*** *confirmed he was happy with this approach.*

2nd October 2008

DL *-* ***Deborah Lee*** *met and briefed* ***Dr Graham Rich****, Chief Executive, UHB re Dr Tomson's correspondence and allegations.*

It is unclear why **Graham Rich** needed to be briefed about any allegations since he and his Chair, **John Savage** had already been briefed in the letter of **15th June 2008** which stated that his Medical Director, **Jonathan Sheffield** had previously been informed of specific concerns, as had **John Murdoch**, his Lead Gynaecological Oncological Surgeon.

15th October 2008

DL *–* ***DL*** *sent letter (in* ***Deborah Evans*** *name) to* ***Graham Rich*** *raising concerns that three weeks had elapsed with no sign of Terms of Reference.*

16th October 2008

DL *-* ***Lisa Manson*** *requested sight of Terms of Reference.*

23rd October 2008

DL *- Terms of Reference for external review of lung pathology services, to be undertaken by Royal College of Pathologists, received by PCT and copied to SHA.*

24th October 2008

DL *– Email to* ***Jonathan Sheffield*** *(copied to Dr* ***Martin Morse****) from* ***DL*** *raising concerns about the limited scope of the review and advising that NBT would be required to confirm they no longer had concerns about breast and gynaecological pathology for PCT to sign off Terms of Reference which limited review to lung only.*

Email from ***Martin Morse*** *expressing his concerns that the Terms of reference were developed without collaboration with NBT despite this having been the agreement.*

No response to ***DL*** *re scope of Terms of Reference.*

4th November 2008

DL *– Email from* ***DL*** *to* ***Jonathan Sheffield*** *enquiring about outcomes from review.*

5th February 2009

DL *- Email from* ***Jonathan Sheffield*** *advising that they are still awaiting NBT's agreement on whether review should include breast and/or gynaecology and whether lung review should extend to both Trusts or solely focus on UHB. This email however noted that* ***The Royal College felt that the cases originally reflected difference of opinion which are in keeping with the accepted variations of pathology reporting****. It is not clear how this view was reached as it appears the*

review has still not taken place.

***DL** emailed **Martin Morse** asking him what was holding up clarification of Terms of Reference for the review. No reply received.*

3rd March 2009

*DL – **DL** admits defeat and escalates to Chief Executives.*

26th March 2009

Deborah Evans informed the Board of NHS Bristol about concerns about quality of histopathology at UHB, **six months** after being informed by **Deborah Lee** about them. **Deborah Lee**, an Executive Member of the NHS Bristol Board, had known about concerns since October 2007, **seventeen months** earlier.

See Chief Executive's Report, Page 5

http://www.bristol.nhs.uk/about-us/how-do-we-work/board-meetings-2009/july.aspx

27th March 2009

Deborah Lee email to **Lisa Manson** with timeline of actions taken between 22nd July 2008 and 3rd March 2009. **"Lisa – my records of attempts to get UHB to take this seriously, now with Deborah E"**

12th May 2009

In response to concerns raised by a member of the public, **Dr Kieran Morgan**, Chair of the Gynaecological Cancer Service Review advised that **Rhona MacDonald**, Chief Executive of NHS BaNES and Chair of the ASWCS Board had sought assurance that the quality of pathology at UHB was "appropriate".

This was **two months** after **Deborah Lee** had **"admitted defeat"** and apparently failed to **"get UHB to take this seriously".**

22nd May 2009

A external clinical panel, commissioned by **Mary Barnes** and **Rhona MacDonald** met in Bristol to review UHB's and the RUH's cases to be the centre for Gynaecological Cancer Surgery. Their report noted that **"The pathology services ..... appear to operate well across the network and did not concern the panel".** There was no specialist pathologist on the Panel. A few weeks later, Private Eye and and the BBC reported on the misdiagnosis allegations, including Gynaecological errors. There is no evidence that **Ms Barnes** and **Ms MacDonald** informed the external panel that there were serious gynaecological histopathology concerns, despite **Ms Barnes** having known of them at least **ten months** earlier, in **July 2008.**

1st June 2009

Monitor was informed of the histopathology allegations by **John Savage** during a routine telephone call.

John Savage had known about them for at least a year as he was copied on the **15th June 2008** letter to **Graham Rich**. Yet neither thought it necessary to inform Monitor as a Foundation Trust regulator. UBHT became a Foundation Trust on 1st June 2008 and was thereafter known as UHB.

Clearly this rankled with **Sonia Mills** and **Martin Morse**. The Minutes of the 3rd June 2008 NBT Medical Advisory Committee meeting record under the Chief Executive's and Medical Director's report that:

"UBHT had been given Foundation Trust status and would henceforth be known as University Hospitals Bristol NHS Foundation Trust. This was thought by NBT to not only be inaccurate but also contentious"

As Chair of the Board of UHB, and therefore a non-executive member, **John Savage** has a **"responsibility to ensure the Board acts in the best interests of the public and is fully accountable to the public for the services provided by the organisation and the public funds it uses"** (*Department of Health, Delivering Quality and Value: A briefing for NHS Chairs and Non-Executive Directors.*)

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4123285

2nd June 2009

Kieran Morgan advised a member of the public that he was **"assured that UHB meet pathology standards as assessed against national standards".** But did not provide any data to support that view. This was **three months** after **Deborah Lee's** admission to Chief Executives of defeat and apparent failure to **"get UHB to take this seriously"**

9th June 2009

Sir Ian Carruthers OBE was verbally briefed about the allegations by **Andrew Millward,** his Communications Director.

10th June 2009

Private Eye Magazine broke the story of the 15 alleged misdiagnoses detailed in the **1st June 2007** letter to **Martin Morse.**

Shortly afterwards, UHB announced an inquiry into the 15 cases of misdiagnosis. Gynaecological allegations were not included in the 15.

http://www.uhbristol.nhs.uk/university-hospitals-bristol-nhs-foundation-trust-launch-independent-pathology-review

19th June 2009

BBC Points West broadcast the pathology allegations, mentioning that there were gynaecological cases identified over a two year period.

http://news.bbc.co.uk/1/hi/england/bristol/8109011.stm

24th June 2009

Murray Cochrane became aware of the allegations when he was asked to draft a letter for **Sir Ian**

Carruthers OBE in response to a letter from a member of the public which contained references to them.

26th June 2009

Deborah Evans said this in response to a letter from a public member or UHB:

"In your letter of 22 June 2009 to Jonathan Sheffield, you talk about gynaecological cases which were misdiagnosed and you ask for a review of these individual cases. I have been unable to establish what you refer to in this instance".

The member of the public pointed out that the cases referred to were the ones the BBC had mentioned a week earlier.

Graham Rich, UHB's Chief Executive and **John Savage**, the UHB Chairman had formally been notified of the gynaecological allegations a year earlier, on **15th June 2008. Jonathan Sheffield**, UHB's Medical Director had known about them before then and **John Murdoch**, UHB's Lead Gynaecological Oncological Surgeon had known about them at least since **June 2008.**

Therefore it is strange that UHB publicly announced an inquiry into the 15 cases without including the Gynaecological cases and apparently only did so when prompted by one if its Foundation Trust Members.

By the end of August 2008, the number of specific allegations was 26 cases, not 15. The increase was presumably due to inclusion of the gynaecological cases, although this was never publicly confirmed.

Until August 2010, NHS Bristol appeared reluctant to explain when its Chief Executive, **Deborah Evans** first knew about the Gynaecological allegations of misdiagnosis, by whom and by what means.

However, Freedom of Information responses from another organisation show that, on **22nd September 2008**, **Ms Evans** was verbally briefed by her Director of Commissioning, **Deborah Lee** on Dr Tomson's letter to **Mary Barnes** of **22nd July 2008.** Dr Tomson's letter referred to Gynaecological allegations.

Furthermore, the Minutes of the Performance Review Meeting for Bristol Primary Care Trust (now NHS Bristol) held Tuesday **4th November 2008** record this:

"Pathology

Deborah Lee explained that the report to the Royal College regarding pathology at University Hospitals Bristol NHS Foundation Trust covered only lungs, whereas gynaecology and breast were also raised as concerns, these issues have not been addressed as yet"

Ms Evans was present at that meeting, yet, **seven months** later, according to the wording of her letter of **26th June 2009** to a public member of UHB, she appeared to deny knowledge of any gynaecological allegations.

One of NHS Bristol's Key Values is Achieving High Performance, **"The safety of patients and users of the service will remain at the top of our agenda".**

http://www.bristolpct.nhs.uk/thetrust/values.asp

30th June 2009

Geoff Upton was informed of the allegations by an email.

1st July 2009

Email from **Deborah Evans** to the Care Quality Commission:

"We have been very keen to establish what action has been taken about the 15 cases that Private Eye brought to our attention.....we would like to get everything on the table at this stage, if possible.

We are prioritising the communication and reputation management aspects of this issue".

Not prioritising protection of patients?

If, in **October 2007**, **Deborah Lee** had insisted that **Martin Morse** and **David Tappin** substantiated the pathology issues mentioned in public by clinicians, she would have received the details of the 15 cases. They are all contained within the letter sent to **Martin Morse** on **1st June 2007.**

Nearly two years was wasted because NHS Bristol did not pursue NBT to reply to its requests for specific information and produce the information its Medical Director possessed about the 15 specific cases.

20th July 2009

Meeting between three members of the public, **Deborah Evans** & **Graham Rich**. **Ms Evans** and **Dr Rich** said they believed that there were approximately 26 cases of possible misdiagnosis and that it was proving quite difficult to get all the details together.

Dr Rich had known about concerns since at least **June 2008**, eleven months earlier, and **Ms Evans** had known about them since at least **September 2008**, nine months earlier.

It has been alleged that at least one person died as a result of a misdiagnosis and some others were seriously harmed. It is now public knowledge that in two of the cases, UHB admitted patients were harmed and financially settled with them. Yet it has never been explained exactly why the two Chief Executives were finding it difficult to get details together five years after serious allegations were raised with UHB in NBT's **August 2004** letter and a year after they were escalated to NBT's Medical Advisory Committee in **July 2008** and formally raised with **Mary Barnes** and **Geoff Pye,** also in **July 2008,** by a Clinical Lead in Patient Safety.

23rd July 2009

NHS Bristol, Chief Executive's report to Trust Board:

"The Private Eye article identified 15 specific individual cases where over or under diagnosis is alleged. NHS Bristol was not previously aware of these cases and North Bristol Trust is currently checking that each of these individual cases has been identified and followed up".

Chief Executive's Report, page 5

http://www.bristol.nhs.uk/about-us/how-do-we-work/board-meetings-2009/july.aspx

Deborah Evans, Chief Executive of NHS Bristol knew about concerns in **September 2008, ten**

months before Private Eye's article. Her Director of Commissioning, **Deborah Lee** knew about concerns **twenty one** months earlier, in **October 2007.**

Yet NHS Bristol claims not to have been aware of the 15 cases that were subject to the concerns, despite them being listed in letters to **Martin Morse** and **Jonathan Sheffield** in **June/July 2007**, despite Deborah Lee's "detailed" discussion about them with Jonathan Sheffield on the **23rd September 2008** and despite discussion of the pathology concerns in NHS Bristol's regular performance reviews with **Lisa Manson**, Associate Director of Performance, NHS South West, during the eight months prior to the Private Eye article.

Do NHS South West and NHS Bristol expect the public to accept that they could effectively discuss the performance of the internal review of pathology without having the most basic information – namely the specific details of very serious allegations of misdiagnosis?

29th July 2009

Meeting of the Joint Meeting of UHB Trust Board and Membership Council. The minutes record that:

"concerns were expressed about the reports of misdiagnosis from the histopathology service and sought reassurance that the Governors had been notified as soon as these problems surfaced. Graham Rich reported that there was no evidence that this was a particular risk and the article in the press had been unexpected. It was acknowledged that Governors should be receive (sic) **briefings that were circulated to Non-Executive Directors on key issues as required".**

See item 14.

http://www.uhbristol.nhs.uk/files/nhs-ubht/03a%20Joint%20Trust%20Board%20and%20Membership%20Council%20minutes%2009%20JUL29.pdf

As the problems had surfaced long before UHB achieved Foundation status on **1st June 2008,** the Governors should have been informed of the problems when they were appointed to the Trust. **Deborah Lee**, the UHB Governor representing NHS Bristol had known about pathology issues since at least **October 2007**. It seems that the other Governors were kept in the dark until the Trust informed them of the serious allegations of misdiagnosis shortly before Private Eye exposed them in **June 2009.**

26th October 2009

John Savage wrote to a public member of UHB:

"You wrote to NHS Bath and North East Somerset on 12th May 2009 about the gynaecological cancer services review. They forwarded it to Graham Rich. Please accept my profound apologies that you did not get a response to that specific email. I can assure you that your concerns were noted and that, in part, this led to the review of pathology services that is now being conducted".

Strange then that the gynaecological cases were not included in the review when it was announced by UHB the following month, on **19th June 2009.**

5th November 2009

In response to public questions, **Kieran Morgan** claimed that NHS BaNES had not withheld

information about pathology during the course of the gynaecology review and that concern about the pathology service in UHB surfaced in the early part of 2009. In fact four members of his Gynaecological Review Steering Group knew that concerns had surfaced much earlier. **Deborah Lee** and **David Tappin** had known since at least **October 2007**, **Jonathan Sheffield** since **August 2004** and **John Murdoch** since at least **June 2008.**

None of these five senior NHS staff, three of them doctors, and subject to the GMC codes of conduct, thought it necessary to tell the patient and public members of the Gynaecological Cancer Services Review that serious allegations of gynaecological misdiagnosis against UHB had been the subject of an NHS internal review involving NHS South West, NHS Bristol and UHB since **September 2008**, **fourteen months** earlier.

Nor did **Rhona MacDonald**, Chief Executive of NHS BaNES, the lead PCT for the Gynaecological Cancer Services Review, and Chair of the ASWCS Board think it necessary to inform patient and public members of the review of the allegations, despite **Mary Barnes**, her Network Director, knowing about them since at least **July 2008.**

25th March 2010

UHB's Lead Governor was informed of at least two further misdiagnoses that had allegedly occurred since the UHB Histopathology Inquiry was instigated. In fact there were three cases:

- A breast cancer diagnosed as grade 1 by UHB, and grade 3 by three NBT specialist pathologists.
- A tuberculosis missed by UHB.
- A patient diagnosed with malignant mesothelioma by UHB. NBT reviewed the case shortly before the patient was scheduled for chemotherapy and diagnosed a benign condition. Consequently the patient was saved from having unnecessary chemotherapy.

27th August 2010

Freedom of Information Response from **Richard Weatherhead** to a member of the public stating:

“On **23rd September 2008**, following her conversation with **Mr Pye** and **Mary Barnes Deborah Lee** orally advised **Deborah Evans** that concerns had been raised including concerns around breast, lung and gynaecological, however there was no supporting evidence or specific cases”

On the contrary, the 15 specific cases of lung, breast and skin were detailed in the letters sent to Martin Morse and Jonathan Sheffield over a year before, in **Summer 2007**. The details of the Gynaecological cases had been provided to John Murdoch, Jonathan Sheffield and Martin Morse during the two years to **June 2008.**

All the details were in documents possessed by the UHB and NBT Medical Directors. For some reason, it appears that NHS Bristol, on behalf of the communities whose safety is at the **“top of its agenda”** was unwilling or unable to extract this information from the two Trusts in order to conduct a proper investigation into serious allegations of misdiagnosis that have festered unresolved for far too long and are still occurring in 2009/2010.

Daphne Havercroft

September 2010

TIMELINE C – Deborah Lee's Timeline

UHB Pathology Issues

Deborah Lee
12th March 2009

NHS Bristol

- **22nd July 2008.**
  Correspondence sent to Mary Barnes, Cancer Network Director from Dr Charlie Tomson, Renal Physician and Safer Patient Initiative Lead raising concerns about the quality of pathology services and citing examples of pathology errors that had led to unnecessary treatment and missed diagnosis of serious conditions in the areas of lung, breast and gynaecology cancer

- **22nd September 2008**
  Geoff Pye and Mary Barnes notified Deborah Lee, Director of Commissioning of correspondence from Dr Tomson
  DL briefed (verbally) Deborah Evans and agreed action including letter to Network staff and Chair raising concerns over delay in reporting such a serious allegation to commissioners and brief to Strategic Health Authority.

- **23rd September 2008**
  Detailed telephone conversation with Dr Jonathon Sheffield who stated that he felt there was nothing in these allegations and that they were vexatious in nature. Discussion reached agreement that an external review of service would be undertaken to demonstrate to all that UHB services were safe and of appropriate quality and that the allegations were unfounded.

- **24th September 2008**
  Lisa Manson briefed and agreed to involve Mike Durkin and seek his confirmation on whether a Royal College Review was considered sufficiently robust for the purpose. MD confirmed he was happy with this approach.

- **2nd October 2008**
  Deborah Lee met and briefed Dr Graham Rich, Chief Executive, UHB re Dr Tomson's correspondence and allegations.

- **15th October 2008**
  DL sent Letter (in Deborah Evans name) to Graham Rich raising concerns that three weeks had elapsed with no sign of Terms of Reference.

- **16th October 2008**
  Lisa Manson requested sight of Terms of Reference

- **23rd October 2008**
  Terms of Reference for external review of lung pathology services, to be undertaken by Royal College of Pathologists, received by PCT and copied to SHA.

- **24th October 2008**
  Email to Jonathan Sheffield (copied to Dr Martin Morse) from DL raising concerns about the limited scope of the review and advising that NBT would be required to confirm they no longer had concerns about breast and gynaecology pathology for PCT to sign off Terms of Reference which limited review to lung only.

  Email from Martin Morse expressing his concerns that the Terms of reference were developed without collaboration with NBT despite this having been the agreement.

  No response to DL re scope of Terms of Reference.

- **4th November 2008**
  Email from Jonathan Sheffield to Martin Morse saying that Terms of reference were submitted as joint review (despite NBT not having discussion of prior sight of them before submission).

- **5th February 2009**
  Email from DL to Jonathan Sheffield enquiring about outcomes from review

- **6th February 2009**
  Email from Jonathan Sheffield advising that they are still awaiting NBT's agreement on whether review should include breast and/or gynaecology and whether lung review should extend to both Trusts or solely focus on UHB. This email however noted that *The Royal College felt that the cases originally reflected difference of opinion which are in keeping with the accepted variations of pathology reporting.* It is not clear how this view was reached as it appears the review has still not taken place.

  DL emailed Martin Morse asking him what was holding up clarification of Terms of Reference for the review. No reply received.

- **3rd March 2009**
  DL admits defeat and escalates to Chief Executives

19. GLOSSARY

AIMS	Adverse Incidents Manegement System
ASWCS	The Avon, Somerset and Wiltshire Cancer Services Network
BHSP	Bristol Health Services Plan - modernising and improving health facilities and services throughout Bristol, North Somerset and South Gloucestershire.
BNSSG	The Primary Care Trusts of Bristol, North Somerset and South Gloucestershire
Care Quality Commission (CQC)	independent regulator of health and social care in England
General Medical Council (GMC)	Regulates doctors and ensures good medical practice
Healthy Futures Programme	A framework for coordinating transformational change across the NHS in Bristol, North Somerset and South Gloucestershire (BNSSG) – successor to BHSP
Her2	human epidermal growth factor receptor 2, one of a family of genes that play roles in regulating cell growth.
Joint Health Scrutiny Committee	A joint committee whose members represent the Health Scrutiny Committees of Bristol, North Somerset, South Gloucestershire and Bath and North East Somerset.
Monitor	Independent Regulator of NHS Foundation Trusts
NBT	North Bristol NHS Trust
NHS Bath & North East Somerset	The Primary Care Trust for Bath & North East Somerset
NHS Bristol	The Primary Care Trust for Bristol
NHS North Somerset	The Primary Care Trust for North Somerset
NHS South Gloucestershire	The Primary Care Trust for South Gloucestershire
NHS South West	The Strategic Health Authority for the South West
PCT	Primary Care Trust
SHA	Strategic Health Authority
STEIS	Strategic Executive Information System – an NHS management reporting tool
SUI	Serious Untoward Incident
UHBristol	University Hospitals Bristol NHS Foundation Trust, formerly known as UBHT (United Bristol Healthcare Trust)