

The Independent Inquiry into Histopathology Services

A report for

University Hospitals Bristol
NHS Foundation Trust

December 2010

PANEL MEMBERS

Jane Mishcon was appointed as Chair of the Inquiry. She is a barrister at Hailsham Chambers in London. She has 30 years' experience and her main area of practice is clinical negligence. She has chaired nine other independent inquiries. She is ranked as a leading barrister in clinical negligence in both the Legal 500 and Chambers UK Directories.

Professor Sir James Underwood is Emeritus Professor of Pathology at the University of Sheffield. He served as President of the Royal College of Pathologists from 2002 to 2005 and latterly was Dean of Sheffield University's Faculty of Medicine. He has had over 30 years' experience as a consultant histopathologist in Sheffield.

Ken Jarrold CBE is Chair of Dearden Consulting, of the County Durham Economic Partnership and of the Partnership Committee of the Child Exploitation On Line Protection Centre [CEOP] and a member of the CEOP Board. Ken was a manager in the NHS for 36 years including three years as Director of Human Resources and Deputy to the Chief Executive of the NHS in England and 20 years as a Chief Executive of Health Authorities including the County Durham and Tees Valley Strategic Health Authority and the Wessex Regional Health Authority.

Dr Margaret Spittle OBE MSc FRCP FRCR AKC is a consultant clinical oncologist and emeritus consultant at University College London Hospitals NHS Foundation Trust and Guys & St Thomas' Hospitals NHS Foundation Trust. She was Dean of the Royal College of Radiologists and is a Government adviser on radiation safety. In January 2010 she replaced **Dr Fergus Macbeth**, consultant oncologist and Director of the Centre for Clinical Practice at the National Institute for Health and Clinical Excellence, following Dr Macbeth's decision to stand down due to his other work commitments.

Michael Summers was the Vice Chairman of the Patients Association, a registered charity, at the time of his appointment to the Panel. He retired from this position during the course of the Inquiry.

ACKNOWLEDGEMENTS

The administration and co-ordination of this Inquiry was undertaken by Ed Marsden and David Jones of Verita. We are extremely grateful to them both, but David, in particular, showed great patience and calm efficiency which made a complicated and lengthy process run so much more smoothly than it might have done otherwise. We would also like to thank Lesley Sargeant for her invaluable help.

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We also appreciated the frank and open way in which the many witnesses gave their evidence to us. This could not have been an easy process for anyone, particularly in the light of the media attention it has attracted, but everyone appeared to be trying to help us find workable and lasting solutions to the issues which we were investigating.

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EXECUTIVE SUMMARY

Introduction

- 1 An Inquiry of this nature, scope and cost would never have been necessary or probably even contemplated had concerns been thoroughly and promptly investigated when and whenever they were raised and the results of those investigations made clear to those who had made the allegations.
- 2 The failure to carry out a thorough and prompt investigation of the concerns when raised meant that matters escalated out of all proportion and the already strained relationship between the histopathology services in the two Bristol Trusts became even more deeply entrenched.
- 3 It was the cumulative effect of repeated allegations being allowed to linger or be unsatisfactorily answered which led to the perceived necessity to ‘blow the whistle’ by going to *Private Eye*.
- 4 It is essential that lessons are learned as a result of our Inquiry by both Trusts, and, most importantly, are acted upon in a spirit of co-operation and with the determination to take any necessary steps towards achieving workable and cohesive solutions to the concerns highlighted in the Report.

- 5 The earliest concerns about histopathology in University Hospitals Bristol NHS Foundation Trust (UHBT) were raised in 2001 regarding paediatric histopathology and were about the lack of sufficient staff and adequate cover. This followed the disintegration of a highly regarded service.
- 6 Then in August 2004 a letter was written by five respiratory physicians from North Bristol NHS Trust (NBT) to a thoracic surgeon at the Bristol Royal Infirmary (BRI) but copied to 14 other individuals including the Medical Directors of both UHBT and NBT and all of the UHBT consultant histopathologists. The letter expressed the physicians’ concern about the reporting of surgical lung biopsy and resection specimens from NBT patients which had been

referred to the histopathology service at UHBT. The concerns were based on the perception that the reporting was being carried out by ‘general pathologists’ at UHBT who were not ‘specialist’ lung pathologists. The letter also stated that “*This has led to a number of incorrect diagnoses and in 2 recent cases serious adverse clinical effects for our patients*” and requested that lung pathology from NBT patients should be transferred back to the NBT histopathologists.

- 7 Between September 2004 and January 2007 the only other concern raised by the NBT respiratory physicians was in March 2005 when one of them wrote to the Medical Director at NBT, describing a recent case of alleged misdiagnosis at UHBT and again asking for surgical lung pathology specimens to be sent back to NBT.
- 8 In January 2007 the Lead Clinician for respiratory medicine at NBT raised further concerns with Dr Jonathan Sheffield, the Medical Director of UHBT, relating to the difficulties experienced by the NBT respiratory physicians in obtaining from the UHBT histopathology department the histology slides of NBT patients for review at their lung cancer MDT meetings. Similar concerns were expressed in July 2008.
- 9 In early July 2007 Dr Nassif Ibrahim, one of the consultant histopathologists at NBT, wrote to Dr Sheffield detailing 11 cases in which he alleged errors in diagnosis had been made by the histopathologists at UHBT.
- 10 Also in 2007 Dr Lynn Hirschowitz, one of the NBT pathologists who was a nationally acclaimed gynaecological histopathologist, raised concerns about the reporting of several gynaecological cases by the UHBT histopathologists.
- 11 In October 2008 Dr Sheffield submitted a formal application to the Royal College of Pathologists (RCPATH) to carry out an external review of UHBT’s histopathology service. It was intended that this should be a joint review with NBT and a letter was sent by Dr Martin Morse, Medical Director of NBT, confirming this.
- 12 The College requested more information and stated that the apparent difference of emphasis between the application from Dr Sheffield and the letter from Dr Morse would need to be reconciled in a revised and joint application by both Trusts with agreed terms of reference. No further application appears to have been made to the College.

- 13** It was not until the publication of the *Private Eye* article on 10 June 2009 that any kind of independent investigation into the concerns which had been raised over the years was actually instigated.
- 14** Within days of the *Private Eye* article, the Trust announced that it was to set up an independent review of histopathology specimens reported by the UHBT pathologists. The Trust commissioned Medical Solutions (since 1 January 2010 known as Source BioScience Healthcare), a company providing diagnostic and screening services to NHS and private healthcare, to carry out this review and also to review 26 specific cases of alleged diagnostic errors by the UHBT histopathologists. Source BioScience subsequently audited 3,500 cases randomly selected from histopathology specimens reported at UHBT in 2007 in addition to the 26 cases.
- 15** In July 2009 the Trust announced that it was to commission an Independent Inquiry to draw conclusions from the results of the independent review, to scrutinise the performance of the histopathology service at UHBT, and to consider whether appropriate action was taken by the Trust to address any concerns which had been raised about the performance of the UHBT histopathology service.
- 16** As stated above, a total of 26 cases had been identified by the clinicians and histopathologists at NBT as being cases in which they felt that the diagnosis given by the original reporting histopathologist at UHBT was questionable. The cases covered an eight-year period between 2000 and 2008.
- 17** As part of the Inquiry process, these 26 cases were reviewed both by Source BioScience and by the Royal College of Pathologists, and we have prepared our own ‘overview’ of these reviews [**See Annexe 4**]. It is these 26 cases which are at the heart of this Inquiry, rather than the 3,500 cases reviewed by Source BioScience.
- 18** The review by the Royal College shows that there were in fact very few cases of misdiagnosis amongst the 26 which were of the kind which no reasonably competent histopathologist should make. However, every single error should be taken extremely seriously and lessons should be learned to try to avoid similar errors re-occurring.
- 19** Because we had concerns about the way in which the 3,500 cases had been selected for audit, we invited Professor Peter Furness, the current President of the Royal College of

Pathologists, to evaluate the evidence relating to this audit which was available to us and to give us his professional judgement on it. Professor Furness's salient findings can be found in the 'Competence' section of this Summary. His Report can be found at **Annexe 6**.

20 In addition we invited a senior and experienced histopathologist from another academic centre, Dr Ray McMahon, Senior Lecturer in Pathology and Honorary Consultant Pathologist in Manchester, to give us expert advice on histopathological diagnosis and on the nature and definition of diagnostic error. His report can be found at **Annexe 3(ii)**.

21 We interviewed 58 witnesses, some of them more than once. The witnesses included four Chief Executives, three Medical Directors, two Heads of Division, three Heads of Department, one Clinical Lead, two Biomedical Scientists, 12 Histopathologists, nine Respiratory Physicians, one Professor of Paediatric Oncology, three Gynaecological Surgeons, one Breast Surgeon, two Cardiothoracic Surgeons, the Medical Director and Director from Cancer Network, the Medical Director of Source Bioscience, the widower of one of the patients whose case was included in the 26 cases, two patient advocates and Dr Phil Hammond who wrote the *Private Eye* articles.

22 The interviews were conducted in private. It was felt to be important that witnesses could come forward, if necessary, without their employers and colleagues knowing that they had, and that they should feel that they could come and talk freely to the Panel. We are extremely grateful for the frankness and openness with which most people gave their evidence, particularly as we were always mindful that it is extremely difficult to criticise colleagues even if one has serious concerns about some areas of those colleagues' practices. We were also anxious that the evidence should be as broad-based as possible and welcomed the fact that a considerable number of witnesses came forward to give positive and supportive comments about the UHBT pathologists as a balance to those who volunteered more adverse criticisms.

23 This Inquiry has been a challenging task. We have been only too aware that many people have high expectations that we will be able to make things change radically for the better. We are also aware that many believe that our report will be a 'whitewash' and will achieve little.

24 We have done our best to make clear, fair and balanced findings and workable recommendations, but real change can only come about with the goodwill and the good intentions of the parties concerned.

25 As the Kennedy Inquiry said:

- *“There are no right answers; just, perhaps, less wrong answers.*
- *Cultural and institutional change takes time and can be slow, requiring patience and forbearance.”*

26 We urge everyone involved in this process to take our findings and recommendations constructively rather than personally and to work together to build a safe and effective histopathology service for the people of Bristol.

Culture/Attitude

27 Originally Bristol had three hospital Trusts, United Bristol Healthcare NHS Trust (UBHT), Frenchay and Southmead. In 1999 Frenchay and Southmead merged to become the North Bristol Trust (NBT) and on 1 June 2008 UBHT became a Foundation Trust known as University Hospitals Bristol NHS Foundation Trust (UHBT).

28 Historically UHBT’s Bristol Royal Infirmary (BRI) considered itself the ‘kingpin’ of the three hospitals in Bristol and this perception still pervades the culture of the BRI and many of its staff, especially those who have been there for some time.

29 As a large university teaching hospital the BRI should strive to achieve national recognition in all its departments, but it is the Panel’s impression that the culture and ambience of the UHBT histopathology department (based in the BRI) does not reflect uniformly what one would normally expect in a prestigious teaching hospital.

30 This is partly the fault of UHBT’s approach to histopathology which historically has been to fail to appreciate adequately how central it is to so many clinical specialties. Histopathology provides crucial information for many diagnoses and can be pivotal to major decisions on the course of treatment for patients (pathology has been described as "the hidden science at the heart of modern medicine") and yet the Trust has not given sufficient priority to its histopathology service, especially in respect of adequate staffing.

- 31** The central issue of concern relating to the UHBT histopathology department is the culture of the department and the attitude of some of the individual histopathologists. The Culture/Attitude section of the Report gives several examples of the kind of behaviour and attitude which has concerned us.
- 32** It is vital that there is an open and learning culture in which pathologists seek the advice of colleagues from within and outside their own department and in which mistakes are acknowledged and lessons learned. There is no place for arrogance or excessive confidence. Even the most experienced pathologists need to be aware of their own limitations, willing to seek advice, respond constructively to criticism and learn from mistakes.
- 33** The culture in the histopathology department at UHBT veers towards the opposite of what is required. We have observed a culture which is at times defensive, responds aggressively to criticism, is sometimes unwilling to acknowledge, let alone learn from, mistakes, and which is based on overconfidence bordering on arrogance.
- 34** There have been errors, although very few of the 26 cases which are at the heart of this Inquiry involved major errors of misdiagnosis. Histopathology relies on judgement and interpretation, and differences of opinion and occasional errors inevitably occur. What matters is not so much the fact that errors or discrepancies have occurred and are discovered, but how often the errors occur, the response to those errors and the quality assurance processes to minimise the frequency and consequence of errors.

- 35** It was evident that, in common with other cities that have more than one NHS Trust, there is an element of professional rivalry and professional jealousy between some of the departments and indeed between some of the clinicians in these Trusts. The effect of this disharmony was described succinctly by one of the witnesses:

“That rivalry has been incredibly damaging to the sane and rational distribution of services.”

- 36** We soon realised that this was particularly the case between some of the individuals within the two histopathology departments in Bristol. It appeared to be a long-standing and deep-seated problem which had led to a lack of respect and trust between them.

- 37 We heard phrases such as *'power struggle'*, *'playground behaviour'*, *'a Bristol disease which chips away at itself'* from various witnesses describing the relationship between the two Trusts, and in particular the two histopathology departments.
- 38 Professional competition is healthy. Professional rivalry which damages the sane and rational distribution of services is not.
- 39 The culture of *'a Bristol disease which chips away at itself'* and attitudes more suitable to the playground than to the NHS must change if there is to be a safe and effective histopathology service for the city's patients.

Management

- 40 We interviewed people at every level of the management structure.
- 41 It appears that the Medical Director, Dr Jonathan Sheffield, decided to take on a direct role in resolving any problems in the histopathology department, despite the fact that we were told by him that as from July 2005 the Medical Director was not the direct line manager in the management structure.
- 42 The Management section in the Report deals with the appropriateness and effectiveness of this decision. It runs to some 87 pages.
- 43 Our Terms of Reference [See **Annexe 1**] did not ask us to (and therefore we did not carry out) a detailed examination of clinical and corporate governance systems, although we do comment on some matters of governance in the Report.
- 44 However, because the concerns about possible misdiagnosis were not reported through the proper channels, and because the investigation of those allegations was not conducted with any kind of systematic approach and was inadequate – mainly because of the underlying belief that they were vexatious – the systems and processes were untested and therefore it probably would not have been possible to identify if or how governance systems failed.

- 45 The first concerns about the UHBT adult histopathologists were contained in a letter dated 31 August 2004 which was written by the NBT respiratory physicians and sent to a consultant thoracic surgeon at UHBT. The letter was copied to 14 other people including Dr Jonathan

Sheffield and Dr Martin Morse (the Medical Directors of UHBT and NBT respectively), clinicians at both Trusts, the Trust Lead for Clinical governance at NBT and Dr Morgan Moorghen, the Head of the Histopathology Department at UHBT.

- 46** This letter contained serious allegations relating to patient safety and made a formal request for the transfer of surgical lung pathology specimens from NBT patients to the NBT histopathologists Dr Ibrahim and Dr Ed Sheffield (who until 2002 had been a histopathologist at UHBT).
- 47** Despite the seriousness of the contents of the letter, it appears that these issues had not previously been raised with Dr Morse, the Medical Director of NBT, and the letter was sent to a surgeon at UHBT and copied in a ‘scattergun’ fashion to 14 other people.
- 48** We deplore the manner in which these concerns were raised. If they were genuine concerns about the competence of the UHBT histopathologists to safely report complex lung pathology, this was not the way to go about addressing those concerns. Making serious allegations about patient safety in a letter copied so widely could only have the effect of entrenching the professional rivalry and resentment between the histopathology departments in the two Trusts, and was yet another example of what one witness described as ‘the playground behaviour’ that at times seems to be the hallmark of the way that the two Trusts deal with each other.
- 49** Some of the NBT physicians who signed the letter now accept that they should not have conveyed their concerns in this way. Unfortunately, the letter of 31 August 2004 was not the only letter or e-mail containing allegations against the UHBT histopathologists which was sent by clinicians at NBT and copied to various colleagues. There appears to have been a tendency to express highly critical views in e-mails and letters which then were copied to a wider audience.
- 50** In our opinion this is an inappropriate and arguably unprofessional way to deal with concerns about patient safety. We have set out in our Recommendations what we consider to be a correct way to raise concerns about the competence of colleagues.
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- 51** In the Management section of the Report we set out in considerable detail the background to what was (or was not) happening between 2004 and 2008 in order to emphasise just how many opportunities were missed to deal with the allegations and to resolve the issues. It perhaps also illustrates how the cumulative effect of a ‘trickle of cases’ (as they were earlier described) led to the escalation of concern in 2008.
- 52** This escalation was fuelled by a lack of appropriate response by management. Neither Dr Sheffield nor Dr Morse appears to have been galvanised into action until 2008, by which time it was too late to deal with the issues ‘in-house’.
- 53** In our opinion the clumsy and unprofessional way in which the initial allegations were made in the letter of August 2004 in many ways set the tone for any response to those allegations.
- 54** Dr Sheffield did not ignore the allegations but he failed to investigate them sufficiently in order to be in a position to make a balanced judgement about the seriousness of the complaints.
- 55** Dr Sheffield told us that he had always felt that the allegations were vexatious in nature and it is clear that this belief coloured his approach to dealing with them.
- 56** When he did decide to act, Dr Sheffield intervened at an inappropriate level and took too much on himself (but then failed to see things through appropriately). There were three levels of ‘management’ below him, Dr Kabala as Head of Division, Professor Pignatelli as Clinical Lead and Dr Moorghen as Head of Department.
- 57** We discovered that Dr Kabala knew virtually nothing about any allegations of histopathological misdiagnosis between 2004 and 2008, despite being Head of Division for most of this time and Professor Pignatelli had very little impact on the issue of the competence of the UHBT histopathology department, despite being Clinical Lead from 2006 to 2009.
- 58** The Medical Director is inevitably remote from the day to day management of the department and we were told that as from July 2005 the Medical Director was not the direct line manager in the management structure of the histopathology department. This, however, makes us wonder why it was that Dr Sheffield assumed the role he did in dealing with the issues raised by NBT.

59 However, neither the Head of Division nor the Clinical Lead appear to have made any constructive contribution to resolving the issues in histopathology. Further clarity is required about individual responsibilities in this management structure.

60 We have absolutely no doubt that Dr Sheffield was trying to do his best, but as we have already said, his approach to the problem was coloured by his belief that the allegations were vexatious (as proved in his eyes by a lack of substantial evidence). When asked what he hoped this Inquiry would achieve he told us:

“We will hopefully put to rest the question about whether or not the allegations are true - that there are poor standards within our histopathology department - which I have never found any convincing evidence of.”

61 It is true that no evidence of actual cases was provided to anyone at UHBT until 2007, but that is because neither Dr Sheffield nor the UHBT histopathologists pursued the identification of the cases mentioned in the NBT physicians’ 2004 letter.

62 Even when 11 cases were identified in 2007, no investigation of those cases was carried out by Dr Sheffield or anyone else. The reason for this failure appears to be partly attitude and partly ineffectiveness.

63 In 2008 the two Medical Directors attempted an appropriate response by making an application for a review by the Royal College of Pathologists, but they gave the College mixed messages and did not pursue the further joint application that the College advised them to make.

64 From all of the evidence which we have seen and heard, it is clear that the concerns were not taken sufficiently seriously and were not properly investigated. Dr Sheffield allowed the histopathologists to respond defensively and aggressively to the original 2004 letter of complaint. No attempt was made to meet with the consultant physicians who raised the concerns. There was no follow up to any request for evidence to support the allegations.

65 Four years passed before an independent investigation was agreed, and even then, the arrangements proceeded ineffectively until the publication of the articles in *Private Eye*. Indeed, we formed the clear impression that this Inquiry was only established because of the

articles in *Private Eye* and that, had it not been for them, the issues would have continued to be ineffectively addressed.

- 66** There was not only a failure to investigate but there was also a failure to reply to letters and e-mails even though they came from senior colleagues and raised serious concerns. There was also the failure to consult the histopathologists and clinicians before making some major decisions which could affect their practices and their patients.
- 67** As we have already said, an Inquiry of this nature, scope and cost would never have been necessary or probably even contemplated had concerns been thoroughly and promptly investigated when and whenever they were raised and the results of those investigations made clear to those who had made the allegations.
- 68** Unfortunately, matters were not dealt with in a timely or an appropriate manner and, as a result, this Inquiry was commissioned and people will be left even more bruised and hurt.
- 69** As Dr Jonathan Sheffield told us:

“The way forward is leadership - and that is senior leadership both from the medical side and from the general management side - where people have one voice about what their goals and outcomes are, and that needs to happen consistently.”

- 70** It is vital that both Trusts’ management show strong leadership in the future to support those criticised in this Report, to help mend relationships, and to action the Recommendations which we make.

Competence

- 71** The competence of the UHBT histopathologists became an issue following allegations made by several NBT clinicians, two NBT histopathologists and in particular following the publication of the first (of many) articles in *Private Eye*.
- 72** A total of 26 cases were identified by the clinicians and histopathologists at NBT as being cases in which they felt that the diagnosis given by the original reporting histopathologist at UHBT was questionable. The cases covered an eight-year period between 2000 and 2008.
- 73** At the Panel's request, these 26 cases have been independently reviewed by Royal College of Pathologists and its findings, together with an overview analysis by Professor Peter Furness,

the current President of the Royal College of Pathologists, can be found at **Annexe 4**. The Royal College of Pathologists reviewers had access both to the slides which had been interpreted by the UHBT histopathologists to produce their original reports and to the clinical information that accompanied the original specimens, and subsequently to the original reports.

- 74** We have further reviewed all of the various opinions relating to these 26 cases and our analysis of them can also be found at **Annexe 4**.
- 75** Although every single error should be taken extremely seriously, the review by the Royal College shows that there were in fact very few cases of misdiagnosis amongst the 26 which were of the kind which no reasonably competent histopathologist should make.
- 76** It should also be remembered that the UHBT histopathologists report about 20,000 cases between them each year. 26 cases have been identified at NBT over almost a decade of such reporting. A sense of proportion must therefore be applied to any concerns arising from those 26 cases, although concern over any diagnostic error is entirely justified.
- 77** We discovered at the outset that the only concerns raised about the UHBT histopathology department had come from clinicians at NBT, and that no concerns had been raised by any clinician at UHBT or at any of the neighbouring Trusts who use the UHBT histopathology service, other than the concerns about the consequences of insufficient staffing in paediatric histopathology which is highlighted in the Paediatric Pathology section of this Summary. We were also told by Dr Martin Morse, former Medical Director at NBT, that on occasions UHBT surgeons had spoken to him and asked if he could use his influence to persuade the UHBT histopathologists to adopt specialist reporting.
- 78** This absence of reported concerns other than from NBT could be explained by a number of factors: either the concerns were unfounded and were driven by some unknown agenda of an individual or individuals at NBT; the concerns had substance and the clinicians at UHBT and the neighbouring Trusts were unaware that some of their patients' biopsies may have been misdiagnosed; or there was some truth in the allegations in that there had been some mistakes made in the reporting of histopathology specimens at the UHBT, but that these mistakes had been recognised and corrected at multidisciplinary team meetings (MDTs) at UHBT and the neighbouring Trusts (as often happens in any histopathology department), and therefore there

was nothing particularly worrying about the overall competency of the UHBT histopathologists.

- 79** Having thoroughly investigated all of the allegations, we have come to the conclusion that the reason why concerns were not raised by anyone outside NBT was a combination of all of the above.
- 80** On 15 November 2010 we were informed by Mr Robert Woolley, Chief Executive of UHBT, that he had only very recently discovered that the Nuffield Hospital in Bristol had undertaken their own random review of their patients where histopathology had been reported by pathologists at UHBT. They apparently did this in reaction to news of this Inquiry.
- 81** Following this review, the Nuffield Hospital notified Dr Jonathan Sheffield in May 2010 of one case of apparent misdiagnosis from 2007 potentially leading to serious harm and also indicated that they had identified two further cases of apparent discrepancy. We understand that a single histopathologist from the Nuffield Health Warwick Hospital carried out these three reviews but we do not know whether this same histopathologist carried out the full review.
- 82** It appears that Dr Sheffield instituted a clinical review by the UHBT consultants who reported on each case, however we do not know what their responses were to the concerns that had been raised about their original reports.
- 83** Because we do not know how many cases were reviewed by the Nuffield Hospital or from what period of time the cases were randomly chosen, we cannot draw any conclusions about the overall frequency of such discrepancies.
- 84** On the same day (15 November) we received information from a different source outside of the Trust which suggested that there may have been a case of wrongly reported cervical smear tests/colposcopy between 2008 and 2010. We were not sent any clinical documentation to support this allegation and therefore we do not know whether or not this was in fact a case where a histopathological error had been made. Nevertheless, we have ensured that the Trust is aware of this case and the concerns about possible misdiagnosis.
- 85** Unfortunately the information about these further cases came to us too late for us to carry out any further investigations before publication of the Report.

- 86** In addition to the 26 cases, an independent review was commissioned by the Trust of 3,500 cases taken from all specialties during 2007. This review was carried out by Pathlore, part of Source Bioscience (formerly known as Medical Solutions) and their results were subsequently analysed by a statistician, Ian White. We had access to both Source BioScience's and the statistician's analyses. Ian White's report can be found at **Annexe 5**.
- 87** We fully appreciate that the 26 cases — rather than the 3,500 cases reviewed by Source BioScience — are at the heart of this Inquiry.
- 88** The Trust's approach, through Dr Sheffield, appears to have been to evaluate competence by reference to whether or not the statistical results of the independent audit fall within 'acceptable' error rates, interpreted as being in the region of 1-2%.
- 89** We do not accept that this is the correct approach. Competence is not judged purely by whether or not results fall within 'acceptable' error rates. Competence is also qualitative, not merely quantitative.
- 90** We realise that the UHBT histopathologists may have been hoping that the independent audit — and this Inquiry — would completely exonerate them. However, in so far as the Panel's findings are based on the independent audit, it is difficult for us to do so.
- 91** We were not satisfied with the way in which the 3,500 cases were selected for audit. In our opinion specimens should have been selected only from those specialties where concerns had been raised, namely respiratory, gynaecology, breast and skin. We understand that the advice of the Royal College of Pathologists was sought by the Trust as to the best way to conduct the review, and that it was the College's advice which led to 3,500 cases from a single year being the basis of the audit. There is no doubt that the final selection has to some extent 'diluted' the effectiveness of assessing competency in these four specific specialist areas of concern.
- 92** We therefore did the one thing that we could do without spending even more money on a further review with more selective sampling: we invited Professor Peter Furness, the current President of the Royal College of Pathologists, to evaluate the evidence which was available to us and to give us his professional judgement on it.

- 93** Professor Furness wrote a detailed report setting out his findings based on the review of the 3,500 cases which can be found at **Annexe 6**. His findings reinforced our opinion that the real problem with the histopathology department at UHBT is not so much the diagnostic competence of the histopathologists, but their culture and attitude.
- 94** These are the salient findings of Professor Furness's report:

Design and Analysis

The case review study is extensive and I am satisfied that it exceeds the recommendations of the RCPATH as set out during initial discussions between the Professional Standards Unit of the RCPATH and the Medical Director of UHBT. However, because the audit was not selective the number of cases reported by each pathologist in each organ system is relatively small, especially in specialties where relatively few specimens are received by the laboratory (e.g. respiratory system). This needs to be considered if statistical analysis of such small sub-groups of cases is attempted...

Case Mix

The types of cases examined represent a broad spread of types of specimen from a variety of different organ systems, as I would have expected. I do not have an analysis of the normal case-mix of the histopathology department at UHBT but I have assumed that the sample examined is representative. It contains specimens from all the areas of principal concern (breast, gynaecology, respiratory and skin). The analysis provided to me includes a numeric breakdown of cases examined in each organ system (breast 257, gynaecology 592, respiratory 100 and skin 641)...

Comments on the frequency and nature of the discrepancies

I was presented with authorised reports identified as B1 discrepancies (A diagnosis which one is surprised to see from any pathologist) without any subsequent supplementary report providing a correction. This suggests that systems to identify errors before they cause patient harm were not in place...

It is notable that remarkably few of the original reports record any mention of seeking a second opinion from another pathologist. The reporting software used in Bristol includes a field identified as 'Additional reporting pathologists' but it is almost invariably empty, even

where the report identifies and discusses an area of diagnostic difficulty...there are some circumstances where there is national guidance indicating that two consultant opinions should always be obtained; for example, suspected epithelial dysplasia in distal oesophageal biopsies. Even in these circumstances the reports are almost invariably attributed to and authorized by a single pathologist...

Many of the reports are remarkably short, and it is not unusual to find reports where important items of information are missing...

Reading the original reports, many are in a style reminiscent of reports one reads when reviewing cases that were reported 10 or 20 years ago. A subjective impression is gained of a department that has not shown enthusiasm to keep up with modern developments. It would be relevant to evaluate the participation of the consultants in national educational meetings and other external CPD activities...

Conclusions

The overall rate of discrepancies identified by the audit suggests that, in 2007, there is some cause for concern about the overall performance of the histopathology department, in respect of areas discussed in my report above. The underlying causes cannot be identified with certainty from the material available to me but I suggest that the broader Inquiry currently being undertaken should examine the working practices in the department, particularly in relation to the sharing of difficult cases, the incorporation of second opinions into reports and checking of particularly significant or unexpected diagnoses, for example through the system of cancer multidisciplinary team meetings. The procedures used by the pathologists to keep up to date should also be scrutinised.

I was unable to detect evidence of any one pathologist giving cause for concern beyond the overall concerns about the function of the department, as discussed above...

I do not believe that a systematic pattern of error is identified, beyond the problems discussed (above)...

I have identified some patterns of discrepancy as set out above, but my firm impression is of a broader problem with the working patterns of the department."

- 95** Nothing that we can say about the competence of the UHBT histopathologists could add anything to Professor Furness's informed opinion, other than to highlight that what he says about the working practices of the department is of real concern to us and we therefore urge the Trust to take his report extremely seriously.
- 96** We also had the opportunity of investigating three alleged cases of misdiagnosis which occurred during the Inquiry process. Our comments on these cases are set out in the Competence section of the Report, and, in particular, our findings concerning a serious misdiagnosis in a case of tuberculosis are dealt with in some depth in the Culture/Attitude Section.
- 97** Competency must be judged not only on statistical results but also on the quality of the service being offered. Patients deserve the best possible service.
- 98** The histopathology department at the Bristol Royal Infirmary (BRI) needs to be brought up to date, not only in terms of the fabric of the building but also in respect of the practice and attitude of some of the histopathologists.
- 99** The histopathologists should be less certain of their diagnoses in intrinsically difficult cases and more willing to seek second opinions. They should participate in regular EQA and CPD activities in all specialties in which they choose to report.
- 100** There have certainly been some serious errors of diagnosis, but on the basis of the evidence that we have seen, it is difficult to judge if the error rate in the UHBT histopathology department is more or less than normal.
- 101** Overall there is no evidence to lead us to believe that the department provides anything other than a safe service, although it still has room and need for considerable improvement.
- 102** However, confidence in patient safety will only be achieved if lessons are learnt from the issues which have been raised in this Inquiry.
- 103** It became clear during the course of this Inquiry, that even if one could reassure everyone about the competence of the UHBT histopathologists, it would not necessarily restore people's confidence in them. It will take collaboration and goodwill between the two Trusts in order to achieve that.

Specialisation

- 104** There is no agreed definition of what a ‘specialist’ histopathologist is. In considering the meaning and relevance of ‘specialist’ in the context of this Inquiry, the Panel has taken account of the authoritative opinion of the Royal College of Pathologists.
- 105** The fundamental issue raised in 2004 was the allegation that the UHBT department was operating on a ‘generalist’ rather than a ‘specialist’ model.
- 106** We acknowledge that the development of specialist interests has been a challenge for many departments and particularly those that are insufficiently well staffed to adopt this method of working.
- 107** The UHBT histopathology department has not been adequately staffed and this has made it more difficult for the pathologists to develop specialist interests to a satisfactory level. There are at present only six full-time adult histopathologists in the department and it is therefore difficult for them to limit themselves to one or two specialist areas of reporting, as there would clearly not be adequate cover during periods of leave or any other absence.
- 108** It seems clear, from their initial response in 2004 and the events that followed, that, in any event, there was a resistance in principle to the development of specialist interests from at least some of the UHBT pathologists and an excessive confidence about their ability to continue to report across a wide range of specialties.
- 109** It will always be the case that pathologists share out much of the non-complex routine work. This happens in the NBT histopathology department. However, it is not only the routine work that is being shared in the UHBT department, even though a consultant with the relevant specialist interest will present the ‘specialist’ case at any MDT.
- 110** What is more worrying is that there also seems to be a reluctance in the UHBT department to participate in external quality assurance and continuing professional development to complement what they claim is their specialist expertise. Since 2004 there has been only a slow and, it seems reluctant, move towards the development of specialist working. However, the cultural resistance to specialising is such that certain individuals seem not to want to let go of their broad spread of work.

- 111** If, in 2004, there had been an acceptance that a generalist model was being operated in the department, and concomitantly an acceptance of the need to change, this Inquiry would probably never have been necessary. Instead, the response from the UHBT histopathologists to the NBT respiratory physicians' letter of August 2004 was to take great offence at being called "*general pathologists*" and to declare "*We challenge the view that we are not in specialist practice*". This was an inappropriate response and it surprises us that the histopathologists did not instead defend being generalists on the grounds that they were such a small department.
- 112** We are satisfied from all the evidence that we have seen that we would expect a trend towards specialisation, especially in an academic teaching hospital department that should be aspiring towards excellence and the development of its role as a referral centre for histopathologists working in neighbouring district general hospitals and further afield.
- 113** We acknowledge that there are not enough histopathologists at the BRI to develop genuine specialisation to the degree practised in many other major teaching hospitals. There is also the added problem that some of the UHBT histopathologists have wanted to 'specialise' in too many areas, taking the reporting lead in at least three specialties. It is difficult to keep up-to-date with EQA and CPD if one is practising in too many specialist areas. Indeed, the more specialties claimed by a histopathologist, the more likely they are to be regarded as a 'generalist'.
- 114** However, we consider it unacceptable that, even today, despite the original (and continuing) concern of the NBT clinicians being that they lacked specialist credentials in respiratory pathology, none of the UHBT histopathologists participates in a respiratory EQA scheme.
- 115** We have recommended that there should be a single histopathology service for the city of Bristol and that specialisation should be developed with full participation in appropriate EQA and CPD. The establishment of a single service will enable the development of specialist reporting. Once the two departments are combined, the people of Bristol will be served by a single team of more than 20 histopathologists. In a team of this size it should be possible to develop specialist reporting and to ensure that reporting is done by histopathologists with the appropriate expertise.
- 116** It will be important to ensure that, whenever clinical services are relocated, careful consideration is given to the consequences for histopathology. For example, the

histopathologists with the appropriate expertise could transfer some of their sessions with the services to the new location and steps taken to ensure that the facilities (e.g. office, microscopes) are satisfactory.

- 117** It will take strong management and exceptional clinical leadership to unify the two histopathology departments, but it can and should be done.
- 118** The histopathology service in Bristol should place the provision of excellent services to patients at the centre of everything it does. Personal and organisational rivalries should not be allowed to stand in the way of the provision of excellent services. The only question should be which histopathologists have the expertise to report on the specimen and thereby to give the greatest benefit to the patient.

Double Reporting

- 119** Some of the NBT histopathologists and clinicians who came to see us were concerned that UHBT histopathology cases were not ‘double reported’, even if complex cases. As can be seen in the ‘Competence’ Section, Professor Furness expressed surprise also at the infrequency of seeking a second opinion.
- 120** The risk of diagnostic errors and misinterpretations leading to patient harm can be reduced if two or more histopathologists review the case and agree on the diagnosis before decisions are made about how the patient should be treated or managed. Case review at MDT meetings often fulfils this, but only if the histopathologist who originally reported the biopsy, etc is not the histopathologist who subsequently reviews it for the MDT meeting.
- 121** Our findings in the Inquiry lead us to recommend that there should be a national protocol or standard for ‘double reporting’, much narrower and more specific than the five alternatives (a–e) mentioned in the College document (*Quality assurance in histopathology and cytopathology reporting practice*, February 2009). The need for standardisation is important to avoid and, if necessary, to resolve rival claims about whether a case has been double reported.
- 122** We recommend that, for a case to be regarded as double reported, two histopathologists should examine and discuss the case and then issue a diagnostic report in their joint names.
- 123** While double reporting, as defined in our recommendation, might be seen as the ideal

arrangement to minimise the risk of diagnostic errors, it cannot be mandated without a very substantial increase in the number of consultant histopathologists nationally.

Paediatric Pathology

- 124** Prior to the public Inquiry into children's heart surgery at the BRI chaired by Professor Ian Kennedy, the paediatric pathology department in Bristol was internationally acknowledged as world-class. The department had four consultant paediatric/perinatal pathologists as well as registrars and specialist technicians. It was situated in St Michael's Hospital (within UBHT).
- 125** The Interim Report of the Kennedy Inquiry (which dealt with organ retention) had a devastating effect on the paediatric pathology department and ultimately resulted in one of the consultant paediatric pathologists taking early retirement, and another, Dr Michael Ashworth, leaving Bristol within months. One of the four consultants had left before 2001 to take up a post in Australia. The remaining consultant, Dr Helen Porter, struggled on for a further year before resigning and obtaining a post elsewhere.
- 126** The 'final straw' for Dr Ashworth had been when he heard of a proposal to move the paediatric pathology department from St Michael's Hospital to the BRI. Neither he nor Dr Porter had been consulted about the intention to move the department.
- 127** The failure to consult those clinicians who had most knowledge about what was important and/or necessary for the paediatric pathology service became a recurring theme throughout the next decade.
- 128** In early 2002 a non-UK trained consultant paediatric pathologist, Dr Consolato Sergi was appointed by UBHT. As far as we are aware he had never practised in the UK before he came to Bristol. No clinical representative from the paediatric services was involved in his appointment.
- 129** Dr Porter resigned at the end of 2002, feeling unsupported, undervalued and undermined. Dr Sergi continued as the sole consultant paediatric pathologist, now covering both paediatric and perinatal cases, and the UBHT adult pathologists continued to report paediatric and perinatal cases in his absence and when there were too many cases for him to deal with alone.

- 130** Concerns were gradually raised about the competence of Dr Sergi, the sole paediatric pathologist in Bristol. Following alleged serious errors by him including misdiagnosis of a child who died of Hirschsprung's disease, he resigned and left the Trust in early 2004.
- 131** In October 2002 a Paediatric Pathology Strategy Group (PPSG) was set up led by Professor Michael Stevens. Its remit was to recommend ways in which paediatric pathology should be developed in the short-term and the medium-term, and then report to the Medical Director and Chief Executive. It was acknowledged that a strategic plan to rebuild paediatric and perinatal pathology in Bristol would need to address both specific local factors in the aftermath of the Kennedy Inquiry and the wider generic issues such as the shortage of paediatric pathologists and trainees and national issues created by the response to organ retention.
- 132** Professor Stevens submitted the PPSG's recommended service model in March 2003. It acknowledged that, whilst all members of the group supported the reconstruction of a strong paediatric and perinatal pathology service within UBHT, important differences emerged in the way this could and should be achieved. Principally these differences arose in two areas: first, in relation to the importance of maintaining a separate laboratory presence at St Michael's Hospital and second to the status and identity of the Paediatric and Perinatal Pathology service within the histopathology department as a whole.
- 133** The main recommendations were that there should be a clear identity for the Department of Paediatric and Perinatal Pathology but that it would function, managerially, within the Department of Histopathology as part of the Division of Laboratory Medicine. One of the consultant medical staff would be appointed as Head of Paediatric and Perinatal Pathology and would act as the lead clinician of the service within the department and the Directorate. The Head would be accountable to the Head of Histopathology and through them to the Clinical Director of the Division of Laboratory Medicine. All elements of paediatric and perinatal post-mortem work except tissue processing and all elements of fetal and perinatal (including placental) pathology except tissue processing would be provided from the St Michael's site with the support of designated technical staff and facilities while all elements of paediatric surgical pathology and tissue processing would be undertaken in the histopathology department at the BRI.

134 The Service Model proposed by the PPSG was never implemented. When we asked Professor Stevens what had happened he told us:

"The problem was that this report went to the executive level in the Trust, but I don't think anyone at the executive level ever ensured that the department, or...the pathology directorate actually implemented these recommendations...I never sensed that anyone thought this was really a problem that was theirs to solve. That probably summarises it best to me: no one really owned it. There wasn't the commitment at the head of pathology or within the directorate management, to see this as a priority...I did feel that people recognised there was an issue, it's just that no one took responsibility for addressing it. I also think that we were going through a very difficult time nationally in terms of the availability of paediatric pathologists, so it was very easy for people to say 'There is no solution to this; it doesn't matter what we do, we're not going to find anyone'."

135 This was perhaps yet another example of the relatively low priority given to paediatric pathology and the general lack of commitment to rebuild a strong paediatric pathology service in Bristol.

136 The PPSG had been set up by the Trust management and yet its recommendations appear to have gone unheeded or at the very least (as acknowledged to us by Professor Stevens who was not sure that it ever gained much steam) *"it certainly ran out of steam"*.

137 In late 2003 two new Consultant histopathologists had been appointed, Dr Pramila Ramani (paediatric pathology) and Dr Margaret Evans (perinatal pathology).

138 By May 2004 Dr Evans was expressing her concern and frustration about the poor clinical service that she perceived was being achieved because the paediatric and perinatal pathology service was on a 'split site', resulting in delays to the reporting of specimens. In early October 2004 she tendered her resignation, repeating her concerns about delays and her feeling of being unsupported. Although she was persuaded for a while to withdraw her resignation, she finally left the Trust in July 2005. Dr Evans' perinatal pathology post remained empty until it was filled by Dr Craig Platt on 1 May 2009.

139 From July 2005 Dr Pramila Ramani, who is highly regarded by the paediatric surgeons and clinicians, soldiered on as the sole paediatric pathologist. In the summer of 2010 a second

paediatric pathologist was appointed to start in September 2010, but unfortunately they decided to take up a post elsewhere shortly before they were due to start.

- 140** Significant problems arose at any time when Dr Ramani was absent (either on holiday or on study or sick leave). Until late 2008 her work was covered by the adult histopathologists. We were concerned when we were told that the paediatric surgeons felt obliged to change their clinical practice whenever Dr Ramani was away and pathological opinion was required for complicated cases.
- 141** We were told by a consultant paediatric surgeon that in autumn 2008 she was invited to represent the paediatric surgeons' point of view when the histopathology service was inspected for CPA accreditation. She told us that she had to say that as a paediatric group they were very unhappy with the service that they were getting, not because they had any problems with Dr Ramani, but that when she was away or on study leave they had no specialist paediatric pathology service at all and they felt that this had significant governance issues. They did not consider that cover by adult histopathologists was appropriate or acceptable. As a result, this was flagged up as a major non-compliance and full CPA accreditation was not given until the matter was addressed.
- 142** Accreditation was given following the appointment of Dr Craig Platt in 2009, but Dr Platt is in fact not a paediatric pathologist but a perinatal pathologist who does not cover any of Dr Ramani's surgical and oncological work.
- 143** In the spring of 2010 advertisements were published for two histopathology posts, one for an adult histopathologist and the other for a paediatric/perinatal pathologist. We were told that once again the paediatric clinicians/surgeons were not consulted at all before the advertisements went out and therefore had no input into their wording. Also there had been a lot of dissent from the Women and Children's division that nobody from their division had been invited to sit on the interview panel for the appointment of the paediatric/perinatal pathologist, which was perhaps surprising as they would be the main users of the services of the new pathologist. Apparently it was raised with the Trust and they subsequently ensured that someone from the Women and Children's division was on the Panel.
- 144** Once again the pattern was repeating itself that the people who had the most knowledge about what was needed in paediatric pathology were not being consulted on important issues

relating to the service. This lack of communication goes right back to the concerns which led to the resignations of two highly respected paediatric pathologists in 2001 and 2002.

- 145** It appeared to us that there was insufficient support for paediatric pathology in the past. It was acknowledged that paediatric pathology involves only a small part of histopathology in general and that the adult histopathologists may well have felt that because the number of cases which are actually being seen in paediatric pathology are much less than their workload, there was no need for any more paediatric pathologists. However, we believe that paediatric and perinatal pathology is extremely important and should be valued and supported by managers, other pathologists and clinicians. Bristol should be encouraged to rebuild its reputation as one of the leading centres in the UK — if not internationally — for paediatric and perinatal pathology.
- 146** We heard evidence of a potential opportunity of joint networking between the paediatric and perinatal pathology services in Bristol, Oxford and Southampton, firstly concentrating on providing clinical services and then perhaps collaborating on research. We recommend that such proposal should be strongly encouraged and that management supports such networking between these three centres to promote a strong paediatric and perinatal pathology service for the south west of England.

Patient Advocacy

- 147** The Panel recognises the considerable value of patient advocacy and believes that it should therefore be encouraged. It can be of great benefit to patients if, properly channelled, it raises awareness of the need to improve clinical services and health care more generally.
- 148** We therefore welcome the involvement of patient advocates in the National Health Service and greatly admire and respect the work that they do.
- 149** Although many people in their lives experience being a patient, there is a heavy responsibility on patient advocates to ensure that they are genuinely representative of their constituency. Therefore, any information which is potentially damaging to the confidence of patients must be evaluated very carefully before it is publicised.
- 150** We appreciate that it is sometimes difficult for a lay person to understand fully the nuances of complex clinical issues. Consequently, we recognise that this may make a lay person

vulnerable to people who do understand the clinical complexities but perhaps have their own agenda.

- 151** We heard and received a great deal of evidence from a patient advocate, Mrs Daphne Havercroft.
- 152** We do not doubt her motivation or sincerity and admire the hard work she does on behalf of patients. However, we have some concern that some information had been provided to her by individuals with their own agendas, the full context and significance of which perhaps she had not fully evaluated.
- 153** Her commitment to patient safety is admirable, but patient confidence is an important part of patient wellbeing, and it is therefore important not to lose sight of that fact when acting as a patient advocate.

Media Handling

- 154** The Trust's 'knee jerk' reaction to the first *Private Eye* article is a good example of its reactive relationship with the media. What is more, the response — which was to commission an independent review of 3,500 histopathological specimens and to set up this Inquiry — provoked several more articles in *Private Eye* as well as articles in the *Sunday Telegraph*.
- 155** We have not carried out a detailed analysis of the Trust's relationship with the media. However, we believe that proactive media relations are even more important in Bristol because of the legacy of the Kennedy Report. A lack of openness can lead to suspicions or accusations of intentional concealment.
- 156** How it handles the publication of our Inquiry report will be a challenge for the Trust and we would recommend that it approaches it — and all future relationships with the media — proactively with an emphasis on openness and honesty and with the involvement of senior management, including the Chief Executive and clinicians. This strategy should reinforce positive relationships with the media and with patients and the public.

Whistleblowing

- 157** The Panel would deeply regret it if this Inquiry and/or our Report in any way deters people in the future from reporting any concerns which they may have about a colleague's practice or competence. This would be entirely contrary to our intentions.
- 158** Although almost every witness we spoke to during the Inquiry process expressed their regret that matters had gone as far as the publication of articles in *Private Eye* and national newspapers detailing concerns about the histopathology department at UHBT, we would not wish it to be thought that we attach any blame to those who 'blew the whistle'. The blame must lie with those who failed to take any effective action when concerns were originally (and repeatedly) raised.
- 159** Although we have been critical of the way in which concerns were transmitted and have made recommendations as to how they should be dealt with in the future, we strongly believe that clinicians are in the best position to recognise deficiencies in the performance or competence of colleagues and that patient safety requires that any concerns relating to performance or competence should be reported promptly but appropriately. Anyone who reports their concerns should be treated with respect and discretion.
- 160** Neither do we blame Dr Hammond for publishing his article. As we have said elsewhere in the Report, we strongly believe that this Inquiry (or any other sufficiently comprehensive and/or independent review) would never have taken place without the appearance of the first *Private Eye* article. Although we would have preferred to have been allowed to conduct and conclude the Inquiry without the intervention of further articles both in *Private Eye* and the *Sunday Telegraph*, we understood fully that the journalists were only doing their job and were attempting to ensure that we were kept 'on our toes'.
- 161** It can never be easy to be a 'whistleblower' of matters involving colleagues, and we would hope that in future it is made easier for people with genuine concerns to pass those concerns on to those who can investigate them and, where necessary, deal with them appropriately.

Recommendations

	Recommendation	Action
A	<p>A single Histopathology Service should be established for Bristol with the potential to be one of the leading service and academic centres.</p> <ol style="list-style-type: none"> 1. Consultant staffing levels should be reviewed in accordance with the Royal College of Pathologists' <i>"Guidelines on staffing and workload for histopathology and cytopathology departments"</i> (2nd edition) June 2005, and, if necessary, adjusted to ensure they are sufficient for a safe, timely and reliable service. 2. The service should for the time being remain on two sites. 3. The unified service should be managed by a lead Trust unless the two Trusts have been merged. 4. The unified service should have strong management and effective clinical leadership. 5. A Job Description for the post of Head of the new integrated department should be prepared with adequate sessional provision for their managerial responsibilities. 6. All future consultant appointments should be joint appointments between the two Trusts unless they have merged. The appropriate clinicians should be involved depending on the specialist interest[s] of the post. 7. Consultants should work across both sites when necessary to provide the optimum service to patients. 8. Specialisation should be developed with full participation in 	<p>UHBT</p> <p>NBT</p>

	<p>appropriate EQA schemes and attendance at relevant CPD events.</p> <p>9. The MDTs in both Trusts should be reviewed to promote collaboration.</p> <p>10. An audit programme should be established for all specialties.</p> <p>11. The BRI histopathology department should be upgraded.</p> <p>12. Implementation of a unified histopathology service for Bristol should be carefully planned and should include direct involvement of all consultants and other staff, facilitation by an experienced external facilitator and the involvement of patient representatives.</p> <p>13. The histopathology service should place the provision of excellent services to patients at the centre of everything it does. Personal and organisational rivalries should not be allowed to stand in the way of the provision of excellent services.</p>	
B	<p>Management Structure</p> <p>If the current management structure for the Histopathology Department is to remain, there should be clarification of the roles and responsibilities of Head of Division, Clinical Lead and Head of Department.</p>	UHBT
C	<p>Relocation of Services</p> <p>Whenever services are re-located, careful consideration must be given to the consequences for histopathology. The histopathologists with the appropriate expertise should transfer with the services to the new location where suitable facilities for them should be provided.</p>	<p>UHBT</p> <p>NBT</p>

D	<p>Double Reporting</p> <p>The term ‘double reporting’ is often used loosely.</p> <p>1. The Royal College of Pathologists should agree a national definition of double reporting which we suggest should be:</p> <p><i>“For a case to be regarded as double reported, two histopathologists should examine and discuss the case and then issue a diagnostic report in their joint names.”</i></p> <p>We suggest that the normal process should be as follows;</p> <p>(a) The pathologist examines the case. If the case is straightforward, and not involving the specialties where double reporting is mandatory, the pathologist should prepare the report.</p> <p>(b) If the case involves the specialties where double reporting is mandatory that should be arranged.</p> <p>(c) If the pathologist feels that it would be helpful to have the views of a colleague informally that should be arranged. Informal consultation of this kind should be encouraged in order to promote a learning culture.</p> <p>(d) If the case is doubtful or difficult, double reporting should be arranged.</p> <p>(e) If a second opinion is required from outside the department that should be arranged. An interim report should be prepared which should make it clear that a second opinion is being arranged.</p> <p>(f) Until the new integrated department is established second opinions from the ‘other’ Bristol department should be regarded as from ‘outside’ the department.</p> <p>(g) Until the new integrated department is established,</p>	<p>RCPATH</p> <p>UHBT</p> <p>NBT</p>
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	<p>histopathologists should be encouraged to ask colleagues in the other Bristol department for a second opinion where appropriate.</p> <p>2. The histological slides should be available for review and presentation at the MDT meeting for any case involving histopathological interpretation.</p>	
E	<p>Raising Concerns</p> <p>1. Any concerns about the standard of pathology reporting should be thoroughly, rapidly and, where appropriate, independently investigated and the results made available to all those involved.</p> <p>2. Concerns should be dealt with at the lowest possible level and not escalated unnecessarily.</p> <p>3. The pathologist(s) involved should be consulted directly.</p> <p>We suggest that the process should be as follows:</p> <p>a) If a pathologist, or any other clinician, is concerned about a pathology opinion the first step should be informal discussion with the pathologist who prepared the report. The spirit of the discussion should be one of enquiry and learning.</p> <p>b) If the matter is not resolved the concern should be raised with the Head of Department of the person raising the concern who should discuss the matter with the Head of Department of the pathologist who prepared the report.</p> <p>c) If the concern is not resolved by the Heads of Department the issue should be raised with the Head of Division of the person raising the concern who should discuss the matter with the Head of Division of the pathologist who prepared the report.</p> <p>d) If the concern is not resolved by the Heads of Division the matter should be raised with the Medical Director of the person</p>	<p>UHB</p> <p>NBT</p>

	<p>raising the concern who should discuss the matter with the Medical Director of the pathologist who prepared the report.</p> <p>e) If the concern is not resolved by the Medical Directors the matter should be raised with the Chief Executive of the person raising the concern who should discuss the matter with the Chief Executive of the pathologist who prepared the report.</p> <p>f) The person raising the concern and the pathologist who prepared the report should be appropriately supported at all stages.</p> <p>Where appropriate, an audit of relevant specimens should be conducted.</p>	
F	<p>Whistleblowing</p> <p>The Department of Health should review advice on whistleblowing to ensure that local policies include clear guidance on raising concerns about the work of a pathologist or any other clinician who works for a different Trust from the Trust employing the person raising the concern.</p>	Department of Health
G	<p>Relationships with the Media</p> <p>Proactive media relations are even more important in Bristol because of the legacy of the Kennedy Report.</p> <ol style="list-style-type: none"> 1. Relationships with the media should be proactive with an emphasis on openness, honesty and the involvement of senior managers and clinicians including the Chief Executive. 2. Relationships with the media should reinforce positive relationships with patients. 3. Service change should be explained. 	UHBT

	<p>4. The Trust website should be kept up to date.</p> <p>5. The handling of our Report will be the first challenge of the new approach to relationships with the media.</p>	
H	<p>Paediatric and Perinatal Pathology</p> <p>1. Paediatric and perinatal pathology should be valued and supported by managers, pathologists and other clinicians.</p> <p>2. The minimum level of staffing should be one paediatric pathologist, one perinatal pathologist and one pathologist trained in both paediatric and perinatal pathology.</p> <p>3. Joint working between the paediatric and perinatal pathologists in Bristol, Southampton and Oxford should be strongly encouraged.</p>	UHBT
I	<p>Patients and Histopathology</p> <p>1. The Department of Health and the Royal College of Pathologists should work together to improve further patients' understanding of the role of histopathology.</p> <p>2. The Trust should develop proactive and constructive relationships with patients and patient advocates.</p> <p>3. Where a patient's care is going to be discussed at a multidisciplinary team meeting, patients should not be given information contained in histopathology reports until the reports have been considered by the multidisciplinary team.</p> <p>4. Where errors of diagnosis are identified, patients should be promptly informed.</p>	<p>Department of Health</p> <p>RCPATH</p> <p>UHBT</p> <p>NBT</p>

J	<p>Specialist Pathology</p> <ol style="list-style-type: none"> 1. The Royal College of Pathologists should review its guidance on ‘specialist’ histopathology with the intention of making it more explicit where possible. 2. There should be at least two specialist histopathologists in each subspecialist area to allow proper review and to provide cover for meetings and periods of leave. 	<p>RCPATH</p> <p>UHBT</p> <p>NBT</p>
K	<p>Trainees</p> <p>Trainees should have supervised involvement in the full range of specimens, including the most complex cases, in accordance with their seniority and experience.</p>	<p>UHBT</p>
L	<p>The Aftermath of this Inquiry</p> <ol style="list-style-type: none"> 1. The histopathologists should be given whatever support they need to face the aftermath of this Inquiry including skilled facilitation. 2. Consideration should be given to inviting the Inquiry Panel to return within the next 12 months to review what steps are being taken to address these Recommendations . 	<p>UHBT</p> <p>NBT</p>

The Independent Inquiry into Histopathology Services

Inquiry report

1. INTRODUCTION

- 1.1** On 10 June 2009 *Private Eye* published an article [See **Annexe 2**] by Dr Phil Hammond, author of the ‘Medicine Balls’ column, which criticised the lack of an independent external review following concerns raised in a letter written in 2007 detailing 11 alleged serious diagnostic errors made by histopathologists based at the Bristol Royal Infirmary (BRI). This large teaching hospital is part of University Hospitals Bristol NHS Foundation Trust (UHBT), formerly United Bristol Healthcare NHS Trust (UBHT).
- 1.2** Within days the Trust announced that it was to set up an independent review of histopathology specimens reported by the UHBT pathologists. The Trust commissioned Medical Solutions (since 1 January 2010 known as Source BioScience Healthcare), a company providing diagnostic and screening services to NHS and private healthcare, to carry out this review and also to review 26 specific cases of alleged diagnostic errors by the UHBT histopathologists. Source BioScience subsequently audited 3,500 cases randomly selected from histopathology specimens reported at UHBT in 2007 in addition to the 26 cases.
- 1.3** In July 2009 the Trust announced that it was to commission an Independent Inquiry to draw conclusions from the results of the independent review, to scrutinise the performance of the histopathology service at UHBT, and to consider whether appropriate action was taken by the Trust to address any concerns which had been raised about the performance of the UHBT histopathology service.
- 1.4** Our Terms of Reference [See **Annexe 1**] did not ask us to (and therefore we did not) carry out a detailed examination of clinical and corporate governance systems, although we do comment on some matters of governance in the Report.
- 1.5** The most widely cited formal definition of clinical governance describes it as:

“A framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.” [Scully and Donaldson, 1998]

1.6 This definition is intended to embody three key attributes: recognisably high standards of care, transparent responsibility and accountability for those standards, and a constant dynamic of improvement.

1.7 In March 2009 the Trust produced a document '*An Organisation-wide Policy for the Management of Incidents*'. It is clear from the document that its content had remained largely unaltered since its original publication in 2003, although an extension of it had been approved in March 2007 by Dr Jonathan Sheffield and Irene Scott who co-chaired the Trust Health and Safety and Clinical Risk Assurance committees

1.8 In the Introduction it is stated:

"As part of the Risk Management Strategy, UH Bristol Trust supports prompt reporting of all incidents whether clinical, non-clinical or 'near misses' to improve patient and staff safety and quality of care..."

Reporting, investigation and learning from incidents is a key element of risk management activity..."

1.9 It can be seen from our Report that we have serious concerns about the reporting and the investigation of the incidents of alleged misdiagnosis of histopathology at UHBT and we also have our doubts as to whether many lessons have been learned since the Kennedy Inquiry.

1.10 The purpose of the Policy was stated to be:

"To ensure there is a structured, consistent and systematic approach to the reporting and investigation of incidents which led to, or could have led to harm."

1.11 However, because the concerns about possible misdiagnosis were not reported through the proper channels, and because the investigation of those allegations was not conducted with any kind of systematic approach and was inadequate – mainly because of the underlying belief that they were vexatious – it has proved impossible to identify if or how governance systems failed.

A Summary of the Background

- 1.12** Concerns had been raised about histopathology services at UHBT before 2007.
- 1.13** The earliest were in 2001 regarding paediatric histopathology and were about the lack of sufficient staff and adequate cover and followed the disintegration of a highly regarded service.
- 1.14** The ‘organ retention scandals’ nationally had a devastating effect on the paediatric pathology department at St Michael’s Hospital (which had previously been internationally acknowledged as world class) and ultimately resulted in one of the consultant paediatric pathologists taking early retirement, and another leaving Bristol within months. One of the four consultants had left before 2001 to take up a post in Australia. The remaining consultant, Dr Helen Porter, a highly respected perinatal pathologist, struggled on for a further year before resigning and obtaining a post elsewhere.
- 1.15** Despite repeated requests for the paediatric pathology department to be replenished as a matter of urgency, there were no new appointments made in 2001.
- 1.16** In August 2001, the UHBT adult pathologists offered to report any paediatric work which could not be dealt with by the sole remaining paediatric pathologist. A decision was made to transfer paediatric pathology to the BRI and for the adult pathologists to report the paediatric cases as well as their own cases (the transfer was made in October 2001 but the perinatal pathology service and Dr Porter remained at St Michael’s Hospital). These decisions were made against the wishes and expressed concerns of the paediatric clinicians who were neither consulted about the transfer nor invited to meetings where these decisions were taken. However, they had made it quite clear that, in their opinion, the adult pathologists at UHBT did not have the requisite expertise in reporting paediatric cases, especially the more complex cases such as Hirschsprung’s disease and Wilms tumours.
- 1.17** Following the transfer of thoracic surgery to the surgeons at UHBT in 1997, all surgical lung pathology cases from across the whole of Bristol were reported by the UHBT pathologists. As a result, Dr Nassif Ibrahim, an NBT histopathologist whose specialist interest was in interstitial lung disease pathology, lost some of his specialist work, although the intention of both Trusts was that Dr Ibrahim would continue to report those specialist cases which would entail spending some of his time at UHBT.

- 1.18** In August 2004 a letter was written by five respiratory physicians from North Bristol NHS Trust (NBT) to a thoracic surgeon at the BRI but copied to 14 other individuals including the Medical Directors of both UHBT and NBT and all of the UHBT consultant pathologists. The letter expressed the physicians' concern about the reporting of lung biopsy and resection specimens of NBT patients which had been referred to the pathology service at UHBT. The concerns were based on the perception that the reporting was being carried out by 'general pathologists' at UHBT who were not 'specialist' lung pathologists. The letter also stated that *"This has led to a number of incorrect diagnoses and in 2 recent cases serious adverse clinical effects for our patients"* and requested that lung pathology should be transferred back to the NBT histopathologists.
- 1.19** Between September 2004 and January 2007 the only other concern raised by the NBT respiratory physicians was in March 2005 when one of them wrote to the Medical Director at NBT, describing a recent case of alleged misdiagnosis at UHBT and again asking for lung pathology to be sent back to NBT.
- 1.20** In January 2007 the Lead Clinician for Respiratory Medicine at NBT raised further concerns with Dr Jonathan Sheffield, the Medical Director of UHBT, relating to the difficulties experienced by the NBT respiratory physicians in obtaining from the UHBT pathology department the pathology slides of NBT patients for review at their lung cancer MDT meetings. Similar concerns were expressed in July 2008.
- 1.21** In early July 2007 Dr Nassif Ibrahim one of the consultant histopathologists at NBT wrote to Dr Sheffield detailing 11 cases in which he alleged errors in diagnosis had been made by the pathologists at UHBT. In October 2007 Dr Ibrahim was quoted in an article about the proposed centralisation of breast surgery at St Michael's Hospital reported in the Bristol Evening Post as saying that *"some aspects of pathology services at St Michael's are not up to standard"*. Six days later a press statement issued by UHBT responding to that article said that the consultant was misquoted and that UHBT's breast pathology service met national cancer standards. However, some months later in 2008 concerns were expressed at NBT about the reporting of breast pathology by the UHBT histopathologists.
- 1.22** Also in 2007 Dr Lynn Hirschowitz one of the NBT pathologists who was a nationally acclaimed gynaecological histopathologist raised concerns about the reporting of several gynaecological cases by the UHBT histopathologists. From 1 April 2007 specialist

gynaecological cancer services had been centralised in Bristol and gynaecological cancer pathology was subsequently reported solely at UHBT. As a result, Dr Hirschowitz was deprived of her specialist interest work.

- 1.23** In October 2008 Dr Sheffield submitted a formal application to the Royal College of Pathologists (RCPath) to carry out an external review of its histopathology service. It was intended that this should be a joint review with NBT and a letter was sent by Dr Martin Morse, the Medical Director of NBT, confirming this. However, because the Trusts appeared to be asking them to conduct the review on slightly different bases, the College was unclear exactly what it was being asked to do and wrote to Dr Sheffield:

“From the information you have submitted it appears that dysfunctional interdepartmental relationships are likely to be an important factor and both Trusts should understand that there is only so much a College review can achieve in resolving these difficulties.

The College is asking for clarity about what we are being asked to review – individual errors, wider working relationships between the two departments, or both.”

- 1.24** The College requested more information and stated that the apparent difference of emphasis between the application from Dr Sheffield and the letter from Dr Morse would need to be reconciled in a revised and joint application by both Trusts with agreed terms of reference. No further application appears to have been made to the College.

- 1.25** It was not until the publication of the *Private Eye* article in June 2009 that any kind of independent investigation into the concerns which had been raised over the years was actually instigated.

The Inquiry Process

- 1.26** The members of the Inquiry Panel were appointed in August 2009. Initially the consultant oncologist on the Panel was Dr Fergus Macbeth (Director of the Centre for Clinical Practice at NICE) but unfortunately, once it was recognised that the Inquiry was likely to take a great deal longer than had originally been anticipated, he had to step down because of his work commitments and in January 2010 he was replaced by Dr Margaret Spittle, Consultant Clinical Oncologist.

- 1.27** One of the first things that the Panel did was to amend their Terms of Reference so that they could inquire into all matters which had led to the concerns raised since 2004 about possible misinterpretation and/or misdiagnosis of histopathology specimens, rather than just inquire into any concerns raised since 2004 (as had originally been proposed by the Trust).
- 1.28** The fact that the Inquiry had been commissioned was widely published locally and the Trust set up a website dedicated to the Inquiry in order to inform any interested parties as to how they could take part in the process and to keep people up to date with the progress of the Inquiry and any relevant developments.
- 1.29** At the beginning the management and administration of the Inquiry was handled by the legal department of the Trust, but the Inquiry Panel were concerned that this might affect (or be seen as affecting) the independence of the Inquiry process and they therefore requested that an independent body should be appointed to run the Inquiry. Therefore, on 20 November 2009, Verita, a specialist management consultancy that conducts and manages independent investigations, reviews and inquiries, were appointed to take over the running of the Inquiry. Both the Panel and the Trust recognised the importance of ensuring that the Inquiry was – and, more importantly, was seen to be – totally independent.
- 1.30** The Panel was initially provided with two lever arch files of documents which mainly consisted of correspondence and minutes of meetings relating to the concerns about the histopathology service which had been raised since 2004. We were also given the details of the 26 cases in which there had been issues raised by clinicians at NBT over the diagnoses reported by the UHBT pathologists, although the cases were anonymised to protect patient confidentiality.
- 1.31** During the course of the Inquiry process we received a great deal more documentation both from the Trust and from individual witnesses.
- 1.32** The interviewing of witnesses began towards the end of November 2009. In total 58 witnesses were seen, some of them more than once. The witnesses included four Chief Executives, three Medical Directors, two Heads of Division, three Heads of Department, one Clinical Lead, two Biomedical Scientists, 12 Histopathologists, nine Respiratory Physicians, one Professor of Paediatric Oncology, three Gynaecological Surgeons, one Breast Surgeon, two Cardiothoracic Surgeons, the Medical Director and Director from Cancer Network, the Medical Director of Source Bioscience, the widower of one of the patients whose case was

included in the 26 cases (unfortunately, until the *Sunday Telegraph* article reported on 29 August 2010, the family were not aware that there was any doubt about the original diagnosis; the patient herself was never told that there was any doubt), two patient advocates and Dr Phil Hammond who wrote the *Private Eye* articles.

- 1.33** Because we had concerns about the way in which the 3,500 cases were selected for audit, we invited Professor Peter Furness, the current President of the Royal College of Pathologists, to evaluate the evidence relating to this audit which was available to us and to give us his professional judgement on it.
- 1.34** One of our main concerns was that the inclusion among the 3,500 cases of *all* specialty areas, particularly those (e.g. gastrointestinal, urological, osteoarticular) where no allegations of misdiagnosis had been made, could conceal significantly high error rates in the specialties (e.g. gynaecological, breast, respiratory) at the focus of this Inquiry. The dilution by specialties of no concern could weaken the statistical reliability of the audit in terms of its ability to confirm or refute significant error rates in the specialties alleged to be unsafe.
- 1.35** Professor Furness's report on the 3,500 case review can be found at **Annexe 6**.
- 1.36** In addition we invited a senior and experienced histopathologist from another academic centre, Dr Ray McMahon, Senior Lecturer in Pathology and Honorary Consultant Pathologist in Manchester, to give us expert advice on histopathological diagnosis and on the nature and definition of diagnostic error. His report can be found at **Annexe 3(ii)**.
- 1.37** As this was not a public inquiry, we could choose to and did hold the interviews in private. This was the Panel's choice, not the Trust's. It was felt to be important that witnesses could come forward, if necessary, without their employers and colleagues knowing that they had, and that they should feel that they could come and talk freely to the Panel. We are extremely grateful for the frankness and openness with which most people gave their evidence, particularly as we were always mindful that it is extremely difficult to criticise colleagues even if one has serious concerns about some areas of those colleagues' practices. We were also anxious that the evidence should be as broad-based as possible and welcomed the fact that a considerable number of witnesses came forward to give positive and supportive comments about the UHBT pathologists as a balance to those who volunteered more adverse criticisms.

1.38 There are two hospital Trusts in the city of Bristol, University Hospitals Bristol NHS Foundation Trust (UHBT) and North Bristol NHS Trust (NBT).

1.39 It was evident that, in common with other cities that have more than one NHS Trust, there is an element of professional rivalry and professional jealousy between some of the departments and indeed between some of the clinicians in these Trusts.

1.40 As one of the witnesses we interviewed so succinctly described the situation:

“That rivalry has been incredibly damaging to the sane and rational distribution of services.”

1.41 We soon realised that this was particularly the case between some of the individuals within the two histopathology departments in Bristol. It appeared to be a long-standing and deep-seated problem which had led to a lack of respect and trust between them.

1.42 We discovered at the outset that the only concerns raised about the UHBT histopathology department had come from clinicians at NBT, and that no concerns had been raised by any clinician at UHBT or at any of the neighbouring Trusts who use the UHBT histopathology service, other than the concerns about the consequences of insufficient staffing in paediatric histopathology which we deal with later in the Report. We were also told by Dr Martin Morse, former Medical Director at NBT, that on occasions UHBT surgeons had spoken to him and asked if he could use his influence to persuade the UHBT histopathologists to adopt specialist reporting.

1.43 This could be explained by a number of factors: either the concerns were unfounded and were driven by some unknown agenda of an individual or individuals at NBT; the concerns had substance and the clinicians at UHBT and the neighbouring Trusts were unaware that some of their patients' biopsies may have been misdiagnosed; or there was some truth in the allegations in that there had been some mistakes made in the reporting of histopathology specimens at the UHBT, but that these mistakes had been recognised and corrected at multidisciplinary team meetings (MDTs) at UHBT and the neighbouring Trusts (as often happens in any histopathology department), and therefore there was nothing particularly worrying about the overall competency of the UHBT histopathologists.

- 1.44** Having thoroughly investigated all of the allegations, we have come to the conclusion that the reason why concerns were not raised by anyone outside NBT was a combination of all of the above.
- 1.45** On 15 November 2010 we were informed by Mr Robert Woolley, Chief Executive of UHBT, that he had only very recently discovered that the Nuffield Hospital in Bristol had undertaken their own random review of their patients where histopathology had been reported by pathologists at UHBT. They apparently did this in reaction to news of this Inquiry.
- 1.46** Following this review, the Nuffield Hospital notified Dr Jonathan Sheffield in May 2010 of one case of apparent misdiagnosis from 2007 potentially leading to serious harm and also indicated that they had identified two further cases of apparent discrepancy. We understand that a single histopathologist from the Nuffield Health Warwick Hospital carried out these three reviews but we do not know whether this same histopathologist carried out the full review.
- 1.47** It appears that Dr Sheffield instituted clinical review by the UHBT consultants who reported on each case, however we do not know what their responses were to the concerns that had been raised about their original reports.
- 1.48** Because we do not know how many cases were reviewed by the Nuffield Hospital or from what period of time the cases were randomly chosen, we cannot draw any conclusions about the overall frequency of such discrepancies.
- 1.49** On the same day (15 November) we received information from a different source outside of the Trust which suggested that there may have been a case of wrongly reported cervical smear tests/colposcopy between 2008 and 2010. We were not sent any clinical documentation to support this allegation and therefore we do not know whether or not this was in fact a case where a histopathological error had been made. Nevertheless, we have ensured that the Trust is aware of this case and the concerns about possible misdiagnosis.
- 1.50** Unfortunately the information about these further cases came to us too late for us to carry out any further investigations before publication of the Report.
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- 1.51** Histopathology is not an exact science. As recognised in the first *Private Eye* article, “*interpreting tissue slides is stressful and complex, and some mistakes inevitably happen.*”
- 1.52** The pathological diagnosis of tissue is a matter of interpretation of the individual pathologist and even the most expert pathologists may well come to different conclusions about difficult specimens. [See Annexe 3]
- 1.53** One must therefore distinguish between a difference of opinion in a difficult case — as sometimes occurs when two histopathologists interpret the same biopsy — and an obvious misdiagnosis which no reasonably competent histopathologist should make.
- 1.54** As already stated, 26 cases had been identified by clinicians at NBT as being a cause of concern, after having been reviewed by NBT histopathologists. The reporting of these 26 cases had taken place between 2000 and 2008.
- 1.55** These 26 cases were further reviewed both by Source BioScience and by the Royal College of Pathologists and we have prepared our own ‘overview’ of these reviews. [For the RCPPath’s and the Panel’s reviews see Annexe 4]
- 1.56** It is these 26 cases which are the heart of this Inquiry, rather than the 3,500 cases reviewed by Source BioScience.
- 1.57** The review by the Royal College of Pathologists shows that there were in fact very few cases of misdiagnosis amongst the 26 which were of the kind which no reasonably competent histopathologist should make. However, every single error should be taken extremely seriously and lessons should be learned to try to avoid similar errors re-occurring.
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- 1.58** An Inquiry of this nature, scope and cost would never have been necessary or probably even contemplated had concerns been thoroughly and promptly investigated when and whenever they were raised and the results of those investigations made clear to those who had made the allegations.

- 1.59** The failure to do so meant that matters escalated out of all proportion and the already strained relationship between the histopathology services in the two Bristol Trusts became even more deeply entrenched.
- 1.60** It was the cumulative effect of repeated allegations being allowed to linger or be unsatisfactorily answered which led to the perceived necessity to ‘blow the whistle’ by going to *Private Eye*.
- 1.61** The concerns which had been raised on various (but not frequent) occasions over several years were about mistakes of varying degrees of seriousness which could, and should, have been dealt with swiftly and without rancour, but at all times in a way which would reassure all parties involved that the concerns had been taken seriously; any issues raised had been thoroughly — and where appropriate independently — investigated; and that steps had been taken to address any ongoing issues highlighted by those investigations.
- 1.62** Diagnostic mistakes have been made by the histopathologists at UHBT, some — but only a few — of them being serious mistakes with a serious adverse outcome for the patients concerned. Most were of lesser significance which could have been — and frequently are — made by any histopathologist and which may happen because the pathologist is overworked, overstretched or failed to ask for a second opinion from colleagues when perhaps they should have done. Every histopathological diagnosis is interpretive and therefore something which one person might call a “mistake” could be considered merely a “difference of opinion” by another. This does not, however, excuse the need to investigate every alleged diagnostic error.
- 1.63** The UHBT histopathologists mainly became the focus of attention when the transfer of certain services from NBT to UHBT or the centralisation of services were being considered, such as the consolidation of histopathology services (being considered from 2005 onwards) the centralisation of breast services (being considered in Spring 2006) the transfer of gynaecological oncology surgery (1 April 2007) the centralisation of breast surgery at St Michael’s Hospital (UHBT) and the recent proposal to transfer gynaecology cancer services from the Royal United Hospital (RUH) in Bath.
- 1.64** We are not suggesting that such events were the motivating force behind these allegations. They may have encouraged people to express their concerns, but we have no doubt that the

NBT clinicians who did so had genuine concerns which should have been promptly and thoroughly investigated.

- 1.65** We have concerns about the UHBT histopathology department which are set out later in the Report. It will be seen that our concerns are more about the culture and attitude of the department than about overall or individual competency.
- 1.66** We also have considerable concerns about the way that allegations were dealt with – both in the way they were raised and – most significantly - in the way that they were handled.

- 1.67** The Kennedy Inquiry into the children's heart surgery cases still casts a shadow over Bristol and therefore any further allegations relating to services provided by the Trust understandably have the potential to make headlines and perhaps cause 'knee-jerk' reactions to adverse publicity.
- 1.68** The title of the Kennedy Inquiry Report was 'Learning from Bristol'. The report stated that one of the purposes of the recommendations it made was that:
- "Sentinel events, that is, errors, other adverse events, and near misses, which occur during the care of patients, must be seen as opportunities to learn, not just as reasons to blame."*
- 1.69** It is essential that lessons are learned as a result of our Inquiry by both Bristol Trusts, and, most importantly, are acted upon in a spirit of co-operation and with the determination to take any necessary steps towards achieving workable and cohesive solutions to the concerns highlighted in this report.
- 1.70** The allegations which were highlighted in *Private Eye* (and subsequently reported in the local and national press) have been hanging over the UHBT histopathologists for far longer than the year since that first *Private Eye* publication. It has left them bruised and demoralised, as well as angry and defensive.
- 1.71** We have been careful to take all of that into consideration when considering our findings and recommendations.

1.72 This Inquiry has been a challenging task. We have been only too aware that many people have high expectations that we will be able to make things change radically for the better. We are also aware that many believe that our report will be a 'whitewash' and will achieve little.

1.73 We have done our best to make clear, fair and balanced findings and workable recommendations, but real change can only come about with the goodwill and the good intentions of the parties concerned.

1.74 As the Kennedy Inquiry said:

- *“There are no right answers; just, perhaps, less wrong answers.*
- *Cultural and institutional change takes time and can be slow, requiring patience and forbearance.”*

1.75 We urge everyone involved in this process to take our findings and recommendations constructively rather than personally and to work together to build a safe and effective histopathology service for the people of Bristol.

2. CULTURE/ATTITUDE

- 2.1** Originally Bristol had three hospital Trusts, United Bristol Healthcare NHS Trust (UBHT), Frenchay and Southmead. In 1999 Frenchay and Southmead merged to become the North Bristol Trust (NBT) and on 1 June 2008 UBHT became a Foundation Trust known as University Hospitals Bristol NHS Foundation Trust (UHBT).
- 2.2** **We have referred to the Trust as UHBT throughout the Report even when dealing with events which occurred prior to 1 June 2008.**
- 2.3** Historically UHBT's Bristol Royal Infirmary (BRI) considered itself the 'kingpin' of the three hospitals in Bristol and this perception still pervades the culture of the BRI and many of its staff, especially those who have been there for some time.
- 2.4** As far as the UHBT histopathology department is concerned, the central issue is the culture of the department and the attitude of some of the individual histopathologists, but we also have some concern about the overall performance of the histopathology department in certain areas. **[See the section on Competence]**
- 2.5** There have been errors, although, as we have said in the Introduction, only very few have been major errors of misdiagnosis. Histopathology relies on judgement and interpretation, and differences of opinion and occasional errors inevitably occur. What matters is not so much the fact that errors or discrepancies have occurred and are discovered, but how often the errors occur, the response to those errors and the quality assurance processes to minimise the frequency and consequence of errors.
- 2.6** It is vital that there is an open and learning culture in which pathologists seek the advice of colleagues from within and outside their own department and in which mistakes are acknowledged and lessons learned. There is no place for arrogance or excessive confidence. Even the most experienced Pathologists need to be aware of their own limitations, willing to seek advice, respond constructively to criticism and learn from mistakes. The culture in the histopathology department at UHBT veers towards the opposite of what is required. We have observed a culture which is at times defensive, responds aggressively to criticism, is

sometimes unwilling to acknowledge, let alone learn from, mistakes, and which is based on overconfidence bordering on arrogance.

- 2.7** As a large university teaching hospital the BRI should strive to achieve national recognition in all its departments, but it is the Panel's impression that the culture and ambience of the UHBT histopathology department does not reflect what one would normally expect in a prestigious teaching hospital.
- 2.8** This is partly the fault of UHBT's approach to histopathology which historically has been to fail to appreciate adequately how central it is to so many clinical specialties. Histopathology provides crucial information for many diagnoses and can be pivotal to major decisions on the course of treatment for patients (pathology has been described as "the hidden science at the heart of modern medicine") and yet the Trust has not given sufficient priority to its histopathology service, especially in respect of adequate staffing.
- 2.9** UHBT has not invested sufficiently in the histopathology department. This is reflected not only in the understaffing of the department but also in the histopathologists' working conditions. Areas of the department are shabby and old-fashioned and neither create a stimulating atmosphere to work in nor an enticing atmosphere to appeal to new recruits.
- 2.10** For much of the last two decades there were only five consultant adult (as distinct from paediatric) histopathologists covering every aspect of histopathological analysis. Four of the consultants have been in the department for much of the last 20 years and one of them, Dr Christopher Collins, even longer. One of the original four, Dr Morgan Moorghen, resigned from his post in June 2010 to take up an appointment at St Mark's Hospital in London.
- 2.11** Before the merger of the Frenchay and Southmead Trusts, the situation was similar in their histopathology departments, but since the formation of the North Bristol Trust, the NBT histopathology department has around 15 consultants, although the workload is larger.
- 2.12** The UHBT consultant adult pathologists, especially the more long-standing of them, seem to lack the drive and ambition one would expect in a major academic centre. They perform their work with a "heads down and get on with it" mentality and some of them are resistant to change. There is little evidence that uniformly they have aspired to gaining national recognition as leaders in their field and yet they give an impression of defiant arrogance in the face of any criticism.

As Professor Michael Stevens told us:

“My sense is that this is a department that does not have the pride and the ambition that you really need from a clinical service. It’s disappointing to have to say that. At a basic diagnostic level we get diagnoses made, pretty much all the time I’m confident; and generally speaking if you go and see them they do as you ask; but is that sufficient in today’s NHS, and is it sufficient in a trust that aspires to a major academic-type role? I’m not sure it is.”

- 2.13** Having said that, there is no doubt that all of the UHBT histopathologists are hard working dedicated professionals who take their responsibilities very seriously.
- 2.14** They have a heavy workload (they each report between about 2,500 and 3,500 cases a year) and work diligently for long hours, but they have been reluctant to let go of any of the work which they already do and appear to be keen to take on any work which has been transferred to UHBT from NBT. As a result they tend to report in too many specialist areas of histopathology but some of them do not have the EQA (External Quality Assurance) and CPD (Continuing Professional Development) profiles to match every specialty which they report.
- 2.15** As has already been said in the Introduction, there is a long-standing and deep-seated antipathy between some of the UHBT histopathologists and some of their NBT colleagues. There has been a history of them regarding each other as predators rather than as partners serving the patients of Bristol.
- 2.16** On UHBT's side this was clearly illustrated in the attitude to Dr Lynn Hirschowitz, a nationally acclaimed histopathologist with a special interest in gynaecology, who joined the NBT histopathology department in late 2005 from Bath. However, she had previously been a consultant at UBHT and had left just before Dr Joya Pawade joined the department. Dr Pawade had effectively inherited her work.
- 2.17** Almost everyone who came to see us who had worked with Dr Hirschowitz spoke highly of her expertise and acknowledged that she had a national, if not an international, reputation as a leader in her field. She is clearly a perfectionist who spends a great deal of time on her analysis of specimens and her extremely detailed reports to ensure a correct and complete diagnosis. One witness described her way of working as *“She offers a fantastic obsessive*

compulsive service". We recognise that her perfectionism and attention to detail could be either intimidating or an irritant to some people however laudable those attributes are.

- 2.18** When she came to NBT Dr Hirschowitz was aware that a decision had been taken to centralise Bristol gynaecological cancer services at UHBT but she came on the understanding that she would still be very much part of the gynaecological pathology team and she believed that she and Dr Pawade (who was the gynaecological histopathology lead at UHBT) would work together to build and provide a service of excellence for gynaecological cancer patients in Bristol. One of the people who had encouraged her to apply for the NBT pathology post was Mr John Murdoch, a consultant gynaecological surgeon at UHBT. She had also been made aware of ongoing plans to unify the pathology services in the two Trusts and assumed that these plans would soon be put into effect which would mean that the gynaecological pathology would in any event become available for her to report.
- 2.19** However, the arrival of Dr Hirschowitz in Bristol was not heralded with enthusiasm by Dr Pawade who perhaps (understandably) felt threatened by the 'intrusion' of an acclaimed expert in the field into her gynaecological 'patch'.
- 2.20** In March 2006, within a very few months of Dr Hirschowitz taking up her appointment in Bristol, these two personalities clashed over a Histopathology Peer Review meeting where it appears that Dr Pawade interpreted comments allegedly made by Dr Hirschowitz as being personally and professionally denigrating to her and was extremely hurt and angry. Dr Hirschowitz however denies having made any comment at all about Dr Pawade at this meeting. Shortly afterwards the two consultants met and Dr Pawade told us that Dr Hirschowitz told her that she wanted to "*do my MDTs for me*". Dr Pawade felt very strongly that whoever had done the work reporting the case should present it at the MDT and told Dr Hirschowitz this. Dr Hirschowitz told us that she only ever wanted to share the work and the MDTs with Dr Pawade.
- 2.21** However, Dr Hirschowitz continued to attend MDTs and would stay for the whole session, not just for those cases which related to NBT patients. We were told that at first she took quite an active part in the MDT, including at times openly questioning aspects of the case being reported by Dr Pawade, but later she would sit in the meeting, not saying anything but making notes.

2.22 This clearly led to a situation where Dr Pawade felt undermined by her and instead of welcoming the chance to work with Dr Hirschowitz, she became increasingly hostile and defensive. From then on it seems as though the relationship between the two consultants was irreparably damaged.

2.23 At the end of December 2006 Dr Hirschowitz wrote to Dr Jonathan Sheffield:

“I understand that John Murdoch will move all gynaecological oncology surgery from Southmead Hospital to UBHT at the beginning of April 2007. Nick Rooney and I have spoken to Martin Morse about the transfer of specialist work between Trusts, and I believe that there is an agreement between you to enable those specialists who will be affected by the transfer of work to continue working in their area of expertise (in some cases even moving to the site to which the work is transferred). I should very much like to continue reporting the histology of the major gynaecological oncology specimens of NBT patients. I am fully aware of the feelings of some of the histopathologists at UBHT and the sensitivities related to this request and would like to make it clear that I have no desire or intention to interfere with the status quo and take over any reporting of specimens from UBHT patients; I simply wish to continue to examine and report on those cases referred from NBT”.

2.24 On 26 March 2007 a meeting was held to discuss the transfer of NBT’s complex gynaecological cases from NBT to UHBT on 1 April 2007. The meeting was attended by Professor Massimo Pignatelli (Clinical Lead for Laboratory Medicine at UHBT), Dr Pawade, Dr Nassif Ibrahim and Dr Chandan Sen (NBT consultant histopathologists), Dr Hirschowitz and Mr. Mark Orrell (Head Biomedical Scientist in histopathology at UHBT).

2.25 It was decided that a short-term temporary solution would be to transfer the NBT gynaecological samples to Southmead Hospital for Dr Hirschowitz and Dr Sen to cut up and report. The reports would then be sent to UHBT. The long-term plan was to establish cross-site reporting teams for all specialties although that did not necessarily mean a single laboratory. This had apparently been agreed between the Clinical Leads, Professor Pignatelli and Dr Rooney, prior to the meeting (but without any consultation with Dr Pawade).

2.26 There was a discussion about cross cover for gynaecological cases. NBT were keen to be part of a citywide solution but Dr Pawade stated that UHBT provided their own cross cover. It was decided that there would be another meeting at the end of June to review this matter and other issues.

2.27 Within days there was further controversy about what had been agreed which led to Mr Murdoch writing the following to Dr Pawade, Dr Hirschowitz and Dr Sen on 9 May 2007:

“I am greatly saddened by the continuing disharmony within Gynae Pathology and its impact on the effective workings of the MDT. I feel that the problems you have are harming the MDT and have a substantial potential for harming patient care. The case of (Patient X) is a clear example of delay in patient care caused by your inability to work effectively together which has resulted in a delay in treatment and in my having to repeatedly see the patient with a different story over the last number of weeks.

I am very well aware that there are a number of compounding issues which are making resolution of the situation difficult. I am no longer willing to have small ad hoc meetings, isolated conversations and episodic e-mails from individuals with their side of the story in an incomplete form which leaves me unable to make judgements of or contribute to a resolution. It seems to me that the managers of pathology in the city have not successfully resolved the problems and my offers to mediate have been ignored.

I am, henceforth, only willing to discuss these issues with the 3 of you in the same room together with whomsoever you feel appropriate to have in attendance as well as to contribute to sorting out a working relationship.

I would like to assure you that I view each one of you as personally likeable and professionally of the highest standard and it grieves me that I have not been able to contribute to a resolution of the problems you have. If, however, I have occasion to believe that patient care is compromised by failure of communication between the 3 of you or obstructiveness in collaborating with a case, I will not hesitate to take the issue with your line managers.”

2.28 Unfortunately matters did not improve and the two consultant histopathologists continued to challenge each other’s diagnoses at times, which entrenched Dr Hirschowitz’s frustration and concern and Dr Pawade’s hostile defensiveness and sense of injustice. Their views about each other’s ‘diagnostic differences’ or ‘errors’ were often repeated and analysed by Dr Hirschowitz in letters or e-mails to Mr Murdoch or the Medical Directors. Dr Pawade would send difficult cases for a second opinion outside Bristol, rather than to Dr Hirschowitz.

- 2.29** On 3 July 2007 Dr Hirschowitz and Dr Ibrahim met with Dr Jonathan Sheffield to discuss their concerns about patient safety because of alleged diagnostic errors which they felt had been made by some of the UHBT histopathologists. On 12 October 2007 Dr Hirschowitz and Dr Ibrahim wrote to Dr Sheffield asking him what steps he had taken to investigate and address their concerns and asking for a detailed response. Dr Sheffield replied on 12 November 2007 reassuring them that any issues raised were investigated on a case-by-case basis although he gave no further details of any investigation. He also reminded them that whenever they believed there to be a diagnostic discrepancy between their opinions and the reporting histopathologist, it was appropriate to write a letter to the reporting consultant in order for them to be able to review the case and seek a second opinion, where necessary.
- 2.30** By the end of 2007 Dr Hirschowitz had become so disillusioned that she applied for a job elsewhere and in January 2008 had a successful interview in Birmingham.
- 2.31** In June 2008, shortly before she left Bristol, Dr Hirschowitz wrote to Dr Graham Rich, the then Chief Executive of UHBT asking him to investigate “*certain deficiencies that I have observed in the cellular pathology service at UBHT because they have serious implications for patient safety*”. In her letter she listed problems with the UHBT pathology service that had been raised at various times by various people and explained that she had met on several occasions with both Dr Sheffield and Dr Morse but was unaware of any steps which had been taken to address her concerns.
- 2.32** Since Dr Hirschowitz’s departure, Dr Pawade has continued as the lead reporting histopathologist for gynaecological cancer cases. It is perhaps noteworthy that, as far as we are aware, there have not been any concerns raised about any gynaecological cancer reporting by Dr Pawade in the last two years since Dr Hirschowitz left Bristol. However we acknowledge that this could be because specialist review of gynaecological cancer cases ceased when Dr Hirschowitz left.
- 2.33** We have some sympathy with Dr Pawade for feeling professionally threatened by Dr Hirschowitz, but feel that she lost sight of the larger picture and as a result an opportunity was lost to create together the service of excellence for gynaecological cancer patients in Bristol which Dr Hirschowitz had envisaged.
- 2.34** There have been other examples of unfortunate attitude in both pathology departments. One of the histopathologists at NBT, Dr Nassif Ibrahim, is considered by some witnesses who

gave evidence to us to be somewhat inflexible at times when he has a different opinion to his UHBT colleagues. As we were told by one of his colleagues at NBT: *“He’s absolutely charming as long as your interests coincide.... Basically, he’s a man who is absolutely set on doing things his own way”*.

- 2.35** Dr Muhammed Sohail, one of the UHBT histopathologists, and Dr Ibrahim have had significant disagreements about HER2 testing and steroid receptor studies on breast cancers. The principal allegation made by Dr Sohail is that Dr Ibrahim does not follow national guidelines. Dr Sohail told us:

“There were also some issues when we were setting out the regional guidelines. I opposed two or three amendments in those regional guidelines. One of these was amending the current method of ER/PR scoring from Quick (Allred) score to Local Score ie any scoring method, which was totally against the joint guidelines by the Royal College of Pathologists and the NHS Breast screening programme. Because he (Dr Ibrahim) insisted on this amendment, now we have accepted this change in guidelines as in the current scenario I do not want any confrontation.”

- 2.36** Dr Ibrahim told us that no other pathologist in the local Network except for Dr Sohail had raised any concern regarding the local method of reporting and that the histopathologists at Frenchay fully complied with national guidelines on ER and PR testing.

- 2.37** It is therefore clear to us that Dr Sohail and Dr Ibrahim still have strong feelings about this issue.

- 2.38** In 2009, Dr Elisabeth Kutt (Head of the Division of Diagnostics and Therapies, UHBT) investigated a complaint that 18 musculoskeletal biopsies referred by NBT histopathologists to Dr Christopher Collins (UHBT) in 2008 for his expert opinion remained unreported or were reported only after considerable delay. Dr Kutt’s report attributes the problem to *“an unsuccessful job planning exercise approximately 2 years ago when no recognition was apparently made of this extra work. ... Pathology specimens and requests for review continued to be sent to him from North Bristol and are to his knowledge still in the department but have not been dealt with. On questioning Dr Collins accepts that he should have sent them back.”*

- 2.39** When some of the UHBT histopathologists have a difficult case, they send it outside Bristol for a second opinion, rather than first sending it to their colleagues at NBT who have the appropriate expertise.
- 2.40** What concerns us most, however, is the attitude amongst some of the UHBT histopathologists that a serious error in diagnosis is not serious if it has been picked up elsewhere (i.e. in an MDT) and the patient has thereby come to no harm.
- 2.41** We experienced this attitude first hand when, in our opinion, a serious error in diagnosis was made during the course of this Inquiry.
- 2.42** On 31 March 2010 we were informed by one of the consultant respiratory physicians at NBT that one of the UHBT histopathologists appeared to have made a serious error in diagnosis in late December 2009. An NBT patient who had previously had a straightforward cancer resected from his lung had another nodule on the other side. This further nodule was resected and sent to the UHBT histopathology department for analysis. The specimen was interpreted by Dr Pawade who issued an initial report based on H&E staining, noting that there was no viable tumour but fibrosis and necrotic tissue and no evidence of granulomas. Her differential diagnosis was between a necrotic tumour nodule and an old tuberculous focus (suggesting that the patient had previously had TB). Dr Pawade issued a supplementary report the following day stating that further special staining had been performed and had not revealed any acid-fast bacilli (if present, these would indicate active TB). In accordance with routine procedure, the report and the histopathology slides relating to the patient were sent to NBT as this was an NBT patient. The slides and the report were then reviewed at the NBT MDT when it was immediately obvious that there were in fact a very significant number of acid-fast bacilli as well as granulomas. This was clear evidence that the patient had active tuberculosis which required treatment and might also be infectious.
- 2.43** The Panel were extremely concerned to hear about this case but wanted to be sure that all the information we had been given was correct; therefore we immediately wrote to Dr Sheffield asking him what steps had been taken to investigate this matter. We also asked Dr Pawade if we could see her and the slides in question on 20 April 2010 when we had a pre-arranged visit to the UHBT histopathology laboratory.

2.44 Just before we saw Dr Pawade on 20 April, we received a copy of a letter dated 19 March 2010 to Dr Sheffield from Dr Morgan Moorghen who had been asked by Dr Sheffield to investigate the matter in his role as Head of Department. In that letter, Dr Moorghen wrote:

“...Joya (Pawade) has reviewed the slides since and she agrees that bacilli were in fact present. She accepts that she missed the organisms but then she points out that the report did not rule out the possibility of TB. She is clearly upset by this incident and also feels that as with other incidents, there is another agenda.

This represents an example where a diagnosis has been refined at a MDT when all the findings are scrutinised in clinical and radiological context. For the patient there has been no breach of duty of care. It is questionable as to whether this should be considered as a clinical incident since this is a refinement in diagnosis and not a new diagnosis. Tuberculosis was still part of the original differential diagnoses. It is unfortunate that some individuals at NBT are using these incidents to harass pathologists at the BRI and further their own agendas....”

2.45 We were concerned that Dr Moorghen described this as a ‘refinement’ in diagnosis. We do not consider that Dr Pawade’s differential diagnosis was ‘refined’ at the MDT. It was established that it was incorrect.

2.46 After having been asked subsequently by Dr Sheffield to investigate the matter as a Serious Untoward Incident, Dr Moorghen now accepts that his initial conclusions were wrong.

2.47 As we arrived at the BRI on 20 April, we were handed the following letter from Dr Sheffield:

“Thank you for your letter regarding the recent case concerning tuberculosis. The Thoracic Surgeon who dealt with the case is quite clear that the case was a ‘tuberculoma’ and was completely excised and therefore presented no risk to other patients.

As far as I am aware there is no history to suggest this as an “open” infectious case of tuberculosis.

As regards the Laboratory Management of the case, full normal precautions were taken as regards the risk to laboratory staff.

I would also want to reiterate a few worrying factors in this case.

The letter from Dr John Harvey alerted this confirmation of a specific diagnosis on 13 January 2009 (sic). There was no contact to this Trust via official routes until 16 February. If there was a risk to patients discovered by the North Bristol team, they should have contacted us as an emergency. Good practice would have been to have alerted us appropriately immediately.”

2.48 Our understanding is that this was a case of active tuberculosis and that there could therefore have been a risk of the spread of infection. We agree with Dr Sheffield that there should be no delay in contacting UHBT on discovery of the specific diagnosis, but we are concerned that Dr Sheffield did not seem to appreciate that a serious diagnostic mistake had been made.

2.49 We can understand that Dr Sheffield’s attitude was influenced by Dr Moorghen’s original interpretation of the situation as a ‘refinement’ of diagnosis rather than a serious clinical incident, however it concerns us that Dr Sheffield did not set in train a more thorough investigation of this incident until after we had taken the action described below.

2.50 After the Panel’s tour of the laboratory, Sir James Underwood, Dr Margaret Spittle and Jane Mishcon saw Dr Pawade on her own (the other two panel members feeling that it would be more sensitive not to have the whole panel present). Dr Pawade displayed the relevant slides on a monitor while she viewed them through a microscope and described what she was seeing and how she had come to miss what she herself described to us as “loads” of acid-fast bacilli. Sir James Underwood also looked at the slides through the microscope and we asked her questions about her original interpretation of the slides and her reaction to having made what she accepted was a mistaken diagnosis.

2.51 We learned that UHBT had had their MDT relating to this patient on the day of Dr Pawade’s first report and that her supplementary report had not been available for that MDT. However, granulomas with giant cells had been clearly visible on the original H&E slide but had not been mentioned in the report.

2.52 During the interview, Dr Pawade handed us a statement in which she had written:

“Following MDT discussion in NBT about a patient with lung cancer and a separate lung nodule reported by Dr Ibrahim, Dr J Harvey had written to the GP of this patient with detailed information about the BRI pathology report. This was copied to NBT medical director and the surgeon Mr Batchelor. There is a handwritten comment on this paper “another serious mistake”. I do not regard this as a serious mistake. In fact I am deeply offended by this and have written to the NBT medical director... I do regard this as ongoing harassment from NBT respiratory team.”

2.53 When questioned about what she would regard as a serious mistake, Dr Pawade said:

“A serious mistake is when something is missed out and the patient gets given completely wrong therapy or gets given completely wrong advice. That is not what happens in these cases. The patient gets picked up at an MDT and something which is called old TB becomes an active TB. To me that is a modification that you do in MDTs, we do it all the time... I don’t regard missing acid-fast bacilli a serious mistake.”

2.54 When it was put to Dr Pawade that what she appeared to be saying was that as long as there is no harm done the patient, it should not be considered a serious mistake, she replied:

“Yes, and also I don’t think missing acid-fast bacilli - especially when I say it’s an old TB and it turned out to be active TB - to me is a serious mistake.”

2.55 We are very perturbed by this response of Dr Pawade that, as long as the patient comes to no harm, such a mistake is not serious. Not only were two clear indicators of active TB – granulomas and acid-fast bacilli – not identified by Dr Pawade in her two reports, but they were expressly ruled out by her. We are of the opinion that to fail to identify these two very obvious indicators (on 20 April Dr Pawade correctly described the presence of the bacilli on the slides as “loads”) was a serious mistake and should have been acknowledged as such. We are concerned that both she and Dr Moorghen in his letter of 19 March 2010 did not consider that there had been any breach of duty to the patient as the mistake had been subsequently picked up and rectified.

2.56 What also concerned us was that at that time Dr Pawade did not express to us any remorse or concern about having made such a mistake, other than regretting how it had impacted on her. As a result the Panel felt obliged to write immediately to Robert Woolley, then Acting Chief Executive of the Trust, explaining our concerns and

recommending that the Trust should consider whether it was safe and appropriate for Dr Pawade to continue to be involved in reporting lung pathology without some review of her current method of practice. In response to this letter, the Trust immediately imposed double reporting on all lung pathology.

2.57 Had the Panel not been faced with this attitude about mistakes not being serious as long as there was not an adverse outcome for the patient and the lack of insight in showing no remorse, we may not have felt so inclined to take the step that we did.

2.58 When we questioned Dr Caroline Calder, another of the UHBT histopathologists, about her thoughts on those cases included in the 26 specific cases on which she had reported, she became very upset and said:

“I still shudder at the (x) case. I do not know how I did it. ...I still do not know how I did it. I did think that the message I could learn from that mistake - I think the thing with mistakes is you hate making them. You have to learn from them though, and also if you make a mistake you have to be big enough to say ‘I made a mistake. I got it wrong. What can I learn from this?’ ”

2.59 Had Dr Pawade’s reaction been similar to that of Dr Calder — that she had learned something positive from this mistake — we would not have been as concerned as we were about her continuing to report lung pathology without a review of her working practice.

2.60 However Dr Pawade has since assured us that she has reflected on her practice and that she now has a heightened awareness of the possibility of making such mistakes which hopefully will enable her to considerably reduce the risk of such an error occurring again.

2.61 Having said that, it must be emphasised that all of the many UHBT clinicians who came to talk to us held Dr Pawade in the highest regard, and even the NBT histopathologists and clinicians who came to see us talked very positively about her reputation as a haematopathologist.

2.62 Haematopathology is Dr Pawade’s main specialist interest with gynaecological and respiratory pathology being her other particular sub-specialties. Further, one of the NBT

histopathologists who worked with Dr Hirschowitz described Dr Pawade as *"perfectly competent"* in reporting gynaecological pathology.

- 2.63** Having adversely criticised the attitude and culture at UHBT, it would be wrong not to criticise the culture of professional rivalry/jealousy which is common to both trusts. One of the real problems is the way in which concerns have been reported and we deal with this elsewhere in the Report.
- 2.64** We heard phrases such as *'power struggle'*, *'playground behaviour'*, *'a Bristol disease which chips away at itself'* from various witnesses describing the relationship between the two Trusts, and in particular the two histopathology departments.
- 2.65** The UHBT histopathologists (and others — some even at NBT) have long believed that one of the NBT histopathologists, Dr Nassif Ibrahim, has been behind the allegations made against them. This allegation is strenuously denied by Dr Ibrahim, but it has fuelled much of the ill-feeling directed by them towards him.
- 2.66** We were told by them that it stemmed back to 1997 when thoracic surgery was transferred to UHBT and all the histopathology associated with thoracic surgery was subsequently reported at UHBT, including the pathology (which includes lung pathology) for all those patients of NBT respiratory physicians who required surgical biopsies.
- 2.67** For many years Dr Ibrahim has been acknowledged nationally as a leader in the field of lung pathology and prior to 1997 had been the lead lung histopathologist in Bristol. Dr Ibrahim told us that following the transfer of thoracic surgery in 1997 he continued to report a significant amount of the lung pathology specimens either by going by invitation to UHBT to report them, or through Dr Ed Sheffield, one of the UHBT histopathologists, who also had a special interest in lung pathology and who succeeded Dr Ibrahim as the lead lung pathologist. Dr Sheffield apparently sent specimens to Dr Ibrahim for a second opinion. However, when in 2003, (we believe at the invitation of Dr Ibrahim) Dr Ed Sheffield left UHBT and went to NBT, perhaps contrary to what Dr Ibrahim had hoped would happen with the arrival of Dr Sheffield, the flow of lung pathology all but dried up and Dr Ibrahim lost the most important part of his work as a lung pathologist. Surgical lung pathology was subsequently reported by any of the UHBT pathologists (although mostly by Dr Pawade and Dr Sohail) but the lung cases were presented at the MDTs by either Dr Pawade or Dr Sohail.

2.68 Other than concerns arising as a consequence of understaffing in paediatric pathology, the first and the most frequent complaints about reporting by UHBT histopathologists related to lung pathology.

2.69 The first letter raising concerns was signed by five NBT respiratory physicians in August 2004 and, although it mentioned two recent (unspecified) cases where incorrect diagnoses had had serious an adverse clinical effect for NBT patients, the main thrust of this letter was that lung biopsy and resection specimens had not been reported by a specialist lung pathologist. The letter in full stated:

“We are writing to express our concern about the reporting of lung biopsy and resection specimens from patients that we refer to you. We are fortunate in Bristol to have two of the country’s leading lung pathologists in Ed Sheffield and Nassif Ibrahim. Unfortunately, however, it is common for lung specimens to be reported by general pathologists at the BRI without reference to the expertise of our lung pathologists. As I am sure you are aware, this has led to a number of incorrect diagnoses and in two recent cases serious adverse clinical effects for our patients.

We are sufficiently concerned about the effect that this may have on our patients to formally request that in future all lung biopsies or resected specimens from our patients are sent for reporting to Dr Sheffield and Dr Ibrahim at Frenchay Hospital. We feel that as we are now in the era of specialist working practices it is not best practice – indeed contrary to best practice and the requirements of clinical governance for lung specimens not be reported by lung pathologists. It is unfair and potentially dangerous for our patients and we would request that in future the specimens be directed to the lung pathologists.”

2.70 The response to this letter was written and signed by the then five adult UHBT histopathologists, Dr Moorghen, Dr Pawade, Dr Collins, Dr Calder and Dr Sohail. The tone of this response was of injured indignation at being described as “general” pathologists. From that time onwards the already strained relationship between the two histopathology departments became entrenched, although it is fair to say that the UHBT histopathologists appear to have no axe to grind with anyone in the NBT histopathology department other than Dr Ibrahim (and Dr Pawade with Dr Hirschowitz).

2.71 Although the NBT respiratory physicians whom we interviewed denied that they had been influenced by Dr Ibrahim to write the letter in 2004, the wording of the letter, in particular the

references to ‘general’ pathologists at UHBT “two of the country’s leading lung pathologists” and “the expertise of our lung pathologists” does suggest that, at the very least, the NBT physicians had listened to the views of Dr Ibrahim at some time prior to writing the letter.

2.72 Also around this time there were ongoing discussions between the two Trusts about how to reorganise and centralise pathology services across the city. Dr Ibrahim supported the argument for a single site in North Bristol whereas the UHBT pathologists were anxious that they should keep a pathology department at the BRI. It is therefore also possible that this issue had some bearing on the views expressed about the UHBT histopathologists.

2.73 We have already commented in the Introduction that whenever there were discussions about centralising a particular clinical specialty (such as breast or gynaecological oncology) allegations about the competence of the UHBT histopathologists service seemed to re-emerge. As far as we are aware, apart from Dr Hirschowitz, Dr Ibrahim was the only NBT histopathologist who ever voiced concerns about the UHBT histopathologists.

2.74 Dr Nicholas Rooney, Director of Pathology Services at NBT, who has been a histopathologist in both UHBT and NBT (and in Bath in between) does not share such views about the competence of the histopathologists at UHBT. He told us:

“I do not share concerns about the individuals. I cannot believe that the BRI has the six most incompetent pathologists in the country. It is just not right. On an individual basis they are fine. I think their vulnerability is in the fact that they do not have sufficient staffing, and they are trying to be an expert in too many different areas”

2.75 Dr Karin Denton, Head of the Histopathology Department at NBT told us:

“I’ve had roles outside North Bristol Trust and I continue to have some – I’m the Quality Assurance Director for cervical screening for the South West region, I have held the same role for breast screening for South West, I’ve been on various College committees, I have been a CPA inspector. I have a lot of experience of what goes on in other pathology departments and I would have to say that I don’t think that the BRI lies outside the spectrum of what is considered acceptable nationally.”

2.76 When we asked her whether her view was the general feeling amongst the NBT pathologists or whether there were a few who thought otherwise, she replied:

“Well, Nassif Ibrahim certainly thinks otherwise. Other than that, I would say that probably most people would share my view that the standards are within the normal range. If you like, output is within the normal range, but I would consider that process, and in particular the approach to criticism, could do with improvement”.

2.77 This was confirmed by one of the NBT histopathologists who told us *“There are no obvious undercurrents between anybody I know at NBT and BRI. All the people who are at Southmead are absolutely fine with people at the BRI...”* Dr Ibrahim is of course still at Frenchay not Southmead.

2.78 Even Dr Ibrahim told us:

“Q. *Can I be clear about the pathologists at BRI that you respect as specialists, who they are and what are their specialist fields. Could you run through them for us?*

A. *Even Joya Pawade I respect her as a specialist in lymphoreticular pathology; Morgan Moorghen, liver and GI pathology; Chris Collins, bone and soft tissue, Newton Wong as GI pathology; Sohail and Chris Collins would be urology and Sohail also does breast, I respect that....*

Q. *You think they would be very competent pathologists if they were restricted to those fields of activity.*

A. *Absolutely.”*

2.79 We have the impression that Dr Ibrahim never really accepted the transfer of thoracic surgery and resented the loss of his specialist work. This led to him developing an overcritical view of the UHBT histopathologists which coloured his attitude to errors which subsequently occurred. However we commend him for having discovered some of these errors and do not criticise him for having raised concerns about them. It is how those concerns were dealt with at NBT and UHBT which have caused us some disquiet.

2.80 The respiratory physicians at NBT would probably have been aware of Dr Ibrahim's feelings and when in 2004 two errors with adverse outcomes for the patients were allegedly made in

the reporting by the UHBT histopathologists of the lung pathology of NBT patients, these errors became an issue which later escalated.

2.81 We fully accept that it is an extremely serious matter if any patient suffers an adverse outcome because of a proved diagnostic error. However the problem in 2004 was that no evidence was ever produced to support the allegations made, and no effective investigation was pursued.

2.82 It is clear that Dr Ibrahim does not like any kind of challenge to the way he works. He could — and probably should — have moved to UHBT when the thoracic surgery (and consequently the surgical lung pathology) was transferred there, but he chose not to do so. For a while he did occasionally go to the BRI to report lung pathology, (as had been informally agreed between the two Trusts) but not often. If it is correct that UHBT did not provide Dr Ibrahim with adequate facilities (office space, a microscope etc), then, in our opinion, they should have done so. It is also our view that Frenchay and UHBT should have formalised arrangements by transferring some of his sessions between the Trusts.

2.83 However recent events have shown that Dr Ibrahim is resistant to moving. Several years ago the histopathology department moved to Southmead Hospital, but he, together with Dr Ed Sheffield and one other histopathologist, remained at Frenchay Hospital. Several attempts have been made recently to get him to move, but he remains at Frenchay.

2.84 Therefore, despite the NBT clinicians' protestations that they were not influenced by Dr Ibrahim, we cannot help but think otherwise. Indeed, it would be strange if they were not, given that he was an eminent pathologist who was a specialist in his field who had worked for many years alongside them. This does not in any way mean that we think that their concerns are groundless. As we have said in the Introduction, we have no doubt that their concerns were genuine and justifiable, although had their concerns been thoroughly and promptly addressed, it is likely that they would have been satisfied that there was no significantly serious cause for concern about the overall diagnostic competency of the UHBT pathology department. (However, we have some real concerns about the department which we set out in the 'Competence' section of the Report.)

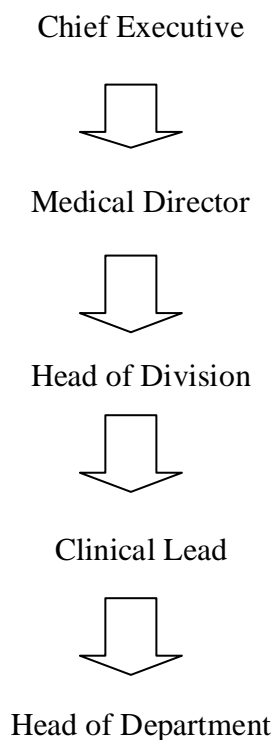
2.85 We were also deeply concerned to hear from one of the consultant thoracic surgeons at UHBT that very shortly after he was appointed as a consultant, he received a call on his mobile phone from Dr Ibrahim who said that he would be happy to report his NHS as well as

his private lung pathology (Dr Ibrahim told us that he reported all the private lung pathology in Bristol). When the consultant responded that he was happy with the arrangements at UHBT, Dr Ibrahim began to denigrate the UHBT histopathologists' work, saying that it was of poor quality and told him that there were numerous litigation cases being brought against them.

- 2.86** This information reinforced the belief that for some years Dr Ibrahim has had his own agenda (to get the surgical lung pathology transferred back to NBT) for challenging the competence of the UHBT histopathologists, (although this comment should not in any way be seen as neutralising his genuine — and in several respects justified — concern about the competence of the UHBT histopathologists) and that that agenda has undoubtedly had some influence upon the clinicians at NBT and has perhaps heightened their concerns more than would otherwise have been the case.
- 2.87** As we have outlined in the Recommendations in this report, we believe that concerns should be dealt with initially at the lowest possible level by discussion between the clinicians actually involved.
- 2.88** Professional competition is healthy. Professional rivalry which damages the sane and rational distribution of services is not.
- 2.89** The culture of 'a Bristol disease which chips away at itself' and attitudes which are more suitable to the playground than to the NHS must change if there is to be a safe and effective histopathology service for the city's patients.

3. MANAGEMENT/ INVESTIGATION OF CONCERNS

The management structure relevant to this Inquiry about the UHBT histopathology service is:



- 3.1 We were told that as from July 2005 the Medical Director was not the direct line manager in the management structure.**
- 3.2** The role of Chief Executive was held from May 2004 to October 2007 by Mr Ron Kerr, from 1 October 2007 until 4 January 2010 by Dr Graham Rich, and since then (first as Acting and then as substantive Chief Executive) by Mr Robert Woolley.
- 3.3** Prior to Dr Jonathan Sheffield's appointment as Medical Director on 1 September 2004, there had been several Acting Medical Directors. He was the first since 2002 to take up the post on a permanent basis. He had formerly been Medical Director in Yeovil. The specialty in which he trained and practiced is histopathology.
- 3.4** Dr Julian Kabala, a consultant radiologist, was Head of Division for Diagnostics and Therapies from June 2005 to July 2008. He was followed in that post by Dr Elizabeth Kutt, also a consultant radiologist. Five sessions are allocated to this role.

- 3.5** Professor Massimo Pignatelli was appointed Clinical Lead for Laboratory Medicine in 2006 and remained in this post until November 2009. He was replaced by Dr Wolf Woltersdorf, a Clinical Chemist.
- 3.6** Since 2004 until he left UHBT in June 2010 Dr Morgan Moorghen has been Head of Department. Prior to 2004 the role was held by Dr Caroline Calder. This is an important role but there is no formal recognition of it by the Trust: there are no sessions allocated to carrying out the role and there is no job description. Dr Moorghen told us that he took on the role because nobody else in the histopathology department wanted it; this was confirmed by the other consultant histopathologists.
- 3.7** We discovered that Dr Kabala knew virtually nothing about any allegations of histopathological misdiagnosis between 2004 and 2008, despite being Head of Division for most of this time and Professor Pignatelli had very little impact on the issue of the competence of the UHBT histopathology department, despite being Clinical Lead from 2006 to 2009.
- 3.8** It appears that the Medical Director, Dr Sheffield, decided to take on a direct role in resolving any problems in the histopathology department. This section deals with the appropriateness and effectiveness of this decision.
- 3.9** As we have said in the Introduction, our Terms of Reference [See Annexe 1] did not ask us to (and therefore we did not carry out) a detailed examination of clinical and corporate governance systems, although we do comment on some matters of governance in the Report.
- 3.10** However, because the concerns about possible misdiagnosis were not reported through the proper channels, and because the investigation of those allegations was not conducted with any kind of systematic approach and was inadequate — mainly because of the underlying belief that they were vexatious — the systems and processes were untested and therefore it probably would not have been possible to identify if or how governance systems failed.
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3.11 The first concerns about the UHBT histopathologists (other than relating to paediatric pathology which is dealt with in a separate section) which were expressed in writing were contained in a letter dated 31 August 2004 which was written by the NBT respiratory physicians and sent to Mr Tony Morgan, a consultant thoracic surgeon at UHBT. The letter was copied to 14 other people including Dr Jonathan Sheffield and Dr Martin Morse (the Medical Directors of both Trusts), clinicians at both Trusts, the Trust Lead for Clinical governance at NBT and Dr Morgan Moorghen, the Head of Department of the UHBT histopathologists.

3.12 This letter must have been one of the very first things to have greeted Dr Sheffield who began his appointment as Medical Director of UHBT on 1 September 2004. That day was the first day at UHBT also for Dr Graham Rich, who was to become Chief Executive on 1 October 2007, but on 1 September 2004 took up his appointment as Chief Operating Officer. The Chief Executive at the time was Mr Ron Kerr, but even he had been in post only since May 2004.

3.13 The letter from the NBT respiratory physicians was short but to the point:

“We are writing to express our concern about the reporting of lung biopsy and resection specimens from patients that we refer to you. We are fortunate in Bristol to have two of the country’s leading lung pathologists in Ed Sheffield and Nassif Ibrahim. Unfortunately, however, it is common for lung specimens to be reported by general pathologists at the BRI without reference to the expertise of our lung pathologists. As I am sure you are aware, this has led to a number of incorrect diagnoses and in 2 recent cases serious adverse clinical effects for our patients.

We are sufficiently concerned about the effect that this may have on our patients to formally request that in future all lung biopsies or resected specimens from our patients are sent for reporting to Dr Sheffield and Dr Ibrahim at Frenchay hospital. We feel that as we are now in the era of specialist working practices it is not best practice - indeed contrary to best practice and the requirements of clinical governance for lung specimens not to be reported by lung pathologists. It is unfair and potentially dangerous for our patients and we would request that in future the specimens be directed to the lung pathologists.”

- 3.14** This letter contains serious allegations relating to patient safety and makes a formal request for the transfer of lung pathology specimens to the NBT histopathologists Dr Ibrahim and Dr Ed Sheffield (who until 2002 had been a histopathologist at UHBT).
- 3.15** Despite the seriousness of the contents of the letter, it appears that these issues had not previously been raised with Dr Morse, the Medical Director of NBT, and the letter was sent to a surgeon at UHBT, although copied in a ‘scattergun’ fashion to 14 other people.
- 3.16** We deplore the manner in which these concerns were raised. If they were genuine concerns about the competence of the UHBT histopathologists to safely report complex lung pathology, this was not the way to go about addressing those concerns. Making serious allegations about patient safety in a letter copied to all and sundry could only have the effect of entrenching the professional rivalry and resentment between the histopathology departments in the two Trusts, and was yet another example of what one witness described as “the playground behaviour” that at times seems to be the hallmark of the way that the two Trusts deal with each other.
- 3.17** Some of the NBT physicians who signed the letter now accept that they should not have conveyed their concerns in this way. Unfortunately, the letter of 31 August 2004 was not the only letter or e-mail containing allegations against the UHBT histopathologists which was sent by clinicians at NBT and copied to various colleagues. There appears to have been a tendency to express highly critical views in e-mails and letters which then were copied to a wider audience.
- 3.18** In our opinion this is an inappropriate and arguably unprofessional way to deal with concerns about patient safety. We have set out in our Recommendations what we consider to be a correct way to raise concerns about the competence of colleagues.
- 3.19** There is no doubt however that both Medical Directors received a copy of this letter.
- 3.20** There was no written response at the time from either Medical director. According to Dr Morse his response was to meet with the NBT histopathologists when he told them that he would not support unfounded allegations being made and therefore he asked them to collate evidence in support of their allegations and to pass it to their colleagues in the UHBT histopathology department.

3.21 Although we can sympathise with Dr Sheffield that the letter must have arrived on his very first day in office, very serious allegations of misdiagnosis with adverse effect for patients had been made against a department in his Trust, and those allegations merited an immediate response even if it was merely an acknowledgement of the letter as a holding position.

3.22 Instead, the response came (dated 17 September 2004) from the then five UHBT adult histopathologists — Dr Morgan Moorghen, Dr Chris Collins, Dr Joya Pawade, Dr Caroline Calder and Dr Muhammed Sohail. It was copied to the same people who had received the NBT letter and also included Dr Graham Bayly, Clinical Director of Laboratory Medicine at UHBT.

3.23 The following are relevant extracts from the letter:

“‘General pathologists at the BRI’. We disagree on your use of the adjective ‘general’ and we find this almost insulting....

We are particularly concerned that there are apparently two recent cases where there have been adverse effects on patients and we are surprised that these have not been brought to our attention....

You ask us to send our lung cases from your patients to Drs Ibrahim and Sheffield and you refer to best practice in clinical governance. This statement is of real concern to us. Fortunately you stop short of making a frank accusation of incompetence. We challenge the view that we are not in specialist practice, that we do not conform to best practices and that we do not satisfy clinical governance requirements....

We hope that with this letter we can lay this matter to rest. It would be utterly fruitless to enter into protracted correspondence and discussion about a controversy which should have been resolved years ago.”

3.24 Although we are sympathetic to the wish of the UHBT histopathologists to respond to allegations made in such an inappropriate and provocative fashion, we are of the view that the response should have come from the Medical Director and not from them.

3.25 It is noteworthy that, although the UHBT pathologists’ letter expresses ‘particular concern’ about the cases where allegedly there had been adverse effects on patients, it

does not specifically ask for those cases to be identified so that they could be investigated.

3.26 At this stage Dr Sheffield had not responded. On 29 September 2004 Mr Simon Cawthorn, Consultant Breast Surgeon at NBT and Medical Director of Avon Somerset and Wiltshire Cancer Services (ASWCS), sent a very brief e-mail to Dr Sheffield saying:

“Nassif Ibrahim, Chairman of the ASWCS Pathology Advisory Group, has brought to my attention problems to do with histopathology reporting at UHBT of lung specimens from the North Bristol Trust MDT”

3.27 Dr Sheffield responded the same day:

“Dear Simon,

It would be entirely inappropriate to meet with you regarding this issue. I am concerned that the chest physicians should take to writing to every person and their dog on this and I will be addressing matters through appropriate managerial routes”.

3.28 On 4 October 2004 Dr Morse e-mailed the NBT respiratory physicians with copies to Mr Cawthorn, saying:

“Whilst I recognise that you must have concerns as to the appropriateness or otherwise of the histology service presently provided for patients with respiratory problems, I cannot recognise that your joint letter of the 31st August is an appropriate method of tackling the issue; indeed I have little doubt that it has probably set back the potential timescale to a resolution by a significant amount. I would be very grateful, therefore, in order to avoid ever more deeply entrenched views being publicised, if you did not reply to the letter of the 17th from the UBHT pathologists, at least until I have had the opportunity to discuss matters informally with Jonathan Sheffield, which I will do on the 21st...”

3.29 **We agree with Dr Morse’s opinion about the inappropriateness of the physicians’ letter and the effect it was likely to have on resolving the matter. Unfortunately, however, he did not appear to be able to restrain clinicians in his Trust from putting their views in writing to colleagues on future occasions.**

3.30 Dr Sheffield replied to Dr Morse’s letter on 5 October 2004:

“I am writing to express my concern on the tone and nature of the letter submitted to Tony Morgan by five Consultant Respiratory Physicians in the North Bristol NHS Trust. To copy the letter widely across the Bristol Healthcare network is entirely inappropriate. The individuals are concerned about errors in diagnoses and mention two recent cases where serious adverse events had affected patients. I would be delighted to know the names of these patients and how these cases were discovered to be incorrect. My interpretation of guidance in these matters is that a formal multi-disciplinary team meeting should occur for discussion of cases and if there is a diagnostic dispute between Pathologists, it would be appropriate for Pathologists to discuss the diagnosis with the Pathologist making the wrong diagnosis. It is therefore very worrying that these clinicians have not performed this action, but decide to mailshot fourteen other doctors and nurses in North Bristol and UBHT.

I hope you have already received the reply sent by the Pathologist (sic) concerned but seek reassurance that the Senior Consultants concerned with this letter understand what appropriate clinical action they should take when they discover such an error rather than a haphazard paper chase, not following formal clinical governance arrangements.”

- 3.31** Again, although Dr Sheffield states that he would be *“delighted to know the names of these patients and how these cases were discovered to be incorrect,”* he did not formally ask for these details and he appeared to be more concerned about the tone of the NBT physicians’ letter and the fact that they had not followed the proper procedure and channels in making their allegations, than about specific details of the cases which had led to an adverse outcome for two patients.
- 3.32** He should have made sure that the two cases were identified and then investigated thoroughly and should have reported the results of the investigation to Dr Morse. If he found any cause for concern about the diagnoses given by the UHBT pathologists in either of the cases, he should have ensured that any concerns were addressed and any problems rectified. If he found that there was no cause for concern, he should have explained, preferably jointly with Dr Morse, why he felt the allegations were without foundation. Had these issues been dealt with properly in 2004, it is possible that concerns would not have been raised again in 2007.
- 3.33** Dr Sheffield told us that the only two things that he did following receipt of the NBT physicians’ letter was to have a discussion with the UHBT histopathologists and to write the

letter of 5 October 2004. He did however tell us that he explained to the histopathologists that the more they could sub-specialise, the better it would be.

3.34 In our opinion, this was an opportunity for Dr Sheffield to put down a marker that specialisation was the route which should be taken and to take steps to ensure that priority was given to staffing the department sufficiently to allow this to take place.

3.35 Had the UHBT histopathologists become more specialised and practised in just one or two sub-specialties each, this Inquiry might have been avoided. However just six consultant adult histopathologists cannot cover all body systems as ‘specialists’ and therefore it was inevitable that they would not be able to move to full specialisation until their numbers were increased although progress towards specialisation could, and should, have been made within existing staffing levels. We deal with Specialisation in a separate section.

3.36 Dr Sheffield’s letter received no response from Dr Morse. The two cases were apparently never identified and it therefore seems as though everyone at UHBT thought that that was an end to the matter.

3.37 However, it does not seem that that was an end to the matter as far as the NBT consultants were concerned. On 3 March 2005 Dr John Harvey, the consultant respiratory physician at NBT who was the driving force behind the letter of 31 August 2004, wrote to Dr Morse:

“John Pounsford mentioned to me recently that you felt you haven’t had enough examples of problems with lung pathology to pursue our concerns actively.

This issue was brought sharply into focus for me when I had a very difficult interview with one of my patients in the clinic.”

3.38 Dr Harvey then described an alleged misdiagnosis by one of the UHBT pathologists who had reported a pleural biopsy as showing malignancy. As a result the patient was told the bad news by the thoracic surgeons and he gave away £30,000 of his money thinking that he only had a short time to live. However, when the specimens were reviewed at NBT it was discovered that he was suffering from a rare chronic infection. The letter continues:

“He looked me in the face and asked me if this has happened before and I had to concede that it had but that we were taking steps to avoid it happening again. He then asked me if I thought it could happen again and I found that difficult to answer.

It seems to me that sooner or later this issue is going to get into the public domain, whether it be through the courts, the media, or the GMC, and I just want to feel confident that we as a Trust have done everything humanly possible to avoid that.

I am sorry to continue to pester you about this, but we all feel badly about what is happening to our patients and, as I’m sure you will appreciate, it is completely avoidable.”

- 3.39** After his somewhat prophetic comment that “sooner or later this issue is going to get into the public domain”, Dr Harvey then identified six specific cases where an alleged misdiagnosis had been made by the UHBT pathologists - all of which were interstitial lung disease cases which involve some of the most complicated lung pathology. He concluded his letter:

“I suppose that all we are really asking, is for our patients’ specimens to be sent directly to the most appropriate pathologist. As things stand, our patients are being told that, amongst other things, they have cancer when they haven’t and are also being reassured that they don’t have cancer when they have! It is then us that have to pick up the pieces – not the Thoracic surgeons, nor the BRI pathologists!

Where would we wish specimens from our own lungs or those of our relatives to be sent?! If it’s good enough for us, our relatives and, so it seems, private patients from the Glen, then why isn’t it good enough NBT’s respiratory patients? I do hope you feel that you can help us sort this out as soon as possible.”

- 3.40** Once again the request was that the lung pathology should be sent to the ‘specialist’ lung pathologists at NBT.
- 3.41** There is nothing in the documentation that we have been given by both Trusts which show that anything was done by Dr Morse at this stage. We are aware that the two Medical Directors did have meetings and/or conversations which have not been formally recorded, but neither of them told us of any steps taken directly to deal with Dr Harvey’s concerns. Indeed Dr Sheffield told us that he was never made aware of the cases listed in Dr Harvey’s letter.

3.42 Around this time there were serious talks going on between the two Trusts to amalgamate pathology services across Bristol into a single service. The talks eventually broke down because NBT wanted to build a single pathology laboratory on one site (in NBT) whereas UHBT wanted to preserve separate sites even if there was a unified service. It may well have been that the Medical Directors believed that unifying the service would remedy any problems about specialisation but, in our opinion, this does not explain why no formal steps to address the allegations were taken at that time. For the first time specific cases had been identified and Dr Harvey had expressed genuine and serious concerns about misdiagnosis, albeit in cases which are notoriously difficult to diagnose. The matter had been placed in Dr Morse's hands but appeared to go no further.

3.43 However, it does not appear that Dr Harvey or any of the other clinicians at NBT pursued their concerns any further with Dr Morse at that stage and for the next two years no allegations of misdiagnosis were made against the UHBT histopathologists by anyone at NBT, although at the end of March 2006, Dr Angela Raffle, Consultant in Public Health at the North Bristol PCT, sent an e-mail to Phil Hall, Assistant Medical Director at UHBT, asking him to make Dr Sheffield aware *"of some worrying data concerning the poor correlation between results of [cervical] histology performed at St Michael's Hospital, and the preceding cytology results for the same patients."*

3.44 It was not until a letter dated 31 January 2007 was written to Dr Sheffield by Dr David Smith, Lead Clinician for Respiratory Medicine at NBT, that any clinician at NBT formally raised any further concern about the UHBT histopathologists. Dr Smith's complaint which was written on behalf of the NBT respiratory physicians and other members of their MDT was not about any diagnostic incompetence on the part of the UHBT histopathologists, but was expressing concern about difficulties they were experiencing in obtaining the pathology slides of NBT patients in time. He wrote:

"As you know, we like to review all surgical slides from our patients at our MDT with the specialist lung pathologists before making any treatment decisions. Unfortunately, it continues to prove difficult to obtain some of the slides in a timely fashion for review. As you will appreciate we are trying to make informed decisions about important treatment, which includes immunosuppressive therapy for alveolitis and adjuvant chemotherapy for cancer.

This has become a serious clinical governance issue and we would like to ask you please to resolve this problem by making arrangements for our thoracic pathology specimens from NBT patients to be reported by the two thoracic pathologists who are based at NBT."

3.45 What is interesting is that once again, instead of just asking Dr Sheffield to ensure that the UHBT histopathologists returned the slides promptly, the request was for the transfer of all thoracic pathology specimens from NBT patients to be reported by Dr Ibrahim and Dr Ed Sheffield at NBT.

3.46 Dr Jonathan Sheffield responded to Dr Smith on 6 February 2007:

"I am very keen on the development of more specialist reporting in Bristol for all histopathology. To that end we have recently appointed Professor Massimo Pignatelli to the position of Clinical Lead in Pathology and he is tasked with developing better links between our Trusts. He is meeting regularly with Dr Nick Rooney and we are trying to develop a unified directory of specialists for the purposes of reporting. I have taken the liberty of forwarding your letter in order for him to address the specific issues raised."

3.47 There is no evidence that the matters raised in Dr Smith's letter were specifically addressed at UHBT but, on the other hand, there appears to have been no 'follow-up' at this time by the NBT respiratory physicians about their request for their patients' lung pathology to be reported by Dr Ibrahim and Dr Ed Sheffield.

3.48 Dr Sheffield told us that Professor Pignatelli was appointed specifically to work with Dr Rooney in NBT to work towards more and more specialist reporting. He said:

"I didn't care whether there were two pathology departments on either side of the city. What I wanted was the free and easy transfer of work between two sites and that people could work in collaboration with each other."

3.49 It should be noted that in December 2006 the entire consultant adult histopathology team at UHBT wrote to the Chief Executive, Ron Kerr, opposing the appointment of Professor Pignatelli as Clinical Lead for Laboratory Medicine on the basis that, because he did not participate in the routine histopathology reporting rota, he would have little insight into current clinical activities.

3.50 This lack of confidence in clinical leadership was an additional stumbling block to sorting out any difficulties.

3.51 The NBT physicians may not have followed up their request for a transfer of lung pathology back to NBT, but Dr Ibrahim did. On 2 July 2007 he wrote to Dr Sheffield:

“Dear Jonathan,

Re: Histopathology at BRI

I have deliberated over writing this letter to you but I felt that I am obliged to bring to your attention the number of the errors in diagnosis which affected NBT (and other patients) that have occurred at the BRI.

As you know, we have been trying to improve the histopathology service across Bristol for many years and we try to do this by moving toward specialist reporting at Pan-Bristol level and to ensure that all pathologists responsible for the delivery of the histopathology service work in teams and participate in appropriate EQA schemes. We at NBT have implemented this but histopathologists at the BRI have consistently obstructed the process. I understand that the BRI consultants claim that they also deliver a specialist reporting service. However, I am concerned that they may be practising what they consider to be a be (sic) specialist reporting in an unsafe way, as some of the histopathologists report on their own and do not refer some of the difficult cases to be reviewed by pathologists outside of the BRI. I have not kept records of all the cases of which I have been made aware, but in this letter I will mention only examples of cases where patients have suffered or died as a result of misdiagnosis. In my opinion these errors could have been minimised or eliminated if pathologists share/refer/consult with colleagues in Bristol, or send difficult cases outside Bristol before giving or suggesting a diagnosis to the clinicians.

Needless to say that we are all human beings and mistakes may happen occasionally but it is only by being made aware and acknowledging those mistakes that we can learn from them...”

3.52 Dr Ibrahim then listed 11 cases (4 breast cases: 3 skin cases and 4 lung cases – 3 of which had been in Dr Harvey’s list contained in his letter to Dr Morse in March 2005) in which he alleged mistakes had been made by the UHBT pathologists and concluded his letter:

“I sincerely hope that this letter will initiate action to improve the histopathology service which the patients rightly deserve. I believe there is a system failure here where cases of serious misdiagnosis are not detected or acknowledged. I would like to see a comprehensive peer review of the histopathology service.”

3.53 Unfortunately this important letter did not initiate any effective action from Dr Sheffield.

3.54 On 1 April 2007 all gynaecological oncology surgery in Bristol had been centralised and from then on complex gynaecological cases from NBT were transferred to UHBT. Dr Lynn Hirschowitz, a consultant histopathologist at NBT with a special interest in gynaecological histopathology for which she has at least a national reputation, had joined the NBT histopathology department in late 2005 from Bath. At the time that she came to NBT she was aware that a decision had been taken to centralise Bristol gynaecological cancer services at UHBT but she came on the understanding that she would still be very much part of the gynaecological pathology team and she believed that she and Dr Joya Pawade (who was the gynaecological histopathology lead at UHBT) would work together to build and provide a service of excellence for gynaecological cancer patients in Bristol. One of the people who had encouraged her to apply for the NBT pathology post was Mr John Murdoch, a consultant gynaecological surgeon at UHBT.

3.55 Dr Hirschowitz was keen to be able to continue working in her area of expertise following the transfer, and had believed that it had been agreed at a meeting on 26 March 2007 that, as a short term measure, she would be reporting gynaecological oncology specimens from NBT patients and that she would cover all gynaecological pathology when Dr Pawade was away. (The long-term plan was to establish cross-site reporting teams for all specialties)

3.56 When she discovered that what she thought had been agreed was not being implemented, she was extremely upset and raised the issue in several e-mails and letters to Professor Pignatelli and Mr Murdoch.

3.57 We were told by Dr Sheffield that he met with both Dr Ibrahim and Dr Lynn Hirschowitz on 3 July 2007 (the day after he received the letter from Dr Ibrahim detailing 11 cases of alleged errors of diagnosis) to discuss their concerns. There are apparently no minutes of these meetings but we questioned Dr Sheffield at some length about what he understood the meeting to be about and what he did as a result of this meeting. He told us that several of the

cases raised at the meeting had already been investigated. He told us that his understanding of what the NBT histopathologists wanted out of that meeting was that the two departments should work much more closely together. He said that he had assumed at the time that individual discrepancies were being discussed between the consultants concerned, but that he now realised that this was not always happening.

3.58 On 24 July 2007 he met with Dr Pawade (who was the lead histopathologist at UHBT for both lung and gynaecological histopathology) to discuss with her the issues raised by the NBT histopathologists about the cases she had been involved in, but he did not meet with any of the other UHBT histopathologists who had allegedly given Drs Ibrahim and Hirschowitz cause for concern. He did not initiate any further investigation of the cases reported to him as having been wrongly interpreted.

3.59 This was another missed opportunity to deal thoroughly with allegations made about the competence of the UHBT histopathology department. Dr Ibrahim's letter is probably the one referred to in *Private Eye*'s first article and, had it been dealt with properly, with the 11 cases investigated and the results of the investigation made known to all interested parties, there may never have been anything to publish in *Private Eye*.

3.60 On 3 September 2007 Dr Hirschowitz wrote to Dr Sheffield complaining that, despite the agreement that NBT gynaecological cases would, as a short-term measure, come to her for dissection and reporting, only 11 specimens had been sent (four of which were small loop biopsies) in the intervening five months. Her letter concluded:

"I am afraid that I have become very disillusioned about the whole situation. I have tried to take a charitable view but it seems to me that there is a concerted, deliberate and vindictive move to de-skill and undermine the gynaecological pathologists at NBT, to demoralise us, to remove any opportunity for pursuing clinical research that stems from participating in a specialist service of this type, and more importantly, to put patients whose diagnostic biopsies we continue to receive at NBT at risk because of lack of ongoing exposure to relevant material.

I very much hope that you do not condone what is happening and look to you to deal with these completely unjustified discriminatory attitudes and behaviour. This situation has now dragged on for five months. I should be grateful if you could advise me when it will be resolved."

3.61 The difficult relationship between Dr Pawade and Dr Hirschowitz and their respective perspectives of the issues raised by each of them are dealt with in the ‘Culture and Attitude’ Section of the report.

3.62 On 7 October 2007 Dr Hirschowitz wrote to Dr Morse :

“You are already aware that I have concerns about the centralisation of Gynaecological Oncology and the effects of this on the gynaecological pathology services at NBT. My concern extends to the management and clinical governance of the new developments in the service. I am writing to you because there is a gridlock in repatriating the gynaecological pathology and I do not know how to address this. As you know, John Murdoch overturned the arrangement that has been agreed between NBT and UBHT pathologists in March this year and said that he would designate selected gynaecological cancer cases to send us for reporting. Over the past 6 months we have received only 12 cases, of which only 8 were major cancer resections. There has been no decline in the number of gynae cancers diagnosed at NBT. Jonathan Sheffield has not responded to any of my letters (which I have copied to you) and has not taken any of the actions that he agreed at our meetings.

The diagnostic errors are causing increasing clinical concern, as they continue to be found in even the small proportion of cases of gynaecological pathology specimens that I still see, and I remain concerned about the adverse impact this has on patients, including those from NBT. It is also leading to the deskilling of the gynaecological pathologists at NBT. The lack of ongoing exposure to relevant material puts the patients whose diagnostic biopsies we continue to receive at risk....”

3.63 On 12 October 2007 Dr Ibrahim and Dr Hirschowitz ‘chased’ Dr Sheffield:

“It is now over 3 months since our meeting with you on July 3rd 2007, when we discussed our concerns about patient safety because of diagnostic errors we felt had been made at the BRI. You will recall that we provided you with the details of several cases in which significant errors had been confirmed. We remain concerned that if urgent steps are not taken to avoid such errors in the future that the potential to seriously compromise patient care will remain. We should be grateful if you would indicate within the next couple of weeks what specific steps you have taken to investigate and address our concerns, and would be grateful if you could provide us with a detailed response about the outcome of your investigations in the hope that this matter can now be satisfactorily resolved at a local level.”

3.64 Once again there was no response from Dr Sheffield.

3.65 On 16 October 2007, following a meeting of the Joint Scrutiny Committee, an article appeared in the *Bristol Evening Post* stating that plans to centralise breast cancer services had been put on hold for reconsideration in December. The article quoted Dr Ibrahim as saying to the Joint Scrutiny Committee that “*Some aspects of pathology services at St Michael’s are not up to standard*”. (St Michael’s Hospital is part of UHBT). Six days later a press statement from UHBT responding to the article stated that Dr Ibrahim had been misquoted and that the UHBT breast pathology service met national cancer standards.

3.66 On 5 November 2007 a Medico-Legal Adviser at the Medical Protection Society (MPS) wrote to Dr Sheffield:

“MPS members: Dr Lynn Hirschowitz and Dr Nassif Ibrahim

I write on behalf of our members and subsequent to their letter of 12 October 2007 and a meeting with you on 3 July 2007. I understand that in accordance with GMC guidance they have informed you they believe that patient safety may be compromised by what they feel are problems with UBHT pathology service.

I understand that so far you have not responded to their letter of 12 October 2007 and I would be grateful if you would write to them and me with confirmation that their concerns have been addressed and with details of the outcome of any investigation that you have carried out. I await your response.”

3.67 On 12 November 2007 Dr Sheffield wrote to Dr Ibrahim and Dr Hirschowitz:

“Thank you for your letter dated the 14th (sic) October. I can reassure you that any issues you raised are investigated on a case by case basis. I would also like to remind you that whenever you believe there is a diagnostic discrepancy between your opinion and the reporting pathologist, it is appropriate for a letter to be written to reporting consultant(sic) in order for them to review the case and seek a second opinion, where necessary”.

3.68 It seems to us that it is an extremely unusual step for any clinician to go to their medical defence organisation in order to invoke a response to a letter from the Medical Director of another Trust, and yet Dr Sheffield does not appear to have responded to the MPS at all and no details were given to Dr Ibrahim and Dr Hirschowitz of the outcome of any

investigation that he had carried out. His response was brief in the extreme given that he had recently received an unusual letter from a legal representative

3.69 Dr Sheffield has been described to us as ‘not a great communicator’ and unfortunately, that appears to be an accurate description, at least as far as written communications on the issues of this Inquiry are concerned. This letter is a good example of Dr Sheffield’s response to such requests for information. Initially there is no response at all, but if put under pressure to respond in writing, any response will be brief and uninformative.

3.70 A Medical Director needs to have good communication skills and had Dr Sheffield dealt with the concerns raised in 2007 by Dr Ibrahim and Dr Hirschowitz in an effective manner, which, in our opinion, would have been to have thoroughly and promptly investigated (preferably independently) every allegation made by the two NBT histopathologists and reported his findings to them, it is likely that events would not have escalated in the way that they did over the next 18 months and this Inquiry could have been avoided.

3.71 Dr Sheffield did however organise numerous meetings over the next few months but on occasions appears to have given mixed messages about the future of histopathology in Bristol.

3.72 On 12 November 2007 Dr Sheffield wrote to Professor Pignatelli (copied to all the UHBT histopathologists) asking him to arrange a clinical meeting with all the consultant histopathologists to discuss the recent allegations in the press, and he wrote to Dr Ibrahim (copied to Dr Morse) requesting a meeting to discuss the allegations made by him in the Evening Post. On the same day he wrote another letter to Dr Ibrahim and Dr Hirschowitz:

“Thank you for your letter dated 14th of October. , I can reassure you that any issues you raised are investigated on a case by case basis. I would also like to remind you that whenever you believe there is a diagnostic discrepancy between your opinion and the reporting pathologist, it is appropriate for a letter to be written to the reporting consultant in order for them to review the case and seek a second opinion, where necessary”

3.73 On 20 November 2007 Dr Sheffield held a meeting attended by Dr Morse, Professor Pignatelli and Dr Rooney at which he made it clear that he wanted a pan-Bristol histopathology service so that the best person for each specialty reported the appropriate

cases, with regular audits on all sites. The NBT histopathologists had hoped that Dr Sheffield would agree to all histopathology specimens for NBT patients being dissected and reported by the NBT histopathologists, but he was not persuaded to do this.

3.74 He did however agree to the harmonisation of cervical cytology and histology reporting to the histopathologists to NBT as well as the transfer of all breast receptor work (although he was surprised and disappointed that that had not already happened as he thought that that had previously been agreed). He also confirmed that he had asked Professor Ian Ellis, an internationally acclaimed expert in breast pathology based in Nottingham, to carry out a review of breast pathology services across Bristol.

3.75 Dr Sheffield told us that the Overview and Scrutiny Committee for Bristol had made it clear that the Primary Care Trust should review the configurations of the total breast service and it was agreed that breast pathology should be part of that overall review.

3.76 Dr Morse told us that there is now a formal agreement in place that the new breast service will be based at the new Southmead Hospital once it is completed (in 2014).

3.77 The following day Dr Rooney reported to Dr Hirschowitz and Dr Ibrahim by an e-mail which concluded:

“It is clear that Jonathan and Massimo want to move away from the current problem we have highlighted. We need to sit down as a department and review what we want to do and then work out with UBHT how we can make it happen. This means agreeing which specialties we want to deal with and which we want others to take responsibility for. Now that we have the commitment of the new build on Southmead site we must work out how best to deliver services together with UBHT. We need a starting point I guess this is probably it.”

3.78 Dr Ibrahim responded the following day to Dr Rooney’s e-mail with an e-mail copied to Dr Hirschowitz, Dr Morse, Dr Sheffield, Professor Pignatelli, Dr Harvey, Mr Cawthorn, Mr Pounsford and Dr Heryet (Laboratory Manager, Cellular Pathology at NBT) which began:

“Clearly we have not moved an inch!”

He continued:

“It is clear from Jonathan Sheffield’s letters to me and Lynn, and also from your meeting with him, Martin Morse and Massimo Pignatelli that our concerns regarding the issues raised will not be addressed properly internally. Jonathan has missed the point and underestimated the strength of our concerns. We are not criticising individual pathologists, and this is not a personal issue or a “witch hunt”.

The cases which I have listed in a letter to Jonathan and Martin were only examples and I can assure you that I could have added 10 more cases to the list. These may be the only cases or may be the “tip of the iceberg”, without a full external investigation we will simply never know. It should be noted that these are only some of the NBT patients whose specimens had been reported at BRI and we do not know how many of UBHT’s own patients had been affected. The only way to find out the extent of the problem is to have independent review of the whole histopathology service. I believe there is a system failure here where errors (which appear to have occurred fairly frequently) are affecting patient care and are not being addressed”...

...I was deeply concerned to have learnt recently from one of my colleagues that Jonathan Sheffield believed that the letters which were sent from the chest physicians in 2004/2005 expressing their concern about errors in lung pathology were a result of me inciting them to write the letters. This is certainly not true and Jonathan Sheffield was wrong to have said this because this undermines my integrity. This was not the way to address concerns regarding patient care by simply dismissing them....

The letter concluded:

“It seems to me that both Medical Directors have not fully appreciated the intricacies of our current situation, and their proposed course of action is not appropriate. I think the Medical Directors should not impose their own views without having a proper and independent review of the service. The longer major changes are delayed the more embarrassing this is likely to be those responsible for causing delays.”

3.79 We believe that this is the first time that an independent review of the UBHT histopathologist service appears to have been suggested. As we say in the Culture/Attitude Section of the report, despite his and the NBT physicians’ denial that Dr Ibrahim had in any way influenced them to write the letters in 2004 and 2005, we believe that it would be strange if he had not had some influence on the physicians’ way

of thinking, given that he was an eminent pathologist who was a specialist in his field who had worked for many years alongside them.

3.80 It is interesting to note that the day after Dr Ibrahim's e-mail, Dr Morse wrote a letter in strictest confidence to Dr Sheffield in which he first of all raised the matter of gynaecological pathology and the relationship between Dr Pawade and Dr Hirschowitz which had deteriorated to the point that Dr Hirschowitz was seriously considering leaving Bristol. He stated:

"You will of course be aware that the perception of inappropriate detention of gynaecological specimens within UBHT is at least in part related to this relationship. I hope we could make progress on the latter issue as a consequence of addressing the former"

He continued:

"The second (matter) again relates to an area which we have previously discussed, but about which there is an ongoing disquiet because of a continuing trickle of cases which appear to represent misdiagnoses in lung pathology, and concern amongst several NBT clinicians that this is not being appropriately addressed..."

...Whatever the basis of the belief, the reality is that a strongly held conviction exists amongst NBT staff that the service currently provided for lung histology is not of the appropriate quality. I think there is no alternative but to look at the evidence base for this concern, and to take action to improve matters if the concern is proved to be genuine. I would be grateful if we could discuss this in greater depth when we next meet. I am happy to provide you with a list of the contentious diagnoses if that would be of help..."

3.81 Once again there was no formal response from Dr Sheffield to Dr Morse's letter. In particular he did not seek further evidence of what had been described by Dr Morse in his letter of 23 November as the *"continuing trickle of cases which appear to represent misdiagnoses in lung pathology"*.

3.82 Although Dr Morse accurately described the situation as a *"trickle of cases"*, (which appears to have been really all it was at that time although every single allegation should have been investigated.) the failure to address promptly any allegations when

they were raised allowed the ‘trickle’ to be portrayed two years later in *Private Eye* as a much more extensive concern.

3.83 On 23 November 2007 Dr Sheffield had a meeting with the UHBT histopathologists to discuss the need for collaboration and to insist on a move to attaining CPA accreditation. The histopathologists were apparently very happy to collaborate but they were not prepared for any work to be sent away. Later that afternoon, Dr Sheffield met with Mr John Murdoch, Consultant Gynaecological Surgeon at UHBT, and Mr Robert Anderson, Consultant Gynaecologist at UHBT, to discuss if they had any concerns about correlation in gynaecological cytology cases.

3.84 On 2 December 2007 Dr Hirschowitz wrote to Professor Pignatelli describing the difficulties experienced by the histopathologists at NBT in obtaining pathology blocks and slides from UHBT for diagnostic review, resulting in delays in diagnosis and treatment. She asked him to draw the matter to the attention of the UHBT histopathologists. The letter was copied to the two Medical Directors and Dr Rooney.

3.85 On 3 December 2007 Dr Sheffield met with Dr Ibrahim. Following the meeting, Dr Ibrahim e-mailed the NBT respiratory physicians:

“I have just returned from a long meeting with Jonathan Sheffield (Medical Director of UBHT). Many aspects of Bristol pathology were discussed, one of these is lung. He is now keen for lung pathology to be reported by lung pathologists and he is happy for ALL lung pathology (not just NBT cases) to be reported by Ed and myself and ALL specimens to be sent to Frenchay for reporting. I hope that this will be implemented sooner rather than later.”

3.86 Dr Ibrahim may have interpreted the meeting this way, but it is unclear whether Dr Sheffield did, and it certainly seems as though the UHBT pathologists and clinicians were unaware of any such decision.

3.87 On 12 December 2007 the NBT respiratory physicians wrote to Dr Morse (the draft was being circulated at the end of November):

“Re: Lung Pathology in Bristol

We felt we should write to you once again about the above issue. We have been routinely requesting that pathological specimens of NBT patients taken for us by the thoracic surgeons

at the BRI are forwarded to the NBT specialist lung pathologists for reporting (following their original processing and reporting at the BRI) for several years. You are aware of the history of this situation and our concern is to provide the best possible service for NBT patients. In recent weeks there have been increasing delays in the receipt of specimens from the BRI which are having a negative impact on the quality of care we are able to offer our patients. The interval between requesting specimens and receiving them regularly exceeds a month. Many of these patients are awaiting MDT decisions on cancer management. At no point have we managed to achieve a workable solution and in recent weeks an already poor situation has deteriorated further, prompting us to write again.

We have in the past provided you details of cases where care and outcomes had been compromised by incorrect reporting of specimens and an inability to obtain timely specialist reporting for our patients. We understood that this was to enable you to “move forward” on reaching a resolution in conjunction with the MD at the BRI. We appreciate that there are issues beyond the realm of respiratory medicine. To date, however we seem no nearer a solution and in recent weeks we feel the situation for respiratory NBT patients has deteriorated significantly.

We would like to request a meeting with you before the end of the year to discuss these concerns. Specifically we would like you to use your influence to ensure that NBT patient specimens requested from the BRI are dispatched in a timely fashion. Furthermore we would be interested to learn the proposed timetable for a more permanent solution benefiting all Bristol respiratory patients which we were led to believe would be forthcoming following our last correspondence on this topic over 2 years ago.”

3.88 There appears to be no formal response from Dr Morse to this letter, nor is there any evidence of Dr Morse taking the issue to Dr Sheffield.

3.89 Dr Morse told us that he met with Dr Nick Rooney to discuss the letter of 12 December and then also met with Dr John Pounsford and Dr David Smith, Lead Clinician for Respiratory Medicine at NBT. He also recalls that the issue was included in discussions with Dr Sheffield, in the context of monthly meetings between the two Medical Directors.

3.90 On 13 December 2007 Dr Sheffield met with Dr Hirschowitz. She apparently wanted all NBT patient cases to be sent to the NBT pathologists and he told her that he was doing

something to try to improve this situation by sending all colposcopy specimens for reporting at NBT.

3.91 On 17 December Dr Sheffield met with Professor Pignatelli and Dr Julian Kabala, Head of Division for Diagnostics and Therapies at UHBT, and emphasised the need to work across the City and to move to CPA accreditation as soon as possible.

3.92 On 11 January 2008 Professor Pignatelli met with Dr Pawade and Dr Sohail to discuss the transfer of lung pathology to NBT. On 14 January, Dr Pawade sent an e-mail to Professor Pignatelli, copied to the other UHBT histopathologists and some of the physicians in which she said:

“You discussed this complex issue of transfer of thoracic work for the first time on Friday with myself. You implied that this was being done to reduce my PAs from 12 to 11.

As you are no doubt aware that comments made by Dr Nassif Ibrahim in the local newspaper, describing St Michael’s pathology services as substandard have deeply offended all the histopathologists in UBHT. This article was on the Theatre noticeboard of St Michael’s Hospital. As one of the lead histopathologists for St Michael’s Hospital I do take this personally. I have yet to see an apology or retraction.

You organised transfer of our work without due consultation with our department to NBT and Dr Ibrahim in particular. I see this as an insult and an attempt to undermine and demoralise us.

You mentioned that Dr Ibrahim is an expert and I pointed out to you that we were delivering the service in UBHT for the past 10 years.

We are all concerned about the increasing workload in this department and welcome help. We would welcome a pathologist with an interest in pulmonary pathology as part of our team in UBHT. I know I speak for all of my colleagues when I say that we want to feel involved in the service as it includes sarcomas and lymphomas and consolidate it with new colleague (sic)

I appreciate that it is difficult for you to understand various practical/organisational problems related to this work and the 2 MDTs that we do. If you had discussed this matter with us and our users you would have realised that this arrangement is not practical”.

3.93 Dr Pawade's e-mail was followed up by an e-mail from Dr Moorghen to Professor Pignatelli copied to the same recipients:

"I understand that you had a meeting with Joya and Sohail on Friday 11 January to announce that all thoracic work (i.e. specimens and MDTs) will be transferred to North Bristol Trust. As Joya pointed out in her e-mail, it is difficult for someone in your position to understand how the delivery of the histopathology service works. For all the consultants in the Department and our users it is blatantly obvious that the arrangement which you are trying to put in place is simply unworkable for clinical reasons. You chose not to seek an input from us and/or the clinicians and instead you made a deal with a consultant from North Bristol Trust who is driving a different agenda and who is also unaware of the detailed nature of the current service in the UBHT. If you now insist on imposing this arrangement the consequences will be serious.

At a recent meeting with Jonathan Sheffield we were told that individuals at NBT would be offered sessions (i.e. PAs) for them to attend this department at specific times to contribute to the lung service. Jonathan also said that these individuals will also have to demonstrate that there is 'space' within their agreed job plans for this work. Jonathan stated clearly that the specimens will stay in this department. Your arrangement is not in line with Jonathan's. You are disrupting clinical adjacencies and you show complete disregard for turnaround times, frozen section work, urgent reporting and adherence to cancer guidelines and other clinical governance matters. Your arrangement will create utter chaos. I urge you therefore to reverse your decision before it is too late. You have to remember that when the service fails it is those of us in the UBHT who are failing our patients and not individual/s at NBT who may then be perfectly justified to make derogatory remarks about us in the press."

3.94 Mr Tony Morgan, Consultant Thoracic surgeon at UHBT who had been copied in to these e-mails, also e-mailed everyone:

"I and my colleagues are the users of this service and I find it breathtaking that such fundamental changes are contemplated with no consultation whatsoever with those who they affect. My view is that to transfer work to NBT is frankly dangerous. The specimens must remain at the BRI. Whether or not pathologists from NBT contribute to the reporting at the BRI is an internal matter for the pathology department. The whole service will collapse if

what is proposed is implemented. I trust that that rarest of commodities - common sense - will prevail here."

3.95 This is another example of the lack of consultation with clinicians prior to major decisions being made.

3.96 In the afternoon of 14 January 2008 Dr Sheffield met with Professor Pignatelli to discuss the ongoing issues with lung and gynaecological pathology. The next day he met with Dr Ibrahim who again made accusations of poor performance from the UHBT histopathologists and he described anecdotal cases.

3.97 On 18 January 2008 Dr Martin Hetzel, a consultant physician at UHBT, sent an e-mail to Jonathan Sheffield with copies to Dr Pawade, Dr Sohail and Dr Moorghen as well as to various clinicians at UHBT, in which he expressed his concern at any proposed transfer of lung pathology to NBT. He also highlighted some delays in decisions because of the histopathologists' workload. He asked for a meeting to discuss the issues and concluded:

"It seems to me that the solution to this problem is having increased manpower on site in UBHT. Moreover, it was my understanding that UBHT aspired to becoming a major cancer centre with an international research portfolio and I would have thought that a well staffed histopathology team that belonged exclusively to UBHT was fundamental to this objective. Relying on support from NBT therefore looks to me like a retrograde step.

I am very sad to see that there is some friction over this issue amongst our pathology colleagues. I do hope that this can be resolved and would also like to say that we have every confidence in the opinion (sic) that Joya and Sohail give us."

3.98 Dr Sheffield responded:

I am very happy to meet with you and discuss. Joya and Muhammed have made it quite clear that they wish to give up lung pathology to adjust their job plans. So I think it is appropriate we meet"

3.99 On receipt of Dr Sheffield's e-mail, Dr Hetzel e-mailed Dr Pawade and Dr Sohail:

"Dear both – can you please clarify your position on this. I was under the impression that you did want to continue doing lung pathology but I may have misunderstood the situation."

3.100 Dr Pawade responded to Dr Hetzel that she and her colleagues did wish to carry on doing lung pathology but had been told by Dr Sheffield and Professor Pignatelli that they could not be the lead in more than two main specialties, which was defined as specialties where they did the MDT. She explained that as she already had been doing gynaecology and haematopathology, and Dr Sohail had been doing urology and breast, there was no option but to accept that they did not have space for lung MDTs in their job plans. She and her colleagues therefore wished to see a new appointment in the department with an interest in lung pathology.

3.101 On the 30 January 2008 Mr Murdoch wrote to Dr Hirschowitz with copies to Dr Pawade and the two Medical Directors. The letter was dealing with a particular patient's case where Dr Hirschowitz had expressed a difference of opinion about the staging of a cancer from that given by Dr Pawade. Mr Murdoch stated that it was unfortunate that Dr Hirschowitz had not brought her difference of opinion to the attention of the MDT and asked that in future any concerns over the final report issued by a colleague should be brought to the attention of the MDT as soon as possible and that, in the event of a discrepancy between two pathologists, they should discuss the case without delay and reach a consensus if possible with the consensus opinion being presented at the next MDT. In the event of an unresolved difference of views, the specimen should be sent off to an independent pathologist for arbitration. He also stated that the practice of NBT pathologists sending cases out for an independent review without first sharing the case with the other internal MDT pathologists must cease.

3.102 On 4 February Dr Sheffield met with Dr Pawade to discuss her relationships with Dr Ibrahim and Dr Hirschowitz. Dr Pawade was apparently very upset about their approach. The next day he had a meeting with the consultant histopathologists at which he emphasised the need for more specialist reporting and CPA accreditation. He told them that he would personally carry out appraisals of each consultant to be reassured that their current training and continuing professional development was up to date.

3.103 On 11 February 2008 Dr Hirschowitz responded to Mr Murdoch's letter of 30 January (copied to the Medical directors and Dr Pawade) in which she defended her position. She also wrote:

"In the event of a discrepancy, I agree that seeking consensus diagnosis is appropriate – i.e. a consensus between specialist histopathologists".

3.104 She ended her letter:

“I do not wish to enter into protracted correspondence and suggest that if you have any further comments about the gynaecological pathology services and patient X in particular, you raise these with your medical director, Dr Sheffield”

3.105 On 21 February 2008 Dr Sheffield met with the histopathology consultants to discuss the possibility of transferring lung pathology reporting to NBT. The following day he attended a lung MDT meeting to discuss future lung pathology reporting. He apparently emphasised the need for specialist reporting and participation in a tripartite agenda. The UHBT clinicians expressed their view that they were very happy with the current situation.

3.106 On 13 March 2008 Dr Sheffield met with Professor Pignatelli, Dr Rooney and Dr Morse to discuss the issues around lung and gynaecological pathology. The poor relationship between Dr Hirschowitz and Dr Pawade was raised and it was mentioned that Dr Hirschowitz might move to Birmingham.

3.107 On 28 March Dr Sheffield attended a lung MDT Meeting attended by Dr Ibrahim and the proposed transfer of lung pathology reporting to Dr Ibrahim and Dr Ed Sheffield was discussed. The UHBT clinicians apparently voiced their fears that the NBT histopathologists were not proposing to work in the BRI laboratory and they were worried about turnaround times and the frozen section service. It was agreed that Dr Ibrahim would put further proposals together.

3.108 **It appears that for a period of some months Dr Sheffield was meeting with many people in order to promote collaboration between the two histopathology departments and to attempt to appease heightened concerns, but he failed to do anything sufficiently constructive to achieve his goals.**

3.109 On 1 April 2008 cervical histology services were transferred to NBT.

3.110 On 4 April 2008 Mr John Murdoch, Consultant Gynaecological Surgeon at UHBT, wrote to Dr Sheffield and Professor Pignatelli:

“As you know, there has been considerable disharmony within gynaecological pathology in Bristol. The ongoing personality clash between Lynn Hirschowitz and Joya Pawade appears to have been resolved with Dr Hirschowitz appointment to a post in Birmingham. However, it

leaves a number of cases which Dr Hirschowitz identified in which she calls into question Dr Pawade's opinion. I am writing to ask you whether you plan any formal review of these cases or any other aspects of Dr Pawade's work. Alternatively, I would like to know if you consider the issue closed.

As you know in modern practice it is not simply acceptable to do a good job but on governance terms to be able to demonstrate that a good job is being done. Dr Pawade engages in multiple audits of her work and also widely disseminates her cases within the department on an ad hoc basis to obtain opinions from her colleagues. She does not, however, engage in formal review of her Gynae pathology with other Gynae pathologists. I wonder if it would be helpful through you to encourage her to set up a process of systematic peer review of cases with existing Gynae pathologists in Bristol and Bath, who contribute to the MDT at St Michael's. I know she has a very good relationship with Dr Sen in Southmead and Roger James in Bath. Such an arrangement would be very valuable to the Gynae pathology team. It might also reduce the rate at which cases are sent elsewhere without reference to Gynae specialist colleagues within the network.

Thirdly, I understand that approval has been given to the appointment of a new pathology post in UBHT. As you will know the absence of a named deputy Gynae pathologist in UBHT is the one remaining obstacle to total IOG compliance. I strongly support Joya Pawade's suggestion that the new appointee should have an interest in Gynae pathology and act as a deputy to her in the MDT. I am very interested to hear your thoughts on these matters."

3.111 Mr Murdoch, who at all times had been Dr Pawade's major supporter, raises three important issues in this letter; whether Dr Sheffield planned any formal review of the cases identified by Dr Hirschowitz in which she called into question Dr Pawade's opinion or whether he considered the issue closed; a suggestion that Dr Pawade should engage in formal review of her gynaecological pathology with other gynaecological pathologists in Bristol and Bath; the appointment of a new histopathologist at UHBT and whether any new appointee should have a special interest in gynaecological pathology. (It should be remembered that in January 2008, just three months earlier, Dr Pawade had been advocating that any new appointee to the histopathology department at UHBT should have a specialist interest in lung pathology).

3.112 This important letter appears to be yet another communication which went unanswered by Dr Sheffield (and Professor Pignatelli). Three days after Mr Murdoch's letter was sent, Dr Sheffield did carry out a formal appraisal of Dr Pawade, but this was not as a result of the letter, but was part of pre-planned appraisal of all the UHBT histopathologists. He told us that the appraisals were one of the ways he addressed concerns which had been raised:

"One of my issues with them is how much they subspecialise and what their interests are, and one of the reasons why I carried out their appraisals personally -- I have 350 consultants in my organisation, I don't appraise consultants normally, but because I was concerned and I wanted to get to the bottom of the issue, I carried out the appraisals of all the consultants in early spring 2008, because I wanted to find out what they were doing and how they were doing things."

3.113 The fundamental requirement for good appraisal is that the appraiser has detailed knowledge of the work of the person being appraised. We therefore question whether it was appropriate for Dr Sheffield to carry out these appraisals because, although he is himself a histopathologist, as Medical Director he could not have had sufficient appreciation of how the individual pathologists in UHBT worked.

3.114 There was no formal review of Dr Pawade's cases identified by Dr Hirschowitz (nor was there any statement that the matter was closed) nor was there any move to ensure that Dr Pawade engaged in formal review of her gynaecological pathology with other gynaecological pathologists in Bristol and Bath. There was no advertisement placed for an appointee to the adult UHBT histopathology Department until 2008 (interviews in January 2009) following which a part-time specialist skin pathologist was appointed for 3PAs. Dr Sheffield told us that the purpose of advertising was to widen specialist expertise, to reduce the burden on the individual pathologists and to increase links with NBT. This appointment followed complex job planning throughout 2007 led by Professor Pignatelli. The UHBT histopathologists did not like the job planning proposals and involved the BMA and Dr Sheffield as some of them did not want to give up any of their specialist interests and were loath to have any changes to their job plans

which would result in a reduction of their PAs. There was no further recruitment until 2010 during the course of this Inquiry.

3.115 On 15 June 2008, shortly before she left Bristol, Dr Hirschowitz sent a long letter to Dr Graham Rich, the Chief Executive of UHBT in which she wrote:

“The sole reason for this letter is that I believe that I have a professional duty to draw to your attention certain deficiencies that I have observed in the cellular pathology service at UBHT because they have serious implications for patient safety.

I feel compelled to request that you investigate the concerns. If they are shown to be groundless that will be reassuring for patients and clinicians alike.....

3.116 Dr Hirschowitz then listed various problems which she said that she had identified in the UHBT cellular pathology service and concluded her letter:

In attempting to address these problems, I saw the NBT and UBHT Medical directors on several occasions and also raised my concerns with Professor Massimo Pignatelli, Clinical Director of pathology services at UBHT..... Every time the concerns were discussed I was given reassurance that they would be investigated and dealt with in an appropriate manner. At my last meeting with Dr Sheffield on December 13th he indicated that he did not feel that it would be helpful to take these matters to the GMC or the Royal College of Pathologists’ Professional Standards Unit and that he would take steps to address the above issues at a local level. As noted above, the reporting of colposcopy specimens has now been transferred to NBT but I am unaware of any steps to address the other concerns. At the meeting on December 13 Dr Sheffield also suggested that he and I should meet with the lead gynaecological pathologist to discuss gynaecological pathology and he agreed to arrange a meeting but this has not materialised.

I should be grateful if you would give these concerns your urgent attention. Under present circumstances it is difficult to build working relationships between pathologists on the NBT and UBHT sites. Patterns of behaviour such as those described above engender mistrust, prevent Bristol pathologists from working together as a team and are much to the detriment of patient care.”

3.117 It was not until 29 August 2008 that Dr Rich responded to Dr Hirschowitz's letter and, although the letter went out in his name and was signed by him, he left the drafting of the letter entirely to Dr Sheffield.

3.118 In the meantime much had been happening in the intervening two months.

3.119 On 6 June 2008 Dr Harvey, one of the respiratory physicians at NBT, sent an e-mail to Dr Charlie Tomson, a consultant renal physician at NBT who was also Lead Clinician, Safer Patients Initiative. The e-mail was copied to various clinicians including Dr Morse and Dr Ibrahim:

"Following the many discussions that we have had on this subject, I have completed an AIMS form for poor Mr A, one of our patients who underwent an open lung biopsy recently. The specimens were not sent to our lung pathologists but were reported by a non-specialist pathologist at the BRI as showing a desmoplastic mesothelioma. This was then communicated via the discharge summary. We eventually got hold of the specimens for review at our Lung MDT by our specialist lung pathologists who have confirmed that this is an entirely benign fibrosing process. Apparently the immunostains had been misinterpreted. As you know, we have also had some of our patients biopsies reported to them as benign and then had to explain to them that they were in fact malignant!"

I am deeply concerned, as are my colleagues here, that this is continuing to happen 4 years after we first reported a catalogue of similar mistakes to both Medical Directors (August 2004). It seems astonishing that we are knowingly depriving our patients of the appropriate expertise that is so readily available to them.

Cognisant of the Kennedy report and the GMC guidelines on duty of care for our patients I wonder whether the Clinical Governance Committee will feel that the time has now come to consider 'whistle blowing' to the GMC/media, albeit very much as a last resort. We would appreciate your and Corinne's advice about this.

Every week at our MDT our patients are made to wait another 4 or 5 weeks - and occasionally months- for their treatment decisions to be made because we can't get their specimens from the BRI pathology Department. At best this is inefficiency and at worst spiteful politics that is clearly harming our patients. Tim Batchelor, our excellent new Thoracic Surgeon, who operated on Mr A and who had to sort out the misdiagnosis, finds

this situation incomprehensible and I must say that I am very embarrassed to have been party to this for so many years, as indeed we all should be....

Do you think we should take this matter formally to the Trust Board? I will forward any advice that you, Martin or Corinne might have to our MDT meeting.”

3.120 This e-mail to Dr Tomson was a crucial event because it escalated the pace of events.

3.121 It is noteworthy that Dr Harvey states in this e-mail that in August 2004 they had reported "a catalogue" of similar mistakes. In fact the 2004 letter referred to only two recent cases which had had an adverse clinical effects on patients. In 2007 Dr Morse had referred to a "trickle" of cases.

3.122 This is a good example of how frustration at allowing matters to go uninvestigated and unanswered can increase their seeming importance in people's minds and can enlarge concern.

3.123 This e-mail set in train a flurry of e-mails over the next six weeks between the clinicians who had been copied in to Dr Harvey's e-mail. Firstly, Dr Morse replied to everyone:

“I have recently again spoken to Jonathan about this who assured me that a final solution was only a few days away. It is immensely dispiriting to get further cases popping up despite this dialogue.

He is fully aware that I have been at the point of escalating this issue more formally but had held off because of his assurances. In the light of this additional case I think I have no choice but to give him an explicit ultimatum. Sonia (Mills. CE of NBT) is aware of the issue and I will discuss this with her next week. I accept that if there is not a rapid resolution we may indeed be into GMC Territory, although the people at risk in such circumstances will not, of course, necessarily be those who made the misdiagnoses, but those with managerial responsibility for the service. Please take no action until I have spoken to Jonathan”

3.124 Dr Tomson responded to everyone at exactly the same time as Dr Morse:

“This is unsafe care and I fully agree that no clinician should continue to operate within a system they know to be unsafe. I don't know anything about the politics of the situation but agree that it is totally unacceptable for inter-Trust politics to get in the way of the best

patient care. It is several months since you first alerted me to this situation and asked for informal advice. My expertise isn't in the 'governance framework' approach to reduction of clinical risk... nor do I have any formal role within the Trust's clinical governance structures, other than sitting as an observer on the Clinical Risk Committee (which, to the best of my knowledge, has not been asked to consider issues relating to mis-reporting of lung pathology specimens, which raises the issue of what has happened as a result of the AIMS forms that you have completed on each of these cases. Do you have copies of the Manager's Report for each of the AIMS forms you have completed, or any other feedback?)

My personal view is that our Clinical Governance structures and procedures are not up to the task of ensuring that NBT becomes an organisation that learns from every mistake and avoidable harm. That doesn't reflect on any of the individuals involved, and is partly a consequence of the weight of regulatory paperwork.

I know that you have flagged this issue to Martin Morse previously.

Martin (Morse), has the Trust Board been informed of these concerns? If so what decision was reached? If not, should they not be? Has the Healthcare Commission been informed of these concerns?

3.125 Dr Tomson then advised everyone concerned to telephone the GMC to ask for advice on how best to proceed and then to do exactly as the GMC adviser suggested.

3.126 Six minutes later Dr Morse replied:

"Please see mine which crossed with Charlie's. The problem with contacting the GMC at this stage is simply that a bandwagon may start to roll which has no simple way of being stopped. If an approach in such circumstances needs to be made to the GMC, there are substantial benefits from making it an organisational, rather than an individual clinician approach, both in terms of weight of concern and subsequent blame apportionment"

3.127 Dr Tomson responded:

Martin, I disagree. The clinicians who have contacted me have individual responsibilities as registered doctors that are not discharged by being told that the Medical Directors are sorting it out between them. If a future Kennedy Report into misdiagnosis of mesothelioma in Bristol was to be set up, I wonder how it would view what could be characterised as inward-

looking and defensive behaviour. Let me put another perspective to you: if we had a member of the patient panel on this e-mail distribution list, or on the clinical risk committee (notwithstanding the fact that this extremely concerning problem has not reached that committee, for reasons that themselves merit enquiry) and this topic had been discussed 6 months ago, since when nothing had been done, would you feel comfortable?

My other recommendation, which I have made before, is that the clinicians concerned implement the procedure in the Trusts whistle blowing policy CG43, which is attached for reference”

3.128 Dr Morse sent a further reply:

“Charlie – I am in the process of getting hold of Jonathan again as we speak. If no progress next week then I agree that further escalation is warranted, but I stand by my belief that an organisational approach (supported of course by individual clinicians involved) is the most valuable route. I also think it probable that the HCC rather than the GMC would be more effective”

3.129 Dr Harvey responded 10 minutes later:

“Both your comments noted. I fully support a measured approach to this, but I do agree with Martin that we need to resolve this between the two trusts both quickly and permanently.”

3.130 Three days later Martin Morse wrote to everyone:

“I have today had a further commitment from Jonathan to meet with Nassif to progress the formal side of the transfer ASAP – I am awaiting definite news of timescale, but have made him aware that unless there is additional rapid progress there would seem little alternative to involvement of external bodies.”

3.131 On 3 July 2008 Dr Tomson e-mailed everyone to ask if there had been any progress. He wrote:

“I feel professionally vulnerable, being party to some of this information and not having acted on it personally.”

3.132 The next day a response came from Corrine Thomas to say that Dr Morse was on leave but that she was aware that the meeting (between Dr Sheffield and Dr Ibrahim) had been due to take place a couple of weeks previously.

3.133 On 14 July Dr Tomson wrote to Dr Morse (the e-mail was copied to the previous recipients):

“I am told by John Harvey that there has been no progress relating to reporting of lung pathology specimens, and have also learned of Lynn Hirschowitz’s resignation on the grounds of similar concerns relating to the non-specialist reporting of gynaecology specimens.

...I contacted NCAS and have attached a copy of their letter of advice to me, which as you see advising me to ensure that all local pathways have been resolved before involving them formally.

Under the Trust’s whistle-blowing policy CG43, therefore, I consider that this has now reached stage 5.6 and would therefore be grateful if you would raise the issue with the Chief Executive, providing her with all the correspondence relating to pathology reporting and the dossier of cases that has previously been sent to you, within the next 10 days unless this has already been done, and provide evidence that this has been done.

If there is no adequate response within the next 15 days, then the Chairman of the Trust Board should also be involved. You may also choose to inform the Medical Director of the SHA, although that is not mentioned under CG 43.

If resolution of the problem does not follow, I would then feel obliged to take this to NCAS with a formal request that they get involved, probably by asking the Healthcare Commission or Royal College of Pathologists, or both, to become involved.

I am aware that CG43 was written to cover safety concerns confined to one Trust, whereas the problem with pathology reporting lies in the UHBT. However, in so far as the problems of inaccurate reporting of lung and gynaecology pathology specimens, and the difficulties experienced in ensuring that those specimens are then reviewed in the appropriate MDT meetings by specialist pathologists, relate to the care of patients cared for by NBT clinicians, I consider that this policy should guide my actions. I have tried hard to find a national policy

related to whistle blowing when the concern relates to a neighbouring Trust, and have been unable to do so.

To my mind, this issue is a critical test of whether we in NBT have a safety culture that genuinely responds to clinicians concerned about safety, however difficult it may be”

3.134 A short while later Dr Harvey replied

“This e-mail came at an appropriate moment. I have just had a conversation with David Smith, who was telling me about a patient who had a lung biopsy taken at the BRI two months (yes that’s months) ago and we are still waiting for the specimens to be forwarded by the BRI pathologists.

This is a regular occurrence and it is becoming increasingly difficult to explain this to our patients, let alone explain to them why they do in fact have cancer when the BRI pathology report missed this fact! (Or vice versa)

I do think that after 5 years of this we really need to solve the problem. Do you want us to forward a copy of the letter we all wrote about the subject in March 2004?”

3.135 The following day Martin Morse responded:

“I think it would be helpful if the designation of no progress came firsthand, i.e. from Jonathan Sheffield.

I have returned from leave today and will e-mail him now to ask what has happened, and include the concern now raised by John regarding the patient with the delayed specimen.

Sonia (Mills: Chief Executive of NBT) and Mike Durkin (MD of the SHA) have been aware of my concerns for some time.

As I have already pointed out, the GMC route does not easily address the problem, given that this is a departmental issue (please spare me the obvious point about responsibility of heads of departments etc)

I will feed back when I have up-to-date information.”

3.136 Dr Morse then forwarded the chain of e-mails to Dr Sheffield with the note:

“Jonathan - the attached is self explanatory

Do you have any news for me?”

- 3.137** On 15 July 2008 Dr Tomson received a copy of an e-mail from Dr Harvey addressed to Sonia Mills, Chief Executive of NBT:

“I gather from Charlie Tomson that in view of the impending investigation by the National Clinical Assessment Service you should have a copy of two of the original letters that we wrote on this subject. The response to our letter from August 2004 by the UBHT Medical Director was essentially one of fury that we should have raised the subject to all! There were frightening echoes of this response to that of the children’s heart scandal... and the same Trust too! I have to say that all of us clinicians are finding it increasingly difficult to manage our patients against this background of incorrect diagnoses. When patients have been told that they have cancer when they don’t (and vice versa) and then ask if this is a problem that has happened before, it is hard to be anything other than honest with them. I really do think that it is time we sorted this out...4 years and still the mistakes occur (2 incorrectly diagnosed cancers in the last month and many cases waiting two or more months for treatment decisions to be made by our MDT)”.

- 3.138** The following day, as Dr Sheffield was on leave until 28 July, Claudette Young, Management Assistant to the Medical Director Team at UHBT, forwarded the e-mails sent by Dr Morse to Professor Pignatelli asking him for his views in the absence of Dr Sheffield. She also showed them to Dr Chris Monk who was covering Dr Sheffield. She told Professor Pignatelli that she would speak to Dr Sheffield the following day as he was in London attending a Health Select Committee.

- 3.139** Later that day Professor Pignatelli responded:

“It seems that there was a delay in sending the slides (not the report) to NBT although it is unclear when the slides were requested. Mark Orrell had already left this afternoon but I will double-check with him tomorrow morning (but it looks like the slides were sent to Nassif Ibrahim 3 days ago).

We are still very committed to get the pathologists from NBT (Ed and Nassif) involved in the provision of the lung pathology service. There were some operational issues related to the

provision of the frozen sections and my understanding is that it was left with Nassif and Ed to come back to us with a proposal to address these issues.

I would like to receive details of these cases of serious misdiagnosis and we will investigate them.”

3.140 On 17 July 2008 Ms Young forwarded Professor Pignatelli’s e-mail to Dr Morse and informed him that she had spoken to Dr Sheffield who had asked her to arrange an urgent meeting between himself, Dr Ibrahim and Dr Ed Sheffield, Dr Moorghen and Professor Pignatelli. She also asked Dr Morse to e-mail Dr Sheffield details of the serious misdiagnosis cases so that an investigation could be undertaken at UHBT.

3.141 **Dr Sheffield should have asked for details of the cases when the issues were first raised.**

3.142 Dr Morse responded:

“Please pass this to Jonathan as soon as he is back. I cannot overestimate the importance of this meeting happening urgently as I was given to understand that Jonathan would arrange to meet Nassif while I was away, which obviously has not happened.

Clearly the concern is that NBT clinicians are not prepared, on the grounds of patient safety, to accept continuing delays and misdiagnoses, which, despite the agreement which had been reached between Jonathan and myself, continue to pose major problems. There would, in spite of those agreements, appear to be some system failure, to be frank probably arising from poor relationships between the two departments. We cannot continue to accept a methodology which is less than robust and fit for purpose, and which allows individual agendas to compromise what has already been agreed. I do not wish to use external agencies unless necessary, but Jonathan will be aware of the huge frustration and concern regarding patient safety which is felt at NBT, both by myself and by clinicians involved in the care of respiratory/thoracic patients, and the inevitable involvement of those agencies if this cannot be resolved as a matter of urgency. I use that reminder not as a threat, but simply to reflect the reality of the magnitude of this problem, and the failure of much work to provide a solution.”

3.143 The same day Dr Morse e-mailed Dr Tomson, copied to the NBT respiratory consultants and histopathologists and to Dr Rooney:

“Jonathan is away on leave but his PA has managed to contact him.

It is now clear to him that the work which he and I and the NBT pathologists put in to provide a robust system appears to be being continued to be undermined by individual agendas. He has therefore agreed to meet as a matter of urgency with Morghen (sic) and Massimo, Nassif, Ed and me. He has also asked for an up-to-date list of all the problem diagnoses and delays in order that he may formally investigate. I will of course insist that any such investigation is not a purely UBHT affair, but also includes appropriate NBT representation.

John H(arvey) – could you update your list please, with both misdiagnoses and delays and let me have it ASAP. I would suggest at this stage that it just needs simple patient identifiers and a very brief summary of the issues for each patient. You may wish to liaise with Nassif and Ed on this”

3.144 Dr Tomson also received the following e-mail from Dr Ibrahim that day:

“No such robust system was ever in place to sort out this problem; there was a lot of talk but no actions. I do not wish to burden you with this problem. Just for your information, I have no intention to waste time in meetings. We have had many meeting over the past 6 years and nothing have been achieved(sic).Bob Slade tried very hard to get thoracic pathology back to NBT with no success. There is no point at all now of a meeting with Morgan, Massimo, Jonathan and Martin just to get them out of trouble. We are now 3 consultants down and we are struggling to cope with the existing workload.

UBHT histopathology needs to be investigated. Anything less than this will be a cover-up. It is not just lung pathology. I have records of many patients, and those patients who have been damaged need to know.”

3.145 It is clear from this e-mail that Dr Ibrahim wanted nothing less than an investigation (presumably independent) of UHBT histopathology and for thoracic pathology to be transferred back to NBT.

3.146 On 22 July 2008 Dr Tomson wrote to Dr Mary Barnes, the Director of the Avon, Somerset and Wiltshire Cancer Services Network (ASWCS) asking her whether the concerns raised by the NBT clinicians had been formally investigated within the Network.

3.147 On 28 July 2008 eight thoracic physicians and surgeons at the BRI wrote to Dr Sheffield expressing their “*very strong concerns*” about the plan to transfer lung pathology services to NBT. They concluded their letter:

“We have confidence in our UHB colleagues who currently provide this service, except that they are overstretched and additional lung pathology sessions are clearly required to provide an efficient service. Their confidence in reporting lung pathology is not in doubt; they refer complex specimens appropriately to national experts when this is necessary.

We have no confidence in the logistical capacity of the North Bristol pathology department to provide an equivalent service, let alone an improved service. Informal discussions lead us to believe that this view is shared by many NBT staff.

We believe this undermines the status of UHB FT as a regional centre for thoracic services and as a cancer centre. If thoracic pathology services need to be centralised in one trust, then that trust should be UHB, as we provide the regional clinical services in these areas. We simply do not understand how the loss of this essential service to another trust can be conceived as being in the interests of our patients or our hospital.”

3.148 On 1 August 2008 the meeting took place between Dr Jonathan Sheffield, Dr Morse, Professor Pignatelli, Dr Ibrahim and Dr Moorghen. Following the meeting Dr Morse wrote to Dr Sheffield summarising what had been discussed and agreed:

“To summarise our discussion, you opened by reiterating your commitment to a high quality pathology service, provided by clinicians across Bristol, both of the patients in Bristol and those from further afield, a view which all present were happy to endorse. I then drew attention to the difficulties that had ensued, particularly in the fields of breast, gynaecological, and lung pathology, the latter of which I specifically wished to focus on at this meeting. It was apparent that, over the last four years, there had been a number of misdiagnoses of lung specimens which had arisen from within the UHB department, in addition to which there were evidenced instances of delays in making reports, specimens, or slides available to NBT pathologists for scrutiny. Despite a number of meetings having been held at various times within this period, both at inter-departmental level and between ourselves, with the specific intent of putting in place systems designed to provide mitigation against these difficulties, it was apparent that any short-term improvements had not been maintained, with intermittent unforeseen recurrence of both problems. Given this situation, I

no longer felt it tenable for NBT as an organisation, either in governance or patient safety terms, to rely on assurances from UHBT that further internally driven system changes could address the problem. I also made you aware of the strength of feeling held by some individual clinicians with NBT, and the resultant steps which they had felt moved to take in considering the reporting of this situation to external agencies.

I tabled a series of recommendations which I wished to see implemented with immediate effect concerning the management of lung pathology specimens relating to NBT patients:

For all patients referred to UHBT thoracic surgeons from NBT consultants, future arrangements will be that:

- 1. All pleural, mediastinal, and lung biopsies will be appropriately fixed and transported to NBT by the next working day after surgery*
- 2. Gross resection specimens will continue to be reported by UHB*
- 3. Reports, blocks, and slides of all such specimens, whether considered to be benign or malignant, will be made available for review by NBT Pathologists within two working weeks of surgery*
- 4. No external second pathological opinion will be sought on any specimen without the express agreement of NBT pathologists*

I also tabled recommendations which I wish to be implemented in regard to a formal review of the situation:

For all patients referred to UHB thoracic surgeons from NBT consultants within the last four years:

- 1. All instances of misdiagnosis and/or significant delays in providing reports, blocks or slides will be investigated*
- 2. The terms of reference of the investigation, and the time scales for reporting, will be agreed by NBT and UHB Medical Directors*

3. *The investigation will involve NBT and UHB representation and will be led by a senior representative of the Royal College of Pathologists, agreed between the College and NBT and UHB Medical Directors*

I am delighted that you felt able to accept both sets of recommendations in their entirety, and that you committed to support the departments in reaching a logistical solution to the arrangements regarding reports on specimens, and to contact the Royal College of Pathologists to discuss an appropriate investigation team.

You will of course recognise that whilst my primary focus of interest must be NBT patients, self evidently I would wish that any improvements in the service should be extended to patients referred within UHB or from other trusts. Similarly, you will recognise that whilst the review is focused specifically on lung pathology issues, I would wish to see that any issues which the review may uncover in terms of general working of the departments are acted on appropriately, and in this regard I would particularly draw attention to the breast and gynaecological services mentioned above.

You will note that I have copied this letter to Graham (Rich), and I understand that he has been made aware of such concerns through other channels, but I will leave it to you to judge how widely you would wish it to be distributed with UHB. I have also copied it to Sonia (Mills) and to those NBT clinicians who are directly involved, with the request that they presently treated as confidential.”

3.149 At the meeting with Dr Sheffield on 1 August, Dr Morse laid down specific stipulations about lung pathology, which were unconditionally agreed by Dr Sheffield, again without any consultation with the UHBT histopathologists or clinicians.

3.150 Dr Tomson received a reply to his letter to Dr Barnes from Mr Geoffrey Pye, the Medical Director of ASWCS, on 7 August 2008:

“Mrs Mary Barnes, ASWCS Network Director, has forwarded to me, as Network Medical Director, your recent e-mail voicing concerns over the standard of histopathological reporting at the BRI, and the failure of those involved to address the situation to your satisfaction.

You ask in your e-mail if the ASWCS cancer Network has been made aware of these issues and undertaken any formal investigation of this matter. I can confirm that I have not previously been made aware of this problem and that no such formal or informal investigation has been undertaken.

The primary responsibility for addressing the issues of clinical governance that you raise lays with the Trust concerned, in this case UHB.

However, the ASWCS Network does have a legitimate role in seeking to ensure the highest possible standards of cancer care within its area.

In view of this, I will enquire of the relevant organisations the steps that they have taken to address the concerns that you have raised, in an effort to ensure that the proper standards of histopathological reporting are available for all patients in the Network's area."

3.151 It appears that although Mr Pye was unaware of the issues raised about UHBT histopathology, Dr Barnes and the ASWCS Board had been made aware of them by Dr Ibrahim and others.

3.152 On 8 August 2008 Mr Pye wrote to Dr Sheffield:

"I have received a communication from Dr Charlie Tomson (Consultant Renal Physician and Lead Clinician, Safer Patient Initiative, NBT) suggesting that there is a major problem with the quality of histopathological reporting of cancer relating to Breast, Gynae and Thoracic tumours at your Trust, and that patients have come to significant harm as a result. He has offered neither detail of the alleged incidents nor any evidence to support the allegations.

In addition, he has suggested that, despite considerable efforts, these concerns have yet to be effectively addressed. He has asked about the Network's knowledge of and actions related to these issues, apparently as a prelude to referring the matter to the Healthcare Commission. As you will know, there has been no formal involvement of the Network in this matter and I was unaware of the alleged problem prior to this communication from Dr Tomson.

It is my view that the primary responsibility to address issues such as this lies with provider organisations.

However, the Network clearly has a legitimate role in seeking to establish and maintain the highest standards of cancer care and to use its influence to ensure that provider organisations discharge their responsibilities in a proper fashion.

It would therefore very much assist me if you would be kind enough to brief me on the UHB view of these allegations and advise whether they are actively under investigation by your organisation.”

3.153 The same day Mr Pye sent an identical letter to Dr Morse asking him for the views of NBT on the matter and to Dr Mike Durkin, Medical Director of NHS South West, asking for the views of the SHA (Strategic Health Authority).

3.154 On 11 August 2008 Dr Morse e-mailed to Mr Pye:

“It looks as if we may actually be making progress – I enclose my last letter to Jonathan (his letter of 1 August 2008) for information, but would be grateful if at present you would treat this as confidential.

Mary will confirm that these issues have popped up from time to time at ASWCS Board level, but always in a relatively informal way. I agree that ASWCS should hold a watching brief rather than becoming directly involved in any review, given the level of external involvement.”

3.155 Dr Sheffield did not respond to Mr Pye’s letter.

3.156 Mr Pye told us:

I was disappointed not to get any sort of response from anybody, apart from Martin Morse, and really, Martin just sent me a letter which predated or was describing a meeting which had predated my first involvement and seemed to be saying, ‘Well, we’ve patched it up a bit for the North Bristol patients.’ That seemed to me to be really missing the point, that as far as North Bristol was concerned, if their patients were going to UHB and the pathology was of poor quality – I don’t know whether it was or not – the solution did not seem to me that you fix the problem for North Bristol and then think you have solved the problem. Clearly, you have not. You have put a sticking plaster over it. So I thought the response from Martin was good as far as it went but it did not go terribly far, in my view.

3.157 We agree with Mr Pye's view that you could not just fix the problem for NBT patients without addressing the wider issues.

3.158 Mr Pye told us that, as it was August he decided that he would give them a few weeks to sort themselves out. He informally asked pathologists in Weston who did sessions in Bristol what was going on. He told us:

"The feedback that I had was largely that there were dysfunctional relationships between the individual consultants involved and that therefore a lot of this might just be that – that people were vying for prestige or whatever, people had moved from one Trust to another, there had been all sorts of goings-on which I never really got into the detail of, because it did not appear to be appropriate for me to do so. But there were clearly some issues between the organisations, between individuals. I was trying to find out whether there was likely to be any validity in the poor histopathology reporting as opposed to the bad behaviour of moving slides around and that sort of thing and I did not really form a view as to whether that was likely or not."

3.159 He told us that none of the pathologists he spoke to expressed any concerns about the competence of the UHBT pathologists. He said:

"It was about behaviour. There were stories, which I can't substantiate, of pathologists from one laboratory going to the other laboratory late at night, taking slides out of the drawer and taking them back and reporting them and doing some things that you would not consider to be quite proper. I cannot remember which pathologists and from which lab to the other lab. It was just strange goings on. That was my impression, that they were the issues that were important, rather than people being bad at looking down a microscope, if you see what I mean."

3.160 When several weeks later nothing had happened, the matter was discussed amongst the Network team and it was agreed that they would inform the Lead Commissioner, which was NHS Bristol. Mr Pye therefore went to see Deborah Lee, Director of Commissioning at NHS Bristol, and discovered that this was the first that she knew about any concerns about the histopathology department at UHBT.

3.161 On 8 August 2008 the six UHBT adult histopathologists wrote to Professor Adrian Newland, President of the Royal College of Pathologists:

“Our Medical Director has contacted the Director of Professional Standards in order to request for a review of our lung histopathology service (sic). We have consulted your document entitled ‘Concerns about performance in pathology: guidance for healthcare organisations and pathologists’. We understand that where one’s professional competence is being challenged, one is entitled to write to yourself with one’s version of events. Although in the present circumstances our professional competence is not being challenged formally, we feel that it is important to write to you with our account of events which surround this request for service review.

1. Background to current issues leading to a request for a review

About 10 years ago as part service (sic) re-configuration in Bristol, thoracic surgery was transferred from Frenchay Hospital (part of North Bristol Trust, to our hospital (UBHT the name of which has recently been changed to University Hospital Bristol Trust, UHB). This caused a lot of unhappiness to one of the consultant histopathologists at Frenchay Hospital, Dr Nassif Ibrahim who was to lose one of his areas of interest. He requested that the samples taken by ‘his’ surgeons who had re-located to us should be sent back to his hospital for processing and reporting by himself. Our Trust could not accommodate his request and instead he was offered sessions in our Trust on an informal basis. For some time he attended our Department for cut-up and reporting and later gave this up. He remained unhappy about these arrangements and made several indirect allegations of poor practice against us. In the meantime two of us (MS and JP) took up the lead in pulmonary pathology and appropriate MDT meetings were set up and our clinicians felt quite comfortable that they were receiving a good and safe service. In 2004 the respiratory physicians from Frenchay Hospital, prompted by Dr Ibrahim wrote a letter to our respiratory physicians and surgeons based at UHB (University Hospital Bristol) to ask them to send all lung biopsies and resected specimens to Dr Ibrahim on the grounds that Dr Ibrahim was one of the country’s “leading lung pathologist” (sic) and that our pathologists had made a few incorrect diagnoses. We replied that we were unaware of any incorrect diagnoses and that if diagnoses had been revised in a MDTM, this represented good practice and was not to be considered to represent poor performance. The details of the so-called misdiagnoses have never been revealed to this day and there has never been any internal investigations (sic).

Between that incident and now we believe that there had been some communication between individuals from North Bristol Trust and our Medical Director but if there had been any complaints, these were not passed on to us for investigation. In one incident Dr Ibrahim was quoted in the local press as saying that histopathologists in our Trust were providing a sub-standard service. We were told by our Medical Director to refrain from responding to the allegation.

2. Management difficulties in our Trust and conflict with our Medical Director

Our Medical Director arrived in the hospital in 2004. Until then he was a consultant histopathologist at Yeovil General Hospital. In his present role he functions as full-time medical manager with no clinical commitments. We have had the misfortune of finding ourselves in conflict with him since his arrival in Bristol. The main issues which have caused tension between us are

- 1. Post-mortems which had been banned by him in the mortuary with no discussion. We are currently not allowed to carry out either hospital consented autopsies or Coroner's autopsies on premises.*
- 2. Job planning which needed a strong input from the BMA with threats of appeals and grievances. We still do not have signed job plans.*
- 3. The role of our current clinical lead in pathology. We raised strong objections to the recent appointment of clinical lead in pathology on the grounds that he was not an active reporting histopathologist and therefore would have no insight in the day-to-day delivery of the histopathology service. We also objected to his minimal clinical role on the grounds that he did not hold the MRCPath qualification by examinations and was therefore unsafe. This met with strong resistance from the Medical Director and led to uncomfortable tensions in the Department.*

3. Events which culminated in request for service review

In the past year our Medical Director and our Pathology lead entered into a dialogue with Dr Ibrahim in order to explore the possibility of transferring lung specimens to Frenchay Hospital in North Bristol trust. This was clearly driven by a need to reduce workload and partly resolve our job planning difficulties. In initial discussions we

were not consulted and we were simply told by our clinical lead acting on behalf of the Medical Director that lung samples would be transferred to Frenchay hospital. We explained that this was undesirable on the grounds of clinical safety relating to the frozen section service, the urgent reporting of bronchial biopsies and pleural biopsies. Our objections were ignored. The proposed arrangements were then presented to our clinicians before the transfer could take place. The clinicians (based at UHB) opposed the move on clinical grounds and nothing happened for a few months. Then Dr Ibrahim supported by his medical director from North Bristol Trust made the allegation that there had been a catalogue of diagnostic errors in relation to biopsies from patients originating from Frenchay Hospital who had been referred to our surgeons in UHB. No details of the errors were provided and they demanded that the specimens originating from their patients (pleural, mediastinal and lung biopsies but not resection specimens and not UHB-generated specimens) should be transferred to Frenchay Hospital to Dr Ibrahim. Our clinicians based at UHB made a counter claim giving strong support to our service and expressing full confidence in our diagnostic abilities. At a meeting held on 1st August 2008, our Medical Director agreed to the demands of North Bristol Trust unconditionally and also said that he would request a College performance review on the grounds of concerns about our performance. On 4 August after having contacted the PSU at the college he announced that he had changed his mind and that there would be a service review and not a performance review. We infer from this that he could not request for a performance review (sic) because he could not provide a list of misdiagnoses or any other objective evidence of under-performance.

We have no objections to a service review and we feel that this would indeed be quite useful if it exposes areas of deficiencies which could be rectified. We do feel however that we are being bullied and undermined by management. You should be made aware of the strong element of managerial conflict which we have outlined. We hope that the review panel can also take into consideration the information included in this letter which provides you with our perspective as consultant histopathologists in the University Hospital Bristol Foundation Trust. Also any advice you can give us on the matter will be much appreciated”.

3.162 It is clear from this letter that the UHBT histopathologists did not feel supported by their Medical Director or their Head of Division and did not trust them to put their side of the story. As stated earlier, the Head of Division, Dr Kabala, had little or no knowledge of what was going on with respect to this issue. We have some sympathy for the UHBT histopathologists in that there appears to have been no clear management of their department, and no one to whom they felt they could turn to represent their interests.

3.163 On 11 August Dr Morse e-mailed Mr Pye:

“Geoff – Charlie Tomson has passed me your reply to him regarding the issues of pathology problems

It looks as if we may actually be making progress – I enclose my last letter to Jonathan for information, but would be grateful if at present you would treat this as confidential

Mary will confirm that these issues have popped up from time to time at ASWCS Board level, but always in a relatively informal way. I agree that ASWCS should hold a watching brief rather than becoming directly involved in any review, given the level of external involvement”

3.164 On 13 August Dr Morse wrote to the NBT respiratory physicians and histopathologists, Dr Tomson, Dr Rooney and Dr Pounsford:

“Dear all – two things

First – I had a message from Nassif this morning suggesting that one of the thoracic surgeons was not prepared to play a part in identifying NBT specimens. I have discussed this with Jonathan and agree that whilst we are clear that any system must be workable and robust, in principle it is not acceptable for anyone to refuse to comply with whatever is agreed as the best way forward. Jonathan will tackle the person involved.

Second – Jonathan and I have also discussed the terms of the RCPATH inquiry – there is a huge amount of basic material that the college requires before deciding in what form it will become involved. Part of this is a list of index cases, examination of which will be a major factor in their decision as to how ‘seriously’ they want to take this. It is therefore absolutely imperative that we give them enough to go on. You will remember that, in the letter I

circulated to them following my last meeting with Jonathan, I said that the review would need to consider 'all instances of misdiagnosis and/or significant delays in providing reports, blocks or slides'. Please understand that, once the index cases are with the college, they will not accept any addition to that list. This list therefore needs to be as complete as is possible, and to reiterate, should include any recorded issues of delay, in addition to those of misdiagnosis. If there are no recorded delays, then I will think of a form of words which factors those concerns in, but it will weaken the case. I would be grateful if you would agree amongst yourselves as to who will be responsible for creating this list, and let me have it ASAP. Jonathan and I have agreed that we would like the completed documentation to be with the college by the end of this month if at all possible.

Please keep me in the loop if this causes any problems."

3.165 On 20 August 2008 Claudette Young on behalf of Dr Sheffield e-mailed a draft copy of the application for an RCPATH review to Dr Morse together with a covering letter explaining the background to the application.

3.166 The draft covering letter stated:

"The University Hospital Bristol NHS Foundation Trust Histopathology Department reports all open lung biopsy specimens from the Thoracic Unit based in the Bristol Royal Infirmary. Patients are referred to the Unit from all hospitals in the Avon, Somerset and Wiltshire Cancer Network. North Bristol NHS Trust Respiratory Team have experienced concerns regarding diagnoses of some pleural and interstitial open lung biopsies through governance processes to their Medical Director who has now formally complained. No complainants (sic) on diagnostic error have been received from other network MDTs.

There have been several cases where review of the University Hospitals Bristol NHS Foundation Trust's Pathology opinion is contrary to the assessment by the North Bristol NHS Trust Pathologists. In cases where an external Independent Pathologist opinion has been sought the diagnosis made by the North Bristol Pathologists have been confirmed (sic).

The problem has been brought to the attention of both Trusts Medical Directors and we would like the College to carry out an independent review on two aspects:

- (1) *Is the reporting of Lung Pathology in Bristol Royal Infirmary following national practice guideline (sic) and is the service in line with standards expected in a Tertiary Referral Centre?*
- (2) *Are the cases highlighted by the North Bristol NHS Trust sufficient cause for concern on the performance of any individual Pathologist providing Lung Pathology reports in Bristol?*
- (3) *The request for a joint independent review will, hopefully, allow clarity regarding the issues raised relate to poor practice or poor communication between professionals (sic)*

The Medical Directors of the Trust are requesting a joint review as there is common consent on tackling the alleged issues in a co-ordinated manner in order for the review to provide support for the Trusts to achieve their shared Lung key Histopathology Service.”

3.167 The following day Dr Morse responded:

“Basically on the right track I think, but there are a few things which I feel do need to be thought about further.

On the covering letter there is some specific wording which could give the wrong impression where it says that ‘In some cases these discrepancies have been confirmed by an Independent External Pathologist supporting the North Bristol opinion’. My understanding is that not all discrepancies have been sent for independent opinion, but where they have, in all cases this has confirmed the NBT opinion – as it is it could be interpreted as that in only some cases referred for independent review has the NBT position been confirmed – an important distinction which seems to minimise the problem.

The letter also gives the impression that the complaints have come from NBT clinicians via the MDT – whilst this is correct I must insist that it is stated that there is a formal complaint made by me on behalf of NBT, and this should be reflected both in the letter and the form itself, with clarity as to my joint involvement in the request for review.

It is also difficult, given that the letter specifically asks whether there are grounds for concern as to any individual pathologist’s performance, that the box on the form relating to concern about poor standards of medical practice is not ticked

By comparison, the one relating to probity is ticked – this presumably relates to concerns that in some cases, subsequent correspondence from the initial reporting pathologist has sought to artificially minimise the differences between the initial report and independent second opinion – perhaps that should be referred to in the letter.

The final thing which I feel must go in is some amplification of the comment about problems working with colleagues or in a team, where I think some indication of the nature of those issues would be helpful ie breakdown of relationships arising from/or resulting in, dependent upon your view, of what are thought to be inappropriate referrals for second opinion, difficulties in making specimens available etc

Jonathan knows that my feelings parallel his in terms of not wanting a witch hunt against any individual pathologists, but also that it is important that all the issues are addressed, particularly given the concerns that have been expressed about not dissimilar issues in other branches of histopathology.

Finally, I think it's important that my letter of the 1st August should be included, in its entirety, in the information going to the college.

I am sorry to be difficult, but I know that Jonathan and I agree that this is an extremely serious issue which needs to be appropriately tackled - minimising it is not in anyone's interest and is detrimental to patient safety."

3.168 On 29 August 2008 Dr Rich finally replied to Dr Hirschowitz's letter of 15 June. His letter, which as we have stated above, was entirely drafted by Dr Sheffield, said:

"Firstly, can I apologise for the delay in replying to your letter but it was important for me to consult with appropriate people prior to my reply and holiday commitments of individuals made it difficult to give you a suitably reassuring response. I would like to thank you for taking the time to express your concerns which you had already expressed with our Medical Director, Dr Jonathan Sheffield.

At University Hospitals Bristol NHS Foundation Trust we take all allegations of poor practice seriously and I would like to reassure you of our efforts to seek assurance on the safety of the service.

In reply to your specific points I would like to say the following:

- *The incidents raised regarding respiratory pathology have been previously brought to the attention of the Medical Director who has sought reassurance. Further issues have now been brought to his attention and appropriate external review has been requested.*
- *The South West QAT review was brought to the attention of Dr Sheffield, Medical Director. The subsequent review highlighted a genuine low correlation rate and highlighted the importance of performing biopsy reporting with cytology. All discrepancies were investigated and apart from one patient lost to follow-up on the Exeter System all patients have been reviewed and confirmed that no harm has arisen from the discrepancy. The outcomes of the investigation and subsequent actions have been approved by Dr Angela Raffle Lead for the Screening Service and by Dr Karin Denton responsible for Quality Assurance in the South West*
- *University Hospitals Bristol NHS Foundation Trust is not responsible for the delivery of the Coroner's Autopsy Service. It is disappointing that individual Pathologists performance is openly discussed by a reviewer who should maintain confidentiality. The Coroner can decide who the appropriate Pathologists are for their service and University Hospital Bristol NHS Foundation Trust has appropriately not been privy to any recent decisions to remove Pathologists from the List.*
- *The meetings with Dr Ibrahim and his concerns have continued. The Trust has insisted the Laboratory undergoes formal CPA accreditation and this will occur in October. Dr Sheffield has made it clear to both Dr Ibrahim and yourself that individual diagnostic errors should be discussed with the appropriate reporting colleagues*
- *The subspecialty Lead Pathologists reporting reviewing and presenting cases at the MDT is not a locally unique situation and reflects the national shortage of Histopathologists. However, in line with National Cancer Standards Dr Sheffield has asked that there is a named Pathologist for each sub-specialty and his expectation is that audit occurs. Furthermore he has requested all sub-specialist interest pathologists are appropriately registered in relevant local and national EQA schemes.*

3.169 Given that concerns about specialisation were first raised in 2004 and continued to be raised over the next four years, we cannot understand why steps were not taken until 2008 (We are not entirely clear whether these steps were actually implemented even then) to ensure that there was a named pathologist for each sub-specialty, that audit occurred and that sub-specialist interest pathologists were registered in appropriate EQA schemes. This should have been done in 2004.

In response to your penultimate paragraph you can be assured that Dr Sheffield has taken further actions subsequent to your meeting on December 13 and he is working closely with Professor Pignatelli to seek reassurance that the service is delivering the appropriate standards for a Major Teaching Hospital with a large Tertiary Practice. If you wish to meet with Dr Sheffield again please do not hesitate to contact his Personal Assistant Claudette Young to arrange a mutually convenient date.”

3.170 On 22 September 2008 Mr Pye wrote again to Dr Sheffield:

“Since writing to you and others on 8 August regarding the alleged shortcomings of the histopathology reporting service in your Trust, Martin Morse has kindly forwarded to me a copy of his letter to you summarising the outcome of your meeting with him on 1 August where you discuss these issues.

That meeting appears to have addressed some of the issues raised in the original e-mail from Dr Tomson, but perhaps not all of them.

I would welcome an update on progress you have made in resolving all the concerns of Dr Tomson.

As you would expect, I have briefed Deb Lee as lead cancer commissioner for the ASWCS PCTs.

I look forward to hearing from you.”

3.171 Once again, Mr Pye received no response to his letter.

3.172 On 23 September 2008, Deborah Lee telephoned Dr Sheffield to discuss the concerns that had been raised by Dr Tomson and was apparently told by Dr Sheffield that he felt there was nothing in the allegations and that they were “vexatious” in nature.

3.173 Ms Lee told us:

“He misread the need to respond whether or not he believed there to be a problem. He was so personally convinced that there wasn’t a problem that he didn’t think he needed to demonstrate that to the external world.... Because there were clearly inter-professional issues he was too willing to just note that to be the problem - and indeed it may well turn out to be the only problem - but he had a duty to demonstrate that there were no other problems.”

3.174 We agree with Ms Lee’s analysis of the situation and feel that Dr Sheffield’s belief that all of the allegations were ‘vexatious’ coloured his view of them and led to his failure to deal with them appropriately.

3.175 During the discussion, Ms Lee and Dr Sheffield agreed that an external review of the histopathology service would be undertaken, hopefully to demonstrate to everybody that UHBT services were safe and of appropriate quality and that the allegations were unfounded.

3.176 That day Ms Lee e-mailed Dr Morse asking him to confirm that the concerns raised by Dr Tomson were handled through the Serious Untoward Incidents (SUI) route and that the SHA was advised.

3.177 On 2 October 2008 Ms Lee met with Dr Rich to discuss Dr Tomson’s correspondence and the allegations.

3.178 On 3 October 2008 Dr Morse replied to Ms Lee:

“On the subject of Charlie’s e-mail, I do not have access to that so cannot be specific as to what he implied. I can however say that in discussion with him just after he had sent it, he was reassured as to what was being done, and, between the lines, I think somewhat concerned that he may have exaggerated the issues because of having only been exposed to one ‘side’ of the evidence.

I would presume from your comments in the companion e-mail to Jonathan that you have had access to my confidential letter to him of the 1st August which I think answers all the points you raised with him. I can confirm that NBT has provided a number of specific patient identified index cases for the purposes of the review.”

3.179 Ms Lee replied:

“My residual concern relates to the limited focus of the review on lung only. Can you confirm whether you wish to raise any concerns, that can be supported by patient identified index cases, beyond lung. Charlie’s e-mail mentioned both gynae and breast.”

3.180 Dr Morse replied:

“As my letter states, there is an acceptance that the lung situation is a proxy for the problem as a whole, but the view is that lung is significantly more problematic. You will see from the final part of the letter that I have specifically asked for the learning from the review to be applied across the whole system, both in terms of referrer and tissue type. That will certainly be part of NBT’s evidence to the review (Jonathan has already agreed that my letter to him will be part of the evidence pack going to the RCPATH)”

3.181 On 16 October 2008 Ms Deborah Evans, Chief Executive of NHS Bristol, wrote to Dr Rich:

“It is now three weeks since Deborah Lee first discussed concerns about UHB pathology services which had been raised by Dr Charlie Tomson from North Bristol Trust. I also understand Deborah discussed this with you when you and she recently met up in Taunton.

The PCT take the allegations raised by NBT very seriously and it is imperative that they are confirmed or refuted as a matter of priority. Jonathan agreed to share with Deborah Terms of Reference for the Royal College of Pathologists, despite two chases these are still outstanding.

I would be grateful if you could personally look into this and provide me with assurance that UHB is responding appropriately to the serious concerns raised and clarify the timeline to external review to commence.

Finally, please can you forward a copy of the Terms of Reference to Deborah by the close of the week.”

3.182 On 23 October 2008 Dr Sheffield submitted his request for a review visit by the Royal College of Pathologists. **Dr Morse was not sent a copy of this letter.**

3.183 On the proforma Request Form for a review visit Dr Sheffield wrote:

“Over the past four years there have been queries regarding diagnoses which when raised have been referred back to the original pathologist and a second Independent Tertiary opinion sought. In July 2007 due to further concerns raised by Dr Nassif Ibrahim, Consultant Histopathologist, these issues resulted in all appraisals for the Consultant Pathologists to be conducted by the Medical Director. Discussions were also commenced in the Spring 2008 for the introduction of Lung Pathology reporting by Dr Ibrahim and Dr Edward Sheffield from Frenchay hospital. This was met with consternation by the UH Bristol Thoracic Surgeons and Chest Physicians as they clearly felt the service provided by UH Bristol Pathologists was of the highest standard. The main cause of concern was the proposal that the Histopathology work would be processed at the North Bristol site introducing delays in turnaround. Matters finally came to a head in July 2008 when the attached letter arrived from North Bristol Trust.

A temporary measure with all North Bristol Pathology being processed and reported in the Frenchay Laboratory...

...Many of the problems that have arisen relates to poor communication between the two pathology departments. This has led to accusations of impropriety on both sides. When investigated rather than the issues being deliberate acts to undermine a colleague’s diagnosis or inappropriate referral for second opinion, there has been a simple explanation of the actions (sic). The accusations of failure to make specimens available has also never been proven and usually again relates to inappropriate communication.”

3.184 Dr Sheffield answered ‘No’ to the questions *“Has an internal investigation of the complaint or allegation been carried out?”* and *“Does/do the pathologist(s) concerned participate in relevant EQA/QA schemes?”* and answered ‘Yes’ to the question *“Are there differences of opinion or interpersonal problems that may be relevant?”*

3.185 In the section asking for the nature of the complaint or allegation, Dr Sheffield had ticked:

- *Concerns about a poor standard of medical practice*
- *Problems in working with colleagues or in a team*
- *Concerns of probity in professional practice*

3.186 The same day the Terms of Reference were e-mailed to Ms Evans, Ms Lee and Dr Rich.

3.187 Dr Morse was not copied into that e-mail.

3.188 The following day Ms Lee sent an e-mail to Dr Sheffield, copied to Dr Morse, raising concerns that the scope of the review was limited to lung pathology and suggesting that it would be appropriate for NBT to confirm that they did not have continuing concerns about breast and gynaecology pathology. She said that without that confirmation it would be difficult to explain to others, should it ever become necessary, why he had limited the College's involvement to lung pathology only.

3.189 Dr Morse replied reminding Dr Sheffield that the Royal College visit should be agreed by both Trusts:

“Jonathan – you will recall our agreement that the request to RCPath would be either jointly from the two organisations, or if not acceptable to them in that form, formally agreed by me on behalf of NBT as being appropriate to the circumstances

It is now nearly 3 months since you agreed to progress this – not only have I not seen any indication of the ToRs, but Claudette's e-mail suggests that these are now in tablets of stone. Can you assure me that this is not the situation, as it would seem counter-productive for NBT to have to open separate discussions with RCPath.”

3.190 There was no response from Dr Sheffield at this time to either Ms Lee or Dr Morse.

3.191 On 28 October 2008 the UHBT histopathology department was granted conditional CPA accreditation. The CPA assessment report shows that there was only one issue of critical non-compliance which prevented full accreditation:

“There is insufficient paediatric consultant staff to meet the needs and requirements of users. This was identified as a significant problem at User Group Meeting. Staff covering paediatric pathology do not all participate in specialist EQA”

3.192 The issues of non-critical compliance were mainly to do with the fabric of the building or equipment. The following are findings set out in the assessment report which may have some relevance to this Inquiry:

“The Quality Manual indicates that Pathology Directorate and Clinical Governance meetings are held monthly. Membership of both of these committees includes the Head of

Department. There is no evidence of attendance in recent minutes. There is therefore no clear evidence of clinical governance feed back above departmental level”

“Laboratory management has not established a procedure for amended reports other than the issue of supplementary reports”

“There is minimal evidence of participation in medical audit”

“The procedure for internal audit contains a number of errors and omissions including:

- Vertical assessment form is not the one used currently by the department. There are no scheduled audit of “Methods & Procedures for Tests” which would include planned Examination Assessments*
- Audit checklists are in insufficient detail to allow for in-depth audits and the criteria are unclear*
- There is no referencing of the method of non-performance recording*
- The audit programme contains incorrect audit frequencies”*

“The procedure for dealing with complaints does not clearly indicate the mechanism for recording and investigation of complaints through the quality improvement process”

“The mechanism for recording of non-conformities does not clearly identify timescales and responsibilities for corrective/preventive actions. The procedure does not include a mechanism for review of preventive actions to ensure that this has been effective”

“Laboratory management has not established quality indicators to monitor and evaluate performance. These have not been documented as part of the annual management review. The procedure for quality improvement does not describe the mechanism for the monitoring of quality indicators.”

“Staff records do not include a record of competency assessments.”

“Competency assessments to perform assigned tasks have not yet been implemented.”

“The training program does not include training in the quality management system”

3.193 We believe that rectifying these non-compliances (critical and non-critical) would not only have enabled the UHBT histopathology service achieve the accreditation it ultimately received, but also yield important evidence about the quality of the histopathology service that could be cited when responding to allegations of substandard performance.

3.194 It should be noted that Dr Ibrahim informed us that the NBT histopathology department has also only had provisional or conditional CPA accreditation for some years and in fact had not yet been granted full accreditation at the time that we interviewed him in April 2010, although he hoped that full accreditation would be granted provided various non-compliances were addressed.

3.195 On 4 November 2008 Dr Sandle, Director of Professional Standards at the Royal College of Pathologists, wrote to Dr Sheffield about his request for a review visit. He stated that although the request came from Dr Sheffield as Medical Director of UHBT, it had explained that it was a joint request with NBT as confirmed by a letter from Dr Morse. The letter went on:

“There is however a discrepancy in what is being requested in the application from UHB and the letter from the Medical Director of NB.

Dr Morse’s letter from NBT requests an investigation of the standard of lung pathology reporting at UHB. It also mentions allegations of problems with reporting breast and gynae pathology at UHB, but then takes this no further. No evidence of these further problems is presented.

UHB is requesting a review of its lung pathology, but suggests that the investigation will have to consider the possible contribution of a breakdown in communication between professionals.

Our histopathologists noted that the actual evidence of misdiagnosis is limited to a few, probably difficult cases, selected from an unknown number. Some of the ‘discrepancies’ actually seem to be differences in emphasis or confidence of diagnosis; e.g. one pathologist suggests a list of possible diagnoses, while the other opts for one diagnosis – that is included in the discussion provided by the first pathologist. There is no consistent independent external opinion.

Conclusions and actions required

From the information you have submitted it appears that dysfunctional interdepartmental relationships are likely to be an important factor and both Trusts should understand that there is only so much College review can achieve in resolving these difficulties.

The College is asking for clarity about what we are being asked to review – individual errors, wider working relationships between the two departments, or both. If the former, there needs to be a more extensive investigation than the few cases documented in the request form before the review can take place. If the concerns include other sub-specialty areas as well as lung pathology, these should also be investigated at the same time. If the College is being asked to investigate allegations of poor professional performance, there needs to be much better supporting evidence than currently provided. A proper independent review of a significant sample of appropriately selected cases should be commissioned. A decision would first be needed on whether the review is limited to lung pathology, or is wider.

If the College undertakes such an investigation it seems likely that whether or not poor performance was confirmed, it would rapidly evolve into an investigation of interdepartmental working relationships and the College cannot ignore dysfunctional relationships if they are seen to be part of the cause of the problem. This would be likely to involve widening the review to include NB as well as UHB so there should, in advance, be an explicit decision on whether such an escalation would be acceptable to both Trusts and the pathologists therein. Otherwise the NBT pathologists might unexpectedly find themselves being investigated.

If the College is being asked to investigate the functioning of and relationships between the two departments, and nothing else, then the further collection of evidence of diagnostic discrepancy is superfluous. However, this would require a change of emphasis on the Medical Director at NB which will need to be resolved between the both of you it would also require evidence that attempts to resolve the problem locally had been made, and have failed.

This apparent difference of emphasis between the application from UHB and a letter from the Medical Director at NB would need to be reconciled in a revised and joint application by both Trusts and signed by both Medical Directors (or Chief Executives). If matters proceed, there will also need to be agreed in a set of terms of reference between all parties involved (sic) (i.e. the Royal College of Pathologists as well as the two Trusts) before any

investigation could proceed. As well as terms of reference there would need to be agreement on appropriate allocation of indemnity, expenses etc, especially to be clear on who is asking for and who is paying for a possible review.

I am sure that both Trusts will want to consider all these points before resubmitting a joint application. I am sorry to cause more work in this way but the consensus from the College is that a full appraisal of all the problems now will lead to a better eventual outcome”

3.196 As far as we are aware, no further application was ever made by either Trust to the Royal College of Pathologists. Dr Sheffield appears to have interpreted the College’s letter as being a rejection of the application to review on the grounds that it was more a question of dysfunctional relationships and the College therefore did not want to become involved. This is not how we interpret the letter, which appears to set out in some detail what was still required for the College to undertake any review, and to anticipate that there would be a further application made by one or both Trusts.

3.197 Dr Morse told us that he never saw the letter from the Royal College of Pathologists and that his understanding of their position was based upon what was reported to him by Dr Sheffield.

3.198 Also on 4 November 2008, Ms Lee e-mailed Dr Morse (with copies to Dr Rich, Jonathan Sheffield’s PA Claudette Young and Ms Evans) asking whether he had had a response to his e-mail to Dr Sheffield of 24 October.

3.199 Dr Morse then e-mailed to all the recipients of Ms Lee’s e-mail:

“Was literally just on the point of chasing!

Jonathan - utter silence from your end- this is less than helpful”

3.200 We agree with this last comment and can understand Dr Morse’s frustration.

3.201 30 minutes later, UHBT’s Chief Executive Dr Rich e-mailed to Dr Sheffield:

“I would be grateful if you could respond to save my embarrassment”

3.202 Two hours later Claudette Young e-mailed Dr Morse saying that Dr Sheffield was in Taunton that day that she had spoken with him and alerted him to Dr Morse’s e-mail. She confirmed

that all the relevant documentation had been sent off to the Royal College of Pathologists on 23 October as a joint request for a review visit. However Dr Morse had neither discussed nor seen the Terms of Reference before they were submitted.

3.203 On 25 November 2008 Dr Rooney e-mailed Dr Sheffield and Dr Morse:

“Investigation of discrepancies.

Karin (Denton) and I discussed this issue this morning. We agreed that breast pathology’s part of a review of services that includes Andy Hanby as an external pathology adviser. We think the issue of discrepant results should be handled there. There is a quality assurance scheme already in place for the management of breast disease so significant problems in this area should be picked up.

For lung cases we understand that the RCPATH has seen the reports of the cases in question. Because the clinicians have raised concerns we think there should be a review of the slides from these cases together with the report to see if the investigation is necessary. If another lung pathologist feels that these are differences of opinion rather than significant errors we need to ensure that the MDT reviews are robust and timely so that patients are managed correctly.

The issue is similar for gynaecological pathology but there are as far as I understand, no complaints from the clinicians. We do not have a list of cases of concern but it is possible that these have been sent to you already. Again we would advise a review of the slides and cases by an external gynaecological consultant to assess whether these are significant errors or “differences of opinion”. Again, the key to correct patient management is a robust system of MDT review to ensure that errors or differences of opinion are highlighted and the significance for the patient assessed.

Expert opinion should not be used as a substitute for providing a comprehensive and integrated pathology service. Expertise is one aspect of diagnosis, the other is access to all the supporting information and techniques necessary to substantiate a diagnosis. For the future of all specialties in Bristol it is essential that there is a clear and non-judgemental communication across the city.”

3.204 On 4 December 2008 there was a meeting of the NBT Medical Advisory Committee at which Dr Morse reported that he was in discussion with the Royal College of Pathologists over the format of the investigation of respiratory histology, but progress was slower than had been anticipated. He said that he would report further at the next meeting.

3.205 On 28 January 2009 Mr Orrell and Dr Moorghen wrote to Mr Philip Shread, the CPA Regional Assessor, about the CPA non-compliances informing him that all non-critical non-compliances had been rectified with appropriate documentation and that the evidence would be provided at the proposed clearances visit. With regard to the single critical non-compliance which related to the paediatric service, the letter said that funding had been identified for the appointment of two further paediatric/perinatal histopathologists, that on 27 January 2009 Dr Craig Platt, a consultant perinatal histopathologist had been appointed and that absences of the paediatric pathologist would be covered by a locum.

3.206 On 4 February 2009 Dr Rooney wrote to the two Medical Directors:

“My understanding was that the College had looked at the reports and felt that it could not comment unless the original slides were reviewed. I have discussed this with Karin and Nassif and we agree that because the question has been raised at specialty level there needs to be some sort of review of the histology. We have already supplied a list of cases where we think there is a cause for concern and we feel that this is the best starting point for the review. If it is felt that some aspect of the review should include NBT then we are in agreement with that. The concern has been raised in the areas of gynaecological pathology and respiratory pathology service so needs to be the starting point. There is already a review of Breast services currently underway in Bristol and that should continue.

We also understand that it had been agreed that all NBT patients attending UHB for their thoracic biopsies would have those biopsies reported at NBT. This does not appear to be happening at the moment and we would ask that that process is reviewed to ensure that it does happen”

3.207 On 5 February 2008 Deborah Lee wrote to Dr Sheffield with copies to Ms Evans, Dr Morse and Dr Rich:

“Can you confirm the status of the external review of pathology services – it is some time since we saw the Terms of Reference and I’d be grateful for an update of progress/findings.

Additionally, can you confirm whether you achieved the necessary histopathology appointment to receive full CPA accreditation or will this remain now conditional”

3.208 Dr Sheffield responded the following day

“I am still awaiting NBT’s agreement that the review of pathology should include lung pathology performance in both Trusts. I have also asked for confirmation from NBT if they wish to extend the investigations, again at both Trusts beyond lung. The Royal College felt that the cases originally reflected difference of opinion which are in keeping with the accepted variations of pathology reporting. I did mention to Martin that I am still unclear how NBT wish to proceed and have also reminded Karin Denton when she acted as external professional rep on the appointments committee for our successful appointment of a Paediatric Pathologist.

This information has been submitted to the CPA and we are awaiting confirmation that we are now fully complaint (sic) with the CPA accreditation in all our Pathology laboratories”

3.209 On receipt of Dr Sheffield’s e-mail, Ms Lee immediately e-mailed Dr Morse asking him to confirm what was holding up progress and Dr Morse responded:

“Nothing from this end.

I very much hope that this is a simple communication issue, my understanding was that Jonathan and I had settled this in previous discussion – you will see therefore that I have copied him in as it would seem unreasonable not to do so.

My issues are as follows

I understand the RCPATH reluctance to be involved on the grounds that this is primarily an issue around working relationships, but I remain very concerned that given the discrepancies noted on the list of signal cases I provided to Jonathan for onward transmission that they allowed the relationship issue to prevail, given that a significant part of the relationship issue arises from just those reporting difficulties

We agreed that, in the absence of RCPATH action, the most sensible way forward was to undertake a case review in the hope that this would flush out underlying issues, or close those

issues down. My understanding was that the design of this was to be suggested by the two heads of department before being agreed by the two MDs – I still await this.

On logistical grounds I saw significant difficulty in widening this to include other areas - to do so would add hugely to the task and the time taken to come to any meaningful conclusions, and would be unlikely to add to the overall view of the problems and the subsequent actions felt necessary to address them

Nothing has changed in terms either of my views or of my understanding of what we had agreed and how we would progress what remains, in my opinion, a very much second best methodology for tackling a substantial problem

The fact that we have apparently lost several weeks is a pertinent reminder that Jonathan and I should have put our agreed thoughts on paper rather than perpetrating a misunderstanding - I hope this goes some way to addressing that.”

3.210 Ms Lee forwarded these e-mails to Ms Evans saying:

“I expected to flush this out with my last e-mail and it is clearly a far from adequate situation – I do have grave concerns about Jonathan’s approach to this ”

3.211 The Medical Directors’ (in particular Dr Sheffield’s) reluctance to put things in writing has made it much more difficult for them to defend their procrastination in getting to grips with the issues as they arose. We do not doubt that there were unrecorded telephone conversations between them at which they assured each other that they were dealing with the issues, but the lack of any record of such conversations, and the lack of any apparent progress in addressing the concerns which had been raised, leads inevitably to the conclusion that matters were not being dealt with effectively.

3.212 On 23 February 2009 there was a further meeting of the NBT Medical Advisory Committee and Dr Morse reported that

“The Royal College of Pathologists was not being very helpful and did not wish to review individual working relationships. There was a way forward however by which a review of cases could be made. Timely reporting would also be considered. Dr Morse and Dr Jonathan Sheffield were considering approaching an independent specialist.”

3.213 As we have already commented, we do not agree that the Royal College was not being helpful. It was merely seeking clarification from the Medical Directors in order to be able to carry out an effective review.

3.214 In March 2009 the issue of pathology at UHBT was added to the corporate risk register of NHS Bristol. This was apparently because of the level of the Board's concern about the lack of progress by UHBT.

3.215 On 3 March 2009 Ms Lee e-mailed Dr Sheffield with copies to Dr Rich, Ms Mills, Ms Evans and Dr Morse:

"Rather than send another of my monthly e-mails chasing you and Martin, to little avail – I now surrender to professional failure in this regard and escalate to Chief Executives for resolution.

I will ask Debra to pick up in her next 121 (sic) with Sonia and Graham.

Sorry to take recourse to this but given it is over 6 months since I began to try and make progress on this I am concerned that patients may be being put at risk due to my inability to galvanise you and Martin into necessary and timely action."

3.216 In our opinion, given the lack of any apparent progress, this escalation to Chief Executives was inevitable, but would have been entirely preventable if the Medical Directors (in particular Dr Sheffield) had responded effectively to so many prompts from so many people to take decisive action.

3.217 On 11 March 2009 Dr Morse wrote to Ms Lee:

"You will recall that I did respond by return e-mail to your note of 6th February regarding your perception of there having been no progress with this review, but given your decision to widen the circulation I feel it might be beneficial if I were to rehearse for others some of the issues which we have already discussed.

You will remember that the request for a review of services was initiated by NBT, with the intent that this should involve the Royal College of Pathologists as a disinterested third party. This was agreed without reservation by UHB, but the college declined to accept a joint request from the two trusts, and the subsequent formal invitation was made by Jonathan,

using collated information supplied by both trusts. Following some deliberation, the college felt it would not wish to be directly involved, on the grounds that it viewed the fundamental issue as being one of inter-personal relationship difficulties between the two departments, rather than a question of professional standards. You will be aware that I continue to feel strongly that this is a somewhat artificial distinction, given that in this instance there is self-evidently a considerable element of chicken and egg. Whilst the college remains definite on that decision, it did, however, suggest that some form of internal case review might be appropriate, and intimated that it would be willing to provide advice on the form of such a review.

Clearly any such case review, which would involve not just examination of the signal cases put forward as evidence to support the original request for the college to be involved, but potentially the re-examination of several thousand specimens, is a huge logistical exercise which needs to be appropriately configured in order for it to have any statistical and professional validity. Jonathan is in ongoing contact with the college as being the best source of advice as to how we should construct that exercise. Nick Mooney and Massimo Pignatelli, the two departmental heads, are also aware of that issue and have it on the agenda of one of their regular meetings next week.

In terms of related concerns you will know that whilst breast and gynaecological pathology have also been noted as problematic, the concerns are of an order of magnitude less significant, and it remains my belief that an attempt to address those issues in a similar methodology as is proposed for lung pathology would require an exercise of enormous logistical complexity, whilst adding very little to the fundamental matters which would be addressed by focusing on lung pathology alone; Jonathan and I are entirely in agreement that any such learning should be transferable between sub-specialty areas.

You will be aware that I stipulated certain actions regarding the handling of lung pathology specimens originating from NBT sources at the time of my original request for external review. I am pleased to say that, with the occasional exception, these arrangements appear to be working well, and it has been suggested that they have gone some way to improving working relationships between the two departments. Most importantly, there have been no further cases of misdiagnosis which have come to light since those actions have been put in place.

In summary therefore, I do accept your concern as to the slow pace of progress with the review, which is shared both by Jonathan and by me, but would suggest that this has arisen primarily because of college involvement, to which there seems little alternative. Clearly there have been some communication issues but I am aware that Jonathan has again reminded them of the urgent need to provide advice around the design of any case review.

It is, of course, impossible to predict future events, but I would take some comfort from the absence of any further signal cases since the actions agreed between Jonathan and I were put into place at the end of the summer. Given the small numbers involved there is inevitably a huge potential for volatility, but nonetheless, to have gone over six months without a recurrence of the issue is heartening; equally clearly the need to progress the review remains unchanged.”

3.218 On 23 March 2009 Dr Morse wrote to Professor Pignatelli with a copy sent to Dr Sheffield:

“I have had my attention drawn by the Pathologists at NBT to concern that the processes put in place last autumn around the reporting of thoracic specimens does not appear to be being complied with fully. Whilst recognising the logistical difficulties this provokes, I would be grateful if you could make sure that these agreed processes are followed...”

3.219 Dr Sheffield wrote to Mr Orrell asking him to ensure that the system in place was robust and delivered the requirements of NBT.

3.220 Dr Martin Morse retired as of 1 April 2009 and was succeeded as Medical Director of NBT by Dr Christopher Burton.

3.221 On 1 April 2009 Dr Mike Durkin, Medical Director of NHS South West, wrote to Dr Sheffield enquiring about the current position regarding the review by the College. He was concerned because he had been informed that it had not been closed.

3.222 On 2 April 2009 Ms Evans, Chief Executive of NHS Bristol, wrote to the Chief Executives of UHBT and NBT expressing her concern that 9 months had gone by since the original concerns were raised in July 2008 and no one was any further forward in understanding whether the concerns which were raised had any validity. She wrote:

“I am wondering whether a practical way forward is to invite Charlie Thompson (sic) who raised the initial concerns to share with us very specifically the examples that he knows of in

relation to lung, breast and gynaecology cancer. One of the reasons I believe this may be helpful is to allow us to be certain about whether the breast and gynaecology examples are new ones or ones which have already been dealt with previously.

I believe it would also be useful to understand specifically what the concerns are in relation to lung cancer and if it is appropriate we might look at specific examples to help inform a decision about whether a large scale case review is needed.”

3.223 She also informed them that the matter was now on the PCT’s risk register at Board level and would remain there until a satisfactory level of assurance was achieved.

3.224 On 3 April 2009 Dr Rich forwarded the letter by e-mail to Dr Sheffield with the message:

“Urgent suggested reply please”

3.225 On 7 April 2009 Ms Evans and Dr Sheffield had a conversation about pathology services following a telephone conference about other issues.

3.226 On 22 April 2009 Ms Evans e-mailed Dr Sheffield setting out her recollection of that conversation:

“I valued the chance to understand the pathology issues in a little more depth and I am now writing to check that my understanding of the next steps is correct.

I think you said that the ball was in your court to write again to the Royal College of Pathologists and propose a methodology for and exercise to look at lung and gynaecology pathology results.

As you know I am now being held to account by my Board for progressing this issue by the end of April so it would be really helpful if you could make this a very high priority.

I’m due to review progress with Graham (Rich) and Sonia (Mills) on Monday 27th of April so it would be really helpful if we have evidence of a positive way forward by then.”

3.227 On 24 April 2009 Ms Evans e-mailed Dr Sheffield again with copies to Dr Rich and Dr Durkin:

“At the NHS South West/NHS Bristol performance review meeting today we were questioned about progress on investigating the concerns which were raised about UHB’s pathology service.

I explained that you have been asked to act on this by Graham Rich and that you had promised to write again to the Royal College of Pathologists to seek a way forward.

As you know, my board has asked me to ensure that this issue is satisfactorily in hand by the end of April. This would mean securing a response from UHB which sets out a timely and appropriate programme for investigating the concerns which were raised a year ago....”

3.228 On 27 April 2009, Dr Sheffield wrote to Dr Moorghen confirming Dr Moorghen’s agreement that he would:

“ (1) Put in place a failsafe system to ensure North Bristol Thoracic Pathology specimens are sent to Frenchay for processing. This involves placing a commitment from the North Bristol MDT to flag appropriate cases to the Laboratory. I would also ask you to ensure that the Thoracic Surgeons are assiduous in appropriately labelling the specimens.

(2) Discuss the process at the next Lung MDT meeting.”

3.229 Dr Sheffield confirmed that he would attend any lung MDT to answer questions regarding the process and would keep all the histopathology consultants informed regarding the review.

3.230 On 29 April 2009, Ms Evans e-mailed Dr Rich:

“Just to let you know that we are chasing Jonathan Sheffield’s office for a response to my e-mail of last week which I copied to you.

I wanted to make sure that you have advance warning that I will have to escalate this to the chairs (sic) if it is not progressed appropriately by the end of April (tomorrow). ”

3.231 Dr Rich responded by saying that Dr Sheffield had advised that he would send a letter by the end of the next day (30 April). Ms Evans replied that she was pleased because she did not want to have to escalate it further.

3.232 On 1 May 2009 Dr Sheffield wrote to Dr Sandle, Director of Professional Standards at the Royal College of Pathologists with copies to Ms Evans, Dr Rich, Ms Mills, Dr Durkin and Dr Christopher Burton (the new Medical Director of NBT):

“Further to your letter dated 4 November 2008 regarding my request for a review visit to University Hospitals NHS Foundation Trust Bristol, I would like to progress matters further following agreement of North Bristol NHS Trust to participate fully in any review. The specific request for which special interests should be explored are Gynaecological cases and Respiratory cases.

Prior to our formal completion of the request, I would like to discuss further with you how you would best like to progress. There is full support to proceed with an investigation by both Trusts.

If you could arrange a booked telephone call with my Personal Assistant... we will arrange a conference call with Dr Chris Burton, the Medical Director of North Bristol NHS Trust.”

3.233 We find it quite extraordinary that Dr Sheffield left it six months before he responded to the College’s letter of 4 November 2008.

3.234 On 5 May 2009 Ms Evans wrote to Dr Rich with copies to Dr Burton, Dr Durkin, Ms Mills, Dr Sheffield and Ms Lee:

“I am writing to confirm that I have received a copy of Jonathan’s letter to Dr Lance Sandle at the Royal College of Pathologists requesting a meeting with him prior to formally requesting a review of gynaecological and respiratory pathology cases.

I am re-attaching the audit trail which shows that it is taken over nine months to get to this stage in substantiating concerns which were raised on 22 July 2008.

As your main commissioner I can take some comfort from your recent pathology accreditation and I would be grateful to receive a copy of this report.

However I would expect University Hospitals Bristol to have responded much more actively to concerns raised by a senior clinician at a neighbouring trust.

I would be grateful if as Chief Executive, you would take responsibility for expediting this matter and as a first step to respond promptly with a confirmed and early date for the meeting with the Royal College of Pathologists.

Could you please agree with them an outline programme for establishing, managing and reporting on this review which we can review at the earliest opportunity.

I am sorry to have to write in such strong terms but am concerned to establish whether we have a service which is compromising clinical outcomes for the people we serve and to take corrective action if we do.”

3.235 On 6 May 2009 Dr Moorghen wrote to Dr Sheffield:

“Following the meeting of Friday 24th of April and your subsequent letter regarding arrangements for the reporting of lung specimens from NBT patients, I have acted upon your instructions as follows:

- 1. I met with the surgeons Mark Yeatman, Tim Batchelor and Frank Collins with whom I shared the recent letter dated 23 March 2009, which Martin Morse had addressed to you and Massimo. The letter referred to arrangements which had been agreed last autumn which do not seem to have been put in practice. The main issue relates to the transfer of specimens from patients originally seen at NBT and treated surgically at UHB. I have asked our surgeons to ensure that these specimens are flagged appropriately so that they can be transferred to NBT after receipt in the department of histopathology.*
- 2. Mark Orrell has contacted the MDT co-ordinator at NBT and she will be sending us lists of patients who will be operated on here at UHB. These lists will be kept in the reception area for the booking clerk to cross-check specimens against.*

You will be aware that there is continuing unhappiness on the part of the surgeons and histopathologists about this arrangement and I am not sure to what extent these instructions were taken on board by the relevant individuals when this was first brought up last year. As you mentioned in your letter, it will be important for you to meet staff at a future MDT to explain these arrangements in the light of the complaints which had been raised and the impending review.”

3.236 This is yet another example of how the lack of consultation with histopathologists and clinicians before making major decisions about where the reporting of certain specimens should take place, can result in confusion and dissatisfaction.

3.237 On 8 May 2009 Dr Sandle wrote to Dr Sheffield:

“My letter of 4th November 2008 described in some detail what the College felt the challenges were facing the two Trusts based on information we have received. I only wish to be helpful but to facilitate this I need some reassurance that you have addressed the issues raised in the first three paragraphs on the second page of my letter. My comments on these issues are as follows:

Clarity about what the RCPATH is being asked to review

Individual errors, wider working relationships between the two departments, or both. If the former, there needs to be a more extensive investigation of a few cases before a review can take place. If the college is being asked to investigate allegations of poor professional performance there needs to be much better supporting evidence than that previously provided. A proper independent review of a significant sample of appropriately selected cases should be commissioned. I stated, “A decision would first be needed on whether the review is limited to lung pathology, or is wider”. Gynaecological cases are now included, though no justification has been given.

Interdepartmental working relationships

From your letter it is clear that, at Board level at least, the two Trusts share problems with regard to the service. We would seek an explicit statement that any need to investigate interdepartmental working relationships would be understood by staff in both Histopathology Departments whether or not poor performance was confirmed.

Scope of the review

If the College is being asked to investigate the functioning of and relationships between the two departments, and nothing else, then a further collection of evidence of diagnostic discrepancy is superfluous. Your reply makes no mention of this. Personal issues formed a significant backdrop to the earlier review application. It is hard to accept that only five months later these have receded to the extent that the only issues to concern us are

Gynaecological and Respiratory Histopathology. If this is indeed the case then a sufficient number of cases need external scrutiny to ensure that any subsequent College review is based on good evidence.

We can of course advise on the extent of external scrutiny required, but I would suggest that the issues outlined above need clear documentation. You can then make a fully informed decision as to whether to proceed with the review application and we would be better placed to have the conversation at that point with the benefit of extra information.”

3.238 Dr Sandle correctly identifies that Dr Sheffield has not addressed the fundamental issues raised in his letter of 4 November 2008, despite having had six months to do so.

3.239 On 12 May 2009 Ms Evans e-mailed Dr Rich informing him that the pathology issue was now on NHS Bristol’s risk register and that he needed to demonstrate that he was taking appropriate action.

3.240 There was a further meeting of the NBT Medical Advisory Committee on 21 May 2009 at which Dr Burton, attending his first meeting as Medical Director after Dr Morse’s retirement, reported that there was much correspondence between the Chief Executives and Medical Directors involved in the pathology issue and that some action was taking place. There was a meeting planned for the following week and he would report in more detail at the next meeting.

3.241 On June 2009 Dr Rich e-mailed Ms Evans, with copies to Ms Lee and Dr Sheffield, confirming that UHBT had full CPA accreditation and that it was no longer conditional.

3.242 On 8 June 2009 Richard Weatherhead, Chair of NHS Bristol’s Board, wrote to John Savage, Chair of UHBT Board:

“I am writing to raise my significant concerns in relation to University Hospitals Bristol’s response to the very serious allegations about the quality of your pathology services. These concerns were first raised with commissioners by a North Bristol Trust clinician in July 2008 and as you will see from the attached chronology of events, this issue remains unresolved.

NHS Bristol has always acknowledged that there is potential for there to be a vexatious component to these allegations. However, it is very clearly for your Trust to investigate them and demonstrate whether they have substance or not.

Such was the scale of our own concern about the lack of progress by your Trust that we added this to our corporate risk register in March 2009 and our Board has tracked progress against this issue since then. I would be grateful for your confirmation that this appears on your own risk register and confirmation of what actions you and your Board have requested as a result. If this has not reached your risk register then I would want to understand the rationale for that also.

This issue has, more recently, attracted the interest of patient stakeholders and as of this week may be featured in Private Eye. We understand that the Care Quality Commission and the Royal College of Pathologists may also now be involved.

Deborah Evans has met with Graham Rich again today to discuss how we collectively respond to this but given that action that is clearly moving toward a satisfactory resolution remains outstanding, this matter has now been escalated to my level.

I would appreciate an urgent response clarifying how you will provide us with the assurance of the quality of your pathology services in the light of the fifteen cases of concern that have been raised.”

3.243 On 8 June 2009 Ms Evans spoke to Dr Rich and told him that *Private Eye* was planning to run a story on the pathology issue. She provided Dr Rich with a copy of the case descriptions which had been sent to Dr Sheffield. She reiterated her concerns that Dr Rich was showing insufficient leadership on this issue and that insufficient progress had been made by the Trust in establishing the veracity of the concerns.

3.244 On 9 June 2009 Ms Evans agreed that NHS Bristol would inform the Care Quality Commission (CQC) and sought confirmation as to whether NHS Bristol or NHS South West would inform Monitor.

3.245 On 10 June 2009 *Private Eye* published an article by Dr Phil Hammond entitled ‘Pathological Sickness’ [See **Annexe 2**]

3.246 Early that morning Dr Rich e-mailed Ms Evans:

“As we suspected, this matter is featured in the Private Eye today in the Medicine Balls section written by Phil Hammond.

A 1-2% error rate was seen by the Royal College of Pathologists as being “acceptable” and within the normal bounds of professional practice. The College used to grade errors in three categories (1-3) with varying degrees of significance for the patient. However it was not clear whether the 1- 2% referred to the most serious category or all three. In 2008 the Royal College issued new guidance covering 5 categories (A-E). The guidance states that errors can only be confirmed after review by two independent pathologists.

We already have the identities of the patients described on the list which was sent to Phil Hammond who passed them to the PCT and CQC. We know that these cases cover at least 8 years as two cases have been subject to legal proceedings and occurred in 2000 and 2008. Also cases were from several different pathologists and several different disease groups. Clearly the Board and external bodies will want to be assured that these cases are not a signal that we have a higher than normal rate of errors. This means that we will conduct a review to confirm whether this is the case or not. However given our pathology department sees 20,000 cases a year, the list does not prove there is a higher than expected error rate.

The Royal College of Pathologists has responded to our requests for a review with questions about the scope and nature requested and we were waiting for them to confirm a meeting date to discuss.

We will:

- 1. Get the list of cases independently reviewed to confirm if these cases are errors or not.*
- 2. Discuss with Pathlore to get advice from Ian Ellis, one of their directors, or one of their managers. They have experience of doing reviews in Dorchester and Hereford. This would give us an indication of how they would approach it, their advice on numbers needed to review and likely costs and timescales. We have a preference for including NBT pathology in this external review but in the interests of speed, we will proceed with the review of our own pathology services rather than wait for agreement with NBT.*
- 3. Discuss with Sir Nicholas Wright, a pathologist at Barts and the London and ask him to review our files and recommend the best approach (e.g. nature of review etc). We anticipated this might take a day of his time.*

4. *Complete our chronology of events to complement that already produced by the PCT. This will be sent to the PCT and the SHA.*
5. *Provide a one page briefing for Monitor*
6. *Contact the local representative of the CQC and share with them the same briefing*
7. *Produce a reactive press statement (this will be shared with the PCT and SHA)*
8. *Once we have completed the work on error rates we will consider whether the relationships between the pathology departments is affecting patient care.*

We are considering examination of cancer registry data against our pathology reports in the last few years to see if this gives some reassurance or not – we will only do this if it makes sense methodologically.”

3.247 Later that day Dr Sheffield drafted and signed a Briefing Document for Monitor:

“In August 2008 Dr Martin Morse and Dr Jonathan P Sheffield, the Medical Directors of North Bristol NHS Trust and University Hospitals Bristol NHS Foundation Trust met following a letter written to Dr Sheffield by Dr Morse raising concerns regarding diagnostic ‘errors’ in pathology reports produced by the University Hospitals Bristol Laboratory. No concerns have been expressed by other hospitals or indeed by the UH Bristol clinicians. Monitor will be aware that the Royal College of Pathologists have redefined error in Histopathology as errors that can only be confirmed if two independent pathologists confirm disagreement with the original diagnosis. Peer review papers on the subject state a 1-2% diagnostic error rate as being within the normal range. In particular, complex cases are frequently an issue of opinion rather than definitive diagnosis.

The Trust agreed immediate actions to allay the concerns of the clinical community in Bristol and to date no further complaints regarding diagnostic error have been received.

In order to further reassure the community, advice was sought from the Royal College of Pathologists regarding the nature or type of review required to exclude a high error rate.

Other actions taken were to inform the multiple pathologists involved in the individual reports of the cases as to the questions raised by North Bristol and to seek Independent Review to confirm an error or refute it. It was also explained that any errors must be

reported to exclude patient harm. The department was also required to complete Central Pathology Accreditation (CPA) to confirm good processes and practices within the laboratory.

The report for review was submitted to the College's Professional Standards Unit. Following the submission of the request the College replied on 4 November 2008, "From the information you have submitted it appears that dysfunctional interdepartmental relationships are likely to be an important factor and both Trusts should understand that there is only so much a college review can achieve in resolving these difficulties". The College went on further to say that "the actual evidence of misdiagnosis is limited to a few probably difficult cases, selected from an unknown number. Some of the discrepancies seem to be differences in emphasis or confidence of diagnosis ..."

The college therefore required a decision whether the review was limited to Lung Pathology or was wider. They would also require a more extensive investigation than the few cases documented in the request form.

The College was also clear that both Trusts would have to agree to the review as any investigation would rapidly evolve into an investigation of interdepartmental relationships.

Dr Sheffield requested from Dr Morse the specific scope of the investigation required by North Bristol Trust.

In January 2009 all CPA non-compliances were met from the September 2008 inspection and confirmation of full accreditation was confirmed in March/April 2009. No specific issues were raised regarding Lung Pathology in the accreditation process.

In February 2009 North Bristol confirmed the areas of concern should focus on Gynaecology and Lung.

In May 2009 the College replied stating that if Gynaecology and Lung were particular areas of concern there would have to be a significant number of cases reviewed by external scrutiny to ensure that any subsequent College review is based on evidence.

A further meeting was held between Dr Sheffield and North Bristol's new Medical Director, Dr Chris Burton, with Dr Nicholas Rooney to discuss the extent of North Bristol's concerns and how to take the case forward. It was agreed to continue the independent review of the

index cases with reporting that back to the NBT Department would be the first and possibly only step (sic). This was reported back to the North Bristol clinicians and is the apparent cause of the leak to Dr Philip Hammond, Private Eye Journalist.

Dr Sheffield has agreed the following actions on behalf of UH Bristol:

- (1) Discussion and confirmation with the Royal College Professional Standards Unit to confirm methodology (i.e. numbers of cases) for a review across all specialties to refute or confirm high rates of diagnostic error.*
- (2) Costing exercise for review with Pathlore UK Ltd*
- (3) Confirmation of review of Index cases*
- (4) Discussion with Independent expert Pathologist to review if any further actions required to be undertaken by the Trust*
- (5) Discussion with North Bristol NHS Trust as to how they wish to proceed with their side of the investigation.*

It is anticipated that these actions will be completed by Friday, 12 June 2009 and an update can be provided early next week as required”.

3.248 We are concerned that this Briefing Document for Monitor makes it look as though concerns about diagnostic errors were only raised for the first time in August 2008. It also states that the UHBT pathologists involved in the individual reports of the cases about which concern had been raised had been informed of those concerns, whereas the UHBT histopathologists told us that they were never informed of the actual individual cases involved. (This is disputed by Dr Sheffield)

3.249 Subsequently, an Independent Review of 3,500 histopathology specimens of all specialties reported by the UHBT histopathologists during 2007 and this Independent Inquiry were commissioned.

3.250 In January 2010, the Royal College of Pathologists received from UHBT a file detailing the 26 cases at the heart of this Inquiry. The file was accompanied by a letter dated 15 January 2010 from Dr Sheffield:

“I have also enclosed the review of the 26 cases which were originally in the allegations in Private Eye. Whilst these will be reviewed as part of the Independent Review Panel I would be grateful if the College are prepared to make any comments on the nature of these discrepancies/errors”.

3.251 However, because the file contained patient identifiable information and the College was concerned that, in holding the documents, it might be in breach of the Data Protection Act. Therefore, on 28 January 2010, Dr Lance Sandle, the College’s Director of Professional Standards, wrote to Dr Sheffield: *“I await your urgent instruction on what to do with the contents of this file”*. The file was returned to UHBT. A new file with anonymised patient details was then received by the College.

3.252 Based on information available to it, the Inquiry Panel had assumed that the College’s review of the 26 cases had been commissioned by UHBT and was proceeding, and that eventually the College’s report would be received. This assumption was reinforced by a letter of 8 June 2010 from Dr Sheffield:

“The Royal College did initially comment on the Lung Pathology cases submitted to them in November 2008 ... I believe that the review [of the 26 cases] has occurred and I am therefore requesting the review to be sent to me, and I will formally submit their report to the Panel as part of the evidence”.

3.253 The Panel was informed by the College that it has no record of commenting on the lung pathology cases in 2008. Furthermore, it soon became clear to the Trust and the Panel that the College’s review of the 26 cases had not actually commenced. Therefore, the College’s review was then promptly commissioned by the Trust in the summer of 2010 with advice from the Panel about the terms of reference.

3.254 We hope that setting out the background to what was (or was not) happening between 2004 and 2009 in some detail will help to emphasise just how many opportunities were missed to deal with the allegations and to resolve the issues. It perhaps also illustrates how the cumulative effect of a "trickle of cases" led to the escalation of concern in 2008.

- 3.255** This escalation was fuelled by a lack of appropriate response by management. Neither Dr Sheffield nor Dr Morse appears to have been galvanised into action until 2008, by which time it was too late to deal with the issues "in-house".
- 3.256** In 2008 the two Medical Directors attempted an appropriate response by making an application for a review by the Royal College of Pathologists, but they gave the College mixed messages and did not pursue the further joint application that the College advised them to make.
- 3.257** We have expressed elsewhere our disquiet at the way that concerns were raised at NBT. In our opinion the clumsy and unprofessional way in which the initial allegations were made in the letter of August 2004 in many ways set the tone for any response to those allegations.
- 3.258** The newly appointed Medical Director, Dr Jonathan Sheffield, did not ignore the allegations but he failed to investigate them sufficiently in order to be in a position to make a balanced judgement about the seriousness of the complaints.
- 3.259** Dr Sheffield told us that he had always felt that the allegations were vexatious in nature and it is clear that this belief coloured his approach to dealing with them.
- 3.260** Mr Geoffrey Pye, Medical Director, Avon Somerset & Wiltshire Cancer Services, told us:
- “My impression is that he decided fairly early on that there was nothing to it, therefore it did not need sorting out. That was my explanation to myself as to why nothing had happened. He was not out of his depth. I think he just decided that it was not a problem.”*
- 3.261** When he did decide to act, Dr Sheffield intervened at an inappropriate level and took too much on himself (but then failed to see things through appropriately). There were three levels of ‘management’ below him, Dr Kabala as Head of Division, Professor Pignatelli as Clinical Lead and Dr Moorghen as Head of Department.
- 3.262** In our opinion the fact that he is a histopathologist by profession meant that Dr Sheffield was too close to the issues and it was unwise of him not to delegate the investigation of the allegations to someone else. By believing that he could rely on his

professional background as a histopathologist, Dr Sheffield deprived other more appropriate individuals of the opportunity to deal effectively with the allegations.

- 3.263** However, neither the Head of Division nor the Clinical Lead appear to have made any constructive contribution to resolving the issues in histopathology. Further clarity is required as to who is responsible for what in this management structure.
- 3.264** The Medical Director is inevitably remote from the day to day management of the department and, as we stated above, we were told that from July 2005 the Medical Director was not the direct line manager in the management structure of the histopathology department. This, however, makes us wonder why it was that Dr Sheffield assumed the role he did in dealing with the issues raised by NBT.
- 3.265** It is difficult to avoid the conclusion that the only “real” management role is that of Head of Department. However there is no job description for the role of Head of Department and no sessions are allocated for carrying it out. It is an unrecognised and unsupported role which effectively means being the spokesman for the Department, although the UHBT histopathology department may not be unusual in this respect.
- 3.266** Dr Moorghen took on the role as Head of Department in 2004 because no one else wanted the job. Dr Moorghen had the respect of his colleagues, but his leadership did little to address the department's resistance to change nor their arrogant defensiveness and insularity. This attitude of leadership was illustrated in the Department's response to the NBT physicians' letter of 31 August 2004 and in Dr Moorghen's response of 19 March 2010 to Dr Sheffield's request for him to investigate the 'TB episode' which we described in the Culture/Attitude Section of the report. We do not however consider that it would have been appropriate for Dr Moorghen to have carried out anything more than an initial investigation of the 2004 allegations in order to report to Dr Sheffield for him to deal with. He was, however, never asked to do so because no one pursued the matter of identification of the cases about which concerns had been raised.
- 3.267** Dr Kabala was paid for five sessions to carry out his role of Head of Division, but as we have said above, he appears to have had very little knowledge of what was going on between the two Trusts and he did not register at all on our 'management radar' between June 2005 and July 2008 when he was Head of Division. His role appears to

have had no impact on the issue as neither Dr Sheffield nor the histopathologists ever approached him to do anything about it.

3.268 Professor Pignatelli's ability to be effective as Clinical Lead was limited by two factors: the opposition and hostility to his appointment shown by the UHBT histopathologists and the fact that he did so little clinical work himself and therefore his colleagues claimed that he had no real knowledge or appreciation of the everyday problems and workloads of the Department. It was therefore very difficult to him to tackle the very challenging objective handed to him on his appointment by Dr Sheffield, namely to bring about both the unification of pathology services across Bristol and specialisation within the UHBT Department.

3.269 In our opinion Professor Pignatelli was not the right person to effect such changes or to impose them on unwilling colleagues who felt that he did not understand or support them.

3.270 We have absolutely no doubt that Dr Sheffield was trying to do his best, but as we have already said, his approach to the problem was coloured by his belief that the allegations were vexatious (as proved in his eyes by a lack of substantial evidence). When asked what he hoped this Inquiry would achieve he told us:

"We will hopefully put to rest the question about whether or not the allegations are true - that there are poor standards within our histopathology department - which I have never found any convincing evidence of."

3.271 This highlights another problem which is Dr Sheffield's interpretation of the results of the independent review of 3,500 cases. His approach to the review is that it shows that any errors fell within an "acceptable" error rate and shows nothing untoward about the reporting skills of the histopathologists and that it has therefore 'exonerated' the UHBT histopathology department. Having just received the provisional statistical analysis of the 3,500 cases when we first saw him in December 2009, he told us:

"From my point of view, this has given me confidence that I still don't have an issue, but that is for other people to decide."

3.272 In our opinion Dr Sheffield's approach is too narrow. It is correct in terms of the interpretive skills of the histopathologists being within 'the norm', but it fails to recognise that the review highlights other problems within the Department. These are illustrated in the Report of Professor Peter Furness, President of the Royal College of Pathologists [See Annexe 6] and our section on Competence.

3.273 It is true that no evidence of actual cases was produced to anyone at UHBT until 2007, but that is because neither Dr Sheffield nor the UHBT histopathologists pursued the identification of the cases mentioned in the NBT physicians' 2004 letter, and Dr Morse did not appear to have told Dr Sheffield of the six cases mentioned by Dr Harvey in his letter of 3 March 2005.

3.274 Even when 11 cases were identified in 2007, no investigation of those cases was carried out by Dr Sheffield or anyone else. The reason for this failure appears to be partly attitude and partly ineffectiveness.

3.275 We only too aware that there were many changes going on in Bristol at this time and that histopathology was not the only problem that Dr Sheffield had to deal with. Several services were in the process of being centralised and the centralisation of others was being discussed; there were negotiations about the unification of the two histopathology departments; and there were even negotiations about merging the two Trusts.

3.276 Mr Richard Spicer, a retired Paediatric Surgeon, summed it up when he told us:

"Jonathan Sheffield - I believe that he has been trying to please too many people in this.....Perhaps he took on too much, had too much on his plate. I used to go to see him quite often, usually about pathology though sometimes about other things, and I had the impression of a man besieged with problems on all fronts.

Q. Did you get the impression that he thought he could sort them out?

A. He told me in as many words. He said, 'Leave it to me, I'll sort it out'.

Q. Did you ever feel that he managed to achieve that?

A. No.

Q. Do you think that he thought he had sorted it out?

- A. *It is difficult to answer that question, I don't know really. I believe he is a man who is struggling with a difficult job on all sorts of fronts and lots of balls in the air, so in a way I felt sorry for him but, in a way, I was fighting this battle and I never quite felt that I had the right big guns on my side."*

3.277 There is a great deal of good that Dr Sheffield has done in the last six years as Medical Director, and as Kieran Morgan, Director of Public Health, NHS Bath and North East Somerset said to us:

"What a shame, how much this sort of thing sours all kinds of other work and development plans."

3.278 However, even making allowances for the fact that for the first two or three years it may have been understandable that histopathology was fairly low down on Dr Sheffield's list of priorities as Medical Director, this does not excuse the failure to take the concerns seriously.

3.279 From all of the evidence which we have seen and heard, it is clear that the concerns were not taken sufficiently seriously and were not properly investigated. Dr Sheffield allowed the histopathologists to respond defensively and aggressively to the original 2004 letter of complaint. No attempt was made to meet with the consultant physicians who raised the concerns. There was no follow up to any request for evidence to support the allegations. Four years passed before an independent investigation was agreed, and even then, the arrangements proceeded ineffectively until the publication of the articles in *Private Eye*. Indeed, we formed the clear impression that this Inquiry was only established because of the articles in *Private Eye* and that, had it not been for them, the issues would have continued to be ineffectively addressed.

3.280 There was not only a failure to investigate but there was also a failure to reply to letters and e-mails even though they came from senior colleagues and raised serious concerns. As we have already acknowledged, we have no doubt that Dr Sheffield had many conversations and meetings with Dr Morse and others about these concerns, but unfortunately there are no Minutes or Attendance Notes of such discussions nor were any apparent action plans produced as a result of them.

3.281 One of the few things that Dr Sheffield did - purportedly to address the allegations of misdiagnosis - was to carry out appraisals of each of the UHBT histopathologists in 2008. As we have said elsewhere, we do not feel that it was appropriate for the Medical Director, who would have had little current knowledge of or involvement in the everyday working practices or workload of the individual histopathologists, to carry out the appraisals himself, despite the fact that he has had full appraisal training.

3.282 There was also the failure to consult the histopathologists and clinicians before making some major decisions which could affect their practices and their patients. In particular, Dr Sheffield agreed to the demands of Dr Morse in August 2008 to transfer NBT patients' lung pathology back to NBT, without any prior consultation with the UHBT respiratory physicians, thoracic surgeons or histopathologists. In fact the demands which were made soon proved to be impracticable and unworkable, and therefore have not since been fully implemented.

3.283 As we said in the Introduction, an Inquiry of this nature, scope and cost would never have been necessary or probably even contemplated had concerns been thoroughly and promptly investigated when and whenever they were raised and the results of those investigations made clear to those who had made the allegations.

3.284 Unfortunately, matters were not dealt with in a timely or an appropriate manner and, as a result, this Inquiry was commissioned and people will be left even more bruised and hurt.

3.285 As Dr Jonathan Sheffield told us:

“The way forward is leadership - and that is senior leadership both from the medical side and from the general management side - where people have one voice about what their goals and outcomes are, and that needs to happen consistently”.

3.286 It is vital that both Trusts' management show strong leadership in the future to support those criticised in this Report, to help mend relationships, and to action the Recommendations which we make.

4. COMPETENCE

- 4.1** The competence of the UHBT histopathologists became an issue following allegations made by several NBT clinicians, two NBT histopathologists and in particular following the publication of the first (of many) articles in *Private Eye*.
- 4.2** A total of 26 cases were identified by the clinicians and histopathologists at NBT as being cases in which they felt that the diagnosis given by the original reporting histopathologist at UHBT was questionable. The cases covered an eight-year period between 2000 and 2008.
- 4.3** We fully appreciate that these 26 cases - rather than the 3,500 cases reviewed by Source BioScience (formerly known as Medical Solutions which has a division known as PathLore) are at the heart of this Inquiry.
- 4.4** At the Panel's request, these 26 cases have been independently reviewed by Royal College of Pathologists and its findings, together with an overview analysis by Professor Peter Furness, the current President of the Royal College of Pathologists, can be found at **Annexe 4**. The Royal College of Pathologists reviewers had access both to the slides which had been interpreted by the UHBT histopathologists to produce their original reports and to the clinical information that accompanied the original specimens, and subsequently to the original reports.
- 4.5** We have further reviewed all of the various opinions relating to these 26 cases and our analysis of them can also be found at **Annexe 4**.
- 4.6** Although every single error should be taken extremely seriously, the review by the Royal College shows that there were in fact very few cases of misdiagnosis amongst the 26 which were of the kind which no reasonably competent histopathologist should make.
- 4.7** It should also be remembered that the UHBT histopathologists report about 20,000 cases between them each year. 26 cases have been identified at NBT over almost a decade of such reporting. A sense of proportion must therefore be applied to any concerns arising from those 26 cases, although concern over any diagnostic error is entirely justified.

- 4.8** There were also three other cases which were brought to our attention since the Inquiry began. We have dealt with the recent tuberculosis case in the ‘Culture/Attitude’ section of the report. This was a serious misdiagnosis.
- 4.9** The second case concerned a difference of grading of a breast core biopsy. Although we are aware that some people consider such a difference of grading to be a concerning error, such differences in grading are common - even sometimes by the same pathologist reviewing the same biopsy on a different occasion.
- 4.10** The third case involved an alleged misdiagnosis of mesothelioma. We were told about this case by Dr Ibrahim, who said he had reviewed a biopsy which had previously been reported at BRI as a malignant mesothelioma and the patient was about to commence chemotherapy that afternoon. His view was that the biopsy was not diagnostic of malignant mesothelioma but showed a florid reactive process and that, although he could not exclude malignancy on the basis of that biopsy, his view was that you could not treat it as mesothelioma. We understood that the chemotherapy therefore did not go ahead that afternoon.
- 4.11** When we asked UHBT management to provide us with details of the case, they were unaware of such a misdiagnosis but investigated the matter and told us that the case in question had been reviewed by Dr Ibrahim and Dr Ed Sheffield and their report indicated that there was insufficient evidence to support a diagnosis of mesothelioma, although it could not be completely excluded.
- 4.12** Apparently in response to their report, an external opinion was sought from Professor Andrew Nicholson at the Brompton Hospital by the UHBT histopathologist who had originally reported the biopsy. We were told that Professor Nicholson had found the biopsy to be strongly suspicious of mesothelioma and that his recommendation was that the patient’s imaging should be reviewed to identify if it showed an invasive process, in which case he would support a diagnosis of malignant mesothelioma. We asked to see Professor Nicholson’s report and further information regarding the patient’s condition and treatment, but at the time of submitting this Report, this further information had not been received. However it appears to us that this was probably another example of the UHBT histopathology department being overconfident about a difficult diagnosis (as highlighted by Professor Furness in his report).
- 4.13** In addition to the 26 cases, an independent review was commissioned by the Trust of 3,500 cases taken from all specialties during 2007. This review was carried out by Pathlore, part of

Source BioScience (formerly known as Medical Solutions) and their results were subsequently analysed by a statistician, Ian White. We had access to both Pathlore's and the statistician's analyses. Ian White's report can be found at **Annexe 5**.

- 4.14** The Trust's approach, through Dr Sheffield, appears to have been to evaluate 'competence' by reference to whether or not the statistical results of the independent audit fall within "acceptable error rates" which they interpret as being something in the region of 1-2%.
- 4.15** We do not accept that this is the correct approach. Competence is not judged purely by whether or not results fall within 'acceptable' error rates. Competence is qualitative not merely quantitative.
- 4.16** We realise that the UHBT histopathologists may have been hoping that the independent audit — and this Inquiry — would completely exonerate them. However, in so far as the Panel's findings are based on the independent audit, it is difficult for us to do so.
- 4.17** We were not satisfied with the way in which the 3,500 cases were selected for audit. In our opinion specimens should have been selected only from those specialties where concerns had been raised, namely respiratory, gynaecology, breast and skin. We understand that the advice of the Royal College of Pathologists was sought by the Trust as to the best way to conduct the review, and that it was the College's advice which led to 3,500 cases from a single year being the basis of the audit. There is no doubt that the final selection has to some extent 'diluted' the effectiveness of assessing competency in these four specific specialist areas of concern.
- 4.18** We therefore did the one thing that we could do without spending even more money on a further review with more selective sampling: we invited Professor Peter Furness, the current President of the Royal College of Pathologists, to evaluate the evidence which was available to us and to give us his professional judgement on it. The Terms of Reference which we gave him were as follows:
- *"Whether the overall design of and analysis provided by the audit meets College guidelines*
 - *To what extent the results of the audit are consistent with a histopathology service of acceptable reliability and to identify areas of improvement*

- *To what extent the general case-mix has affected the assessment of areas of principal concern (breast, gynaecology, respiratory and skin)*
- *To comment on whether error or discrepancy rates give cause for concern about either individual pathologists or specific organs/systems (e.g. breast, gynaecology)*
- *Whether the audit reveals any systematic pattern of diagnosis or error*
- *To consider the reported discrepancies on a case by case basis and report on patterns as seems appropriate*
- *To provide a written report to the Inquiry and, if necessary, to explain the findings.”*

4.19 In addition we invited a senior and experienced histopathologist from another academic centre, Dr Ray McMahon, Senior Lecturer in Pathology and Honorary Consultant Pathologist in Manchester, to give us expert advice on histopathological diagnosis and how to define a diagnostic error. He is the Chair of Histopathology Examiners for the Royal College of Pathologists and also Chair of the College’s Steering Committee for Interpretive EQA Schemes.

He told us:

“Histopathological diagnosis is a composite of many different factors which contribute to patient management. Unlike other aspects of pathology, it is not possible to provide absolute values and to a greater or lesser extent depending on circumstances, all histopathology reports provide an opinion rather than an absolute fact. The relative certainty of that opinion is variable and in the great majority of cases there is little or no dispute about that opinion. Nonetheless it is important to remember there is considerable variation in the difficulty of cases. Histopathological diagnosis is not a ‘black and white’ exercise and there are many recognisable, predictable ‘grey’ areas that should be appreciated.”

“A discrepancy is a variation between one pathologist’s opinion and another, whereas an error is one where that discrepancy is confirmed by a third independent person. I think that is a useful way of doing things.

Now, I know that in a lot of departments the potential for this to occur is minimised by other methods, like double reporting of primary diagnosis of malignancy... It is not official College

policy because there is an economic issue in there as well, in that the number of pathologists required to be able to double report all diagnoses would be prohibitive in terms of provision of pathologists. Nonetheless it is recognised as good practice to have systems such as that in place.”

4.20 It became clear during the course of this Inquiry, that even if one could reassure everyone about the competence of the UHBT histopathologists, it would not necessarily restore people's confidence in them. It will take collaboration and goodwill between the two Trusts in order to achieve that.

4.21 Dr James Calvert, Consultant Respiratory Physician at NBT, said to us:

“I hope that the Panel will look at not only the veracity of the reporting but also the relationships that exist between different professionals, and also the processes that are in operation. I do quite a lot of work on patient safety and quality improvement, and there is a maxim that any system is perfectly designed to achieve the outcome it achieves. At the moment our system, for whatever reason, isn't achieving the outcomes that I think it ought to be achieving, and I think it's because the system is at fault particularly. A kernel of mistrust has been introduced into things, and I don't know whether it's true or not, but I am concerned that everything should be open and that there should be a free exchange at a professional and personal level with colleagues who work in other hospitals. I am very unhappy with the current situation.”

4.22 Professor Furness wrote a detailed report setting out his findings based on the review of the 3,500 cases which can be found at **Annexe 6**. His findings reinforced our opinion that the real problem with the histopathology department at UHBT is not so much the diagnostic competence of the histopathologists, but their culture and attitude.

4.23 We should point out that Professor Furness discovered that in the most important category — B1 (a diagnosis which one is surprised to see from any pathologist) — the overall rate was 0.9% which he would regard as worrying even though any pathologist will occasionally generate a category B1 discrepancy. However, he emphasises that a total of 17 such discrepancies were reported in gynaecological pathology (equivalent to 2.9%) and that although, *prima facie*, this would appear to be unacceptable and suggest a specific problem with this organ system, he suspected that the high rate of B1 discrepancies within gynaecological pathology was due to the approach of a single

Source BioScience reviewer who repeatedly reported B1 discrepancies on the basis of disagreement with the tumour grade, notably in cervical biopsies. For this reason Professor Furness was led to question the opinion of this particular reviewer. The high rate of gynaecological B1 discrepancies would obviously ‘skew’ the overall figure for B1 discrepancies. We were therefore of the opinion that the B1 discrepancy rate could not necessarily be relied on, particularly insofar as it relates to gynaecological pathology. The Royal College of Pathologists’ review of the 26 cases which we asked the Trust to commission confirmed that Professor Furness’s instincts about the Source Bioscience reviewer were correct.

- 4.24** These are the salient findings of Professor Furness’s report on the review of the 3,500 cases (his findings following the Royal College of Pathologists’ review of the 26 cases can be found at **Annexe 6**):

Design and Analysis

The case review study is extensive and I am satisfied that it exceeds the recommendations of the RCPATH as set out during initial discussions between the Professional Standards Unit of the RCPATH and the Medical Director of UHBT. However, because the audit was not selective the number of cases reported by each pathologist in each organ system is relatively small, especially in specialties where relatively few specimens are received by the laboratory (e.g. respiratory system). This needs to be considered if statistical analysis of such small sub-groups of cases is attempted...

Case Mix

The types of cases examined represent a broad spread of types of specimen from a variety of different organ systems, as I would have expected. I do not have an analysis of the normal case-mix of the histopathology department at UHBT but I have assumed that the sample examined is representative. It contains specimens from all the areas of principal concern (breast, gynaecology, respiratory and skin). The analysis provided to me includes a numeric breakdown of cases examined in each organ system (breast 257, gynaecology 592, respiratory 100 and skin 641)...

Comments on the frequency and nature of the discrepancies

I was presented with authorised reports identified as B1 discrepancies (A diagnosis which one is surprised to see from any pathologist) without any subsequent supplementary report providing a correction. This suggests that systems to identify errors before they cause patient harm were not in place..

It is notable that remarkably few of the original reports record any mention of seeking a second opinion from another pathologist. The reporting software used in Bristol includes a field identified as ‘ Additional reporting pathologists’ but it is almost invariably empty, even where the report identifies and discusses an area of diagnostic difficulty... there are some circumstances where there is national guidance indicating that two consultant opinions should always be obtained; for example, suspected epithelial dysplasia in distal oesophageal biopsies. Even in these circumstances the reports are almost invariably attributed to and authorized by a single pathologist..

Many of the reports are remarkably short, and it is not unusual to find reports where important items of information are missing...

Reading the original reports, many are in a style reminiscent of reports one reads when reviewing cases that were reported 10 or 20 years ago. A subjective impression is gained of a department that has not shown enthusiasm to keep up with modern developments. It would be relevant to evaluate the participation of the consultants in national educational meetings and other external CPD activities...

Conclusions

The overall rate of discrepancies identified by the audit suggests that, in 2007, there is some cause for concern about the overall performance of the histopathology department, in respect of areas discussed in my report above. The underlying causes cannot be identified with certainty from the material available to me but I suggest that the broader Inquiry currently being undertaken should examine the working practices in the department, particularly in relation to the sharing of difficult cases, the incorporation of second opinions into reports and checking of particularly significant or unexpected diagnoses, for example through the system of cancer multidisciplinary team meetings. The procedures used by the pathologists to keep up to date should also be scrutinised...

I was unable to detect evidence of any one pathologist giving cause for concern beyond the overall concerns about the function of the department, as discussed above.

I do not believe that a systematic pattern of error is identified, beyond the problems discussed (above)

I have identified some patterns of discrepancy as set out above, but my firm impression is of a broader problem with the working patterns of the department”

4.25 Dr McMahon told us that having read Professor Furness’s report:

“I had a feeling of a department that had not moved with the times.”

4.26 Nothing that we can say about the competence of the UHBT histopathologists could add anything to Professor Furness’s informed opinion, other than to highlight that what he says about the working practices of the department is of real concern to us and we therefore urge the Trust take his report extremely seriously.

4.27 As we have already said, competency must be judged not only on statistical results but also on the quality of the service being offered. Patients deserve the best possible service.

4.28 The histopathology department at the BRI needs to be brought up to date, not only in terms of the fabric of the building but also in respect of the practice and attitude of some of the histopathologists.

4.29 The histopathologists should be less certain of their diagnoses in difficult cases and more willing to seek second opinions. They should participate in regular EQA and CPD activities in all specialties in which they choose to report.

4.30 The 2008 Quality Manual for the Department of Cellular Pathology at the BRI has the following ‘Department Mission Statement’:

“The Pathology Department of the University Hospitals Bristol NHS Foundation Trust aims to provide a timely, efficient, cost-effective, and high quality pathology service to the National Health Service, the Trust and its various divisions and facilities, general practitioners and the local community”.

4.31 The ‘Department Philosophy’ includes:

- *“High-quality laboratory services will be provided in a cost-effective and efficient manner. Effective service delivery, program design, and policy development will be based on the development of sound evaluation, research and Quality Assurance programs....*
- *The laboratory environment will promote enquiry, learning and scholarship essential to the attainment of excellence in pathology services”*

4.32 It is admirable to have such a philosophy, but there is no point in such rhetoric if it is not listened to and followed.

4.33 We have the impression that, even before this Inquiry process began, the UHBT histopathologists felt unappreciated and undervalued. As we have already said, any concerns about the competency of the UHBT histopathology department should have been thoroughly investigated whenever they were raised. This would have saved the histopathologists years of vilification. This Inquiry and the media coverage that has accompanied it has had them ‘under siege’ for more than a year and has left them bruised and demoralised.

4.34 The UHBT histopathologists will need some compassion and considerable support as they face the challenge of achieving the excellent service that the people they serve have a right to expect.

4.35 There have certainly been some serious errors of diagnosis, but on the basis of the evidence that we have seen, it is difficult to judge if the error rate in the UHBT histopathology department is more or less than normal.

4.36 Overall there is no evidence to lead us to believe that the Department provides anything other than a safe service, although it still has room and need for considerable improvement.

4.37 However, confidence in patient safety will only be achieved if lessons are learnt from the issues which have been raised in this Inquiry. Unfortunately it is clear that some lessons were not learnt following the Kennedy Inquiry and therefore, to a certain extent, history is now repeating itself. This is what undermines public confidence. The Trust must take steps to ensure that this does not happen again.

4.38 The Trust's 'Quality Management Plan 2008/2009' stated:

"In future, the quality management programme should be developed to enable errors to be avoided and the best possible service provided to all patients, and clinicians. This will require the quality manager to drive the programme forward and for all senior managers to provide the support needed for all staff to develop and improve the service."

4.39 An identical statement is repeated in the 2009/2010 Quality Management Plan.

4.40 The Trust must adhere to its own Quality Management Objectives.

5. SPECIALISATION

5.1 There is no agreed definition of what a ‘specialist’ histopathologist is. In considering the meaning and relevance of ‘specialist’ in the context of this Inquiry, the Panel has taken account of the authoritative opinion of the Royal College of Pathologists.

5.2 In June 2006, following consultation with members of the College on the nature of specialisation in cellular pathology (which includes histopathology), the Royal College of Pathologists published ‘*The Recognition and Roles of Specialist Cellular Pathologists*’. It states:

“This document reviews some of the complex issues surrounding the recognition of special experience in pathology. The intention is to provide guidance to individuals and organisations on the range of personal and professional attributes that may contribute to the ability to provide an opinion in a defined area of pathology practice. The document does not attempt to define the organisation or attributes of a specialised pathology service....

The main areas in which it may be desirable to clarify the nature of a ‘specialist’ pathologist are in relation to:

- *diagnostic pathology, where healthcare organisations and networks may need to define the range of expertise available and where pathways of referral are required for particular types of case, e.g. uncommon cancers, or specialised laboratory tests.*

The College is not a statutory organisation and could not therefore be responsible for maintaining a statutory register of accredited specialist. Voluntary registration of special interest may not serve any useful purpose if it is not subject to some form of validation...

In many organisations, diagnostic pathology is increasingly provided by specialist teams that match the increasing specialisation of clinical services and the development of networks. For example, it is now a requirement that specialist lead pathologists are involved in the work of cancer treatment centres and that some uncommon cancers have the diagnoses reviewed by designated specialist pathologists.

Currently, consultant cellular pathologists may practice as general pathologists, but will often provide local leadership in particular aspects of diagnostic work for the purposes of multidisciplinary meetings. In larger departments or networks, consultants may concentrate their work into one or a small number of areas, usually defined by anatomical site, e.g. renal, gastrointestinal or breast pathology. It is not unusual for an individual's specialist areas to evolve during the course of their career, as experience increases and the demands of the diagnostic services change. It is therefore necessary to recognise that the attributes appropriate for specialist practice in a local healthcare organisation may be different from specialist practice at network, national or international levels....

A specialist may be defined as 'a pathologist of consultant grade (or equivalent status, who delivers a service of a high standard in a specific area of diagnostic pathology or medicolegal practice'.

All trained pathologists are on the Specialist Register of the General Medical Council and, as indicated above, the College recognises specialisation within the broad context of pathology. It is suggested that phraseology such as 'cellular pathologist with special expertise in breast disease' may be more readily understood by those outside the pathology community than 'specialist breast pathologist'...

There is no absolute distinction between general and special pathologists and each individual should be judged on their experience and the demands of their current appointment. A general pathologist will typically cover a broad range of diagnostic work while specialist pathologists usually see a more restricted range of work. General and specialist pathologists will work to the same standards, as defined by guidelines and satisfactory performance in external quality assurance (EQA) schemes. Therefore, there should not be any justification for 'referral for specialist opinion' in the vast majority of diagnostic work...

THE ATTRIBUTES OF A 'SPECIALIST' PATHOLOGIST

A specialist pathologist should be:

- aware of current clinical and scientific aspects of a particular subject*
- aware of the needs of specialist clinicians in other disciplines as they relate to a specific disease or tumour site*

- *prepared to be self-critical and provide an independent view on a specific problem*
- *prepared, and have the time, to help other pathologists in their diagnostic work.*

A wide range of attributes may contribute to a particular level of expertise. The complexity of modern pathology practice suggests that it is, at present, impractical for the College to develop guidelines to indicate what level of evidence is required to be regarded as a local, network or national specialist pathologist.... It is suggested that evidence of 'specialist' practice could be provided by a portfolio approach.

The portfolio might contain evidence relating to some, but not necessarily all, of the following aspects.

- *Evidence of day-to-day involvement in a particular area of practice. This would normally be recognised by the employer, for example, and specific time allocated in the job plan to the provision of specialist advice. A job plan could also helpfully indicate the arrangements for the provision of cover during leave and succession planning.*
- *Evidence of specific training e.g. attendance on courses, specific training attachments*
- *Evidence of substantial experience in a particular area. This may relate to the volume of work or, for less common diseases of low volume, the number of years of involvement in that area of disease*
- *Publications in peer-reviewed journals*
- *Contributions to postgraduate teaching*
- *Evidence of continuing audit and satisfactory performance in relevant EQA schemes*
- *Participation in the work of a relevant specialist group of pathologists*
- *Evidence of esteem by colleagues e.g. details of secondary referral practice, 360° appraisal by other members of a clinical team"*

- 5.3** The fundamental issue raised in 2004 was the allegation that the department was operating on a ‘generalist’ rather than a ‘specialist’ model.
- 5.4** We acknowledge that the development of specialist interests has been a challenge for many departments and particularly those that are insufficiently well staffed to adopt this method of working.
- 5.5** The UHBT Histopathology Department has not been adequately staffed and this has made it more difficult for the pathologists to develop specialist interests to a satisfactory level. There are at present only six full-time adult histopathologists in the department and it is therefore difficult for them to limit themselves to one or two specialist areas of reporting, as there would clearly not be adequate cover during periods of leave or any other absence.
- 5.6** It seems clear, from their initial response in 2004 and the events that followed, that, in any event, there is a resistance in principle to the development of specialist interests from at least some of the UHBT pathologists and an excessive confidence about their ability to continue to report across a wide range of specialties.
- 5.7** It will always be the case that pathologists share out much of the non-complex routine work. This happens in the NBT histopathology Department. However it is not only the routine work that is being shared in the UHBT department, even though a consultant with the relevant specialist interest will present the ‘specialist’ case at any MDT.
- 5.8** What is more worrying is that there also seems to be a reluctance in the UHBT Department to participation in external quality assurance and continuing professional development to complement what they claim is their specialist expertise. Since 2004 there has been only a slow and, it seems reluctant, move towards the development of specialist interests. However, the cultural resistance to specialising is such that certain individuals seem not to want to let go of their broad spread of work.
- 5.9** If, in 2004, there had been an acceptance that a generalist model was being operated in the department, and an acceptance of the need to change, this Inquiry would probably never have been necessary. Instead, the response from the histopathologists to the NBT respiratory physicians’ letter of August 2004 was to take great offence at being called “*general pathologists*” and to declare “*We challenge the view that we are not in specialist practice*”.

This was an inappropriate response and it surprises us that the histopathologists did not instead defend being generalists on the grounds that they were such a small department.

- 5.10** Dr Sheffield, or some other appropriate person, should have sat down with the UHBT histopathologists in 2004 and persuaded them that they must move towards specialisation. It is clear that Dr Sheffield felt that specialisation was the only way forward. Indeed he told us that he appointed Professor Pignatelli to the role of Clinical Lead in 2006 with the task of bringing about specialisation in the histopathology department as one of his main responsibilities.
- 5.11** We are satisfied from all the evidence that we have seen that we would expect a trend towards specialisation, especially in an academic teaching hospital department that should be aspiring towards excellence and the development of its role as a referral centre for histopathologists working in neighbouring district general hospitals and further afield.
- 5.12** However, we acknowledge that there are not enough histopathologists at the BRI to develop genuine specialisation to the degree practised in many other major teaching hospitals. There is also the added problem that some of the UHBT histopathologists have wanted to ‘specialise’ in too many areas, taking the reporting lead in at least three specialties. It is difficult to keep up-to-date with EQA and CPD if one is practising in too many specialist areas. Indeed, the more specialties claimed by a histopathologist, the more likely they are to be regarded as a ‘generalist’.
- 5.13** As can be seen from the Royal College of Pathology’s guidance set out above, if a histopathologist claims to be a specialist in, say, breast pathology, the College would expect that pathologist to participate in breast EQAs and breast oriented CPD, to have published articles related to breast pathology and to be recognised as a specialist in that field by their peers. It is really only possible to be expert in a very limited number of areas, maybe two, but arguably an absolute maximum of three.
- 5.14** Dr McMahon, the histopathologist we consulted to give us expert advice, told us:

“Within a department which has gone down the specialist route it would be difficult to accept a pathologist dealing with say more than two or three areas of specialism. I certainly find that my clinicians in particular areas are very well-read, very up-to-date in particular things, and I feel I need to keep up to speed with them so that in MDTs I am not caught out in

particular areas, and I think it is very difficult to do that if one is working in more than two or three areas”

- 5.15** The UHBT histopathologists work very hard over a wide range of specialties. It is just not possible to participate in EQAs and CPDs for all the specialties they have to cover.
- 5.16** It is clear from the evidence that we have heard that some, if not all, of the UHBT histopathologists are recognised by their peers to have considerable experience and expertise in at least one specialist area. The problem is that, because they are understaffed, (and because some enjoy reporting a variety of specialties) they attempt to report too many specialist areas of cases, their workloads mean working longer hours, and they have no time to attend continuing professional development courses and to participate in EQAs for all the specialties they report.
- 5.17** However, we consider it unacceptable that, even today, despite the original (and continuing) concern of the NBT clinicians being that they lacked specialist credentials in respiratory pathology, none of the UHBT histopathologists participates in a respiratory EQA scheme.
- 5.18** We are also very concerned that none of the UHBT histopathology clinical audits carried out since 2004 focuses on any aspect of respiratory histopathology or mesothelial disease. This is surprising given the longstanding allegations of diagnostic errors in these specialised areas of practice. This deficiency in the UHBT histopathology audit portfolio renders the department vulnerable to criticism and has weakened its ability to respond positively and constructively to allegations of substandard performance.
- 5.19** Another problem arising out of the fact that there are only six histopathologists working in the UHBT department is that there should be at least two consultants practising in each specialist area in order to provide cover during leave and other absences.
- 5.20** The Minutes of a Combined Departmental/Consultants’ Meeting held on 6 January 2009 when considering Specialist Reporting acknowledged:

“Current arrangements are not ideal and that a fully specialist reporting system could not be implemented until the full complement of staff were appointed in the department...”

- 5.21** We have prepared a graphical analysis comparing the distribution of work by specialty (i.e. organ or system) between individual consultants at UHBT and NBT. This can be found at **Annexe 7**.
- 5.22** The attitude to specialisation also seems to have affected the attitude to co-operation with pathologists in North Bristol. Difficult personal relationships seem to have been allowed to take priority over the interests of patients.
- 5.23** It is difficult to understand why lung pathology specimens requiring expert opinion are sent to the Brompton Hospital and to other specialist centres, rather than to pathologists in North Bristol who are widely recognised as providing a specialist service.
- 5.24** It is also difficult to understand why a pathologist working in North Bristol, with widely recognised expertise in gynaecological pathology, was excluded from providing a service after the transfer of gynaecological cancer surgery to UHBT.
- 5.25** We have recommended that there should be a single histopathology service for the city of Bristol and that specialisation should be developed with full participation in appropriate EQA and CPD.
- 5.26** The establishment of a single service will enable the development of specialist reporting. Once the two departments are combined, the people of Bristol will be served by a single team of more than 20 histopathologists. In a team of this size it should be possible to develop specialist reporting and to ensure that reporting is done by histopathologists with the appropriate expertise.
- 5.27** It will be important to ensure that, whenever clinical services are relocated, careful consideration is given to the consequences for histopathology. For example, the histopathologists with the appropriate expertise could transfer some of their sessions with the services to the new location and steps taken to ensure that the facilities (e.g. office, microscope) are satisfactory.
- 5.28** It will take strong management and exceptional clinical leadership to unify the two histopathology departments, but it can and should be done.

5.29 Dr McMahon described to us what happens in the Manchester area where there is not yet unification of the various pathology services, but there is great collaboration between the pathologists in the various surrounding Trusts:

“In Manchester there are various network arrangements between adjacent Trusts and hospitals, and we link for example with Tameside Hospital for some cancers, with Pennine for others, with Stockport for others. We tend to run our meetings by video conferencing, and so we see each other, we hear each other. We do not look at the slides at that point, but if it appears that there is a variation between what a pathologist at one centre says and how the patient is behaving at the other centre, then we would ask that the material come to us in Central Manchester and we would then review the material, show it round among the specialist group and come up with a further report.”

5.30 The histopathology service in Bristol should place the provision of excellent services to patients at the centre of everything it does. Personal and organisational rivalries should not be allowed to stand in the way of the provision of excellent services. The only question should be which histopathologists have the expertise to report on the specimen and thereby to give the greatest benefit to the patient.

6. DOUBLE REPORTING

- 6.1** Some of the NBT histopathologists and clinicians who came to see us were concerned that UHBT histopathology cases were not ‘double reported’, even if complex cases. As can be seen in the ‘Competence’ Section, Professor Furness expressed surprise also at the infrequency of seeking a second opinion.
- 6.2** The risk of diagnostic errors and misinterpretations leading to patient harm can be reduced if two or more histopathologists review the case and agree on the diagnosis before decisions are made about how the patient should be treated or managed. Case review at MDT meetings often fulfils this, but only if the histopathologist who originally reported the biopsy, etc. is not the histopathologist who subsequently reviews it for the MDT meeting.
- 6.3** The concept of “double reporting”, as a means of reducing the risk of interpretive errors in diagnostic histopathology, is considered in the Royal College of Pathologists’ document ‘*Quality assurance in histopathology and cytopathology reporting practice*’ from which this relevant extract is taken:

“3. Factors determined by local practices and protocols.

a. 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.

b. Formal review by a second pathologist of cases of a particular diagnostic type, e.g. first diagnoses of malignancy, or a subset of cases as part of audit. It should be noted that this is not mandated by The National Institute for Health and Clinical Excellence (NICE) or College guidance for the generality of specimen types or diagnoses. Exceptions, where double reporting is recommended (if resources allow), are:

- gastrointestinal dysplasia (high grade dysplasia in Barrett’s oesophagus and in ulcerative colitis)*
- dysplastic naevi/malignant melanoma.*

c. Formal review for the multidisciplinary team (MDT) by the pathologist who will present and discuss the case at the local MDT meeting.

d. Formal review for a specialist MDT as part of a Network referral pathway for specialist MDTs. NICE's Improving Outcomes Guidance (IOG) indicates that review by a specialist pathologist is required for a few relatively uncommon cancer types (thyroid, sarcoma, lymphoma) in order to facilitate consistency of diagnosis and/or where highly specialised investigations may be required to ensure optimal treatment.

e. Tertiary referral of diagnostically difficult or rare cases to pathologists with local or national expertise in a specific clinical area.

4. The concept of 'double reporting' could refer to any of the quality assurance aspects in paragraph 3, and may range from a rapid review of slides to validate the accuracy of the diagnostic category to a full review of all the slides from a case in their clinical context (including review of imaging reports). The level of documentation involved is also potentially variable, as is the extent to which the reviewing pathologist is aware of the first pathologist's diagnosis. It is important to clarify the requirements in any service level agreement. Clearly, a case that is originally diagnosed by a specialist pathologist will not need to be reported by a second pathologist before the specialist MDT meeting in order to comply with IOG guidance.

However specialist pathologists must be mindful of the need for appropriate EQA participation, discussion of difficult cases with a colleague and clinicopathological audit of their diagnostic work."

6.4 At UHBT and NBT, and perhaps elsewhere, there is inconsistency about what procedures can be accepted as "double reporting". Such latitude is, in fact, reflected in the RCPATH guidance:

"The concept of 'double reporting' could refer to any of the quality assurance aspects in paragraph 3, and may range from a rapid review of slides to validate the accuracy of the diagnostic category to a full review of all the slides from a case in their clinical context (including review of imaging report)."

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

6.5 One of the options for "double reporting" listed in paragraph 3 of the RCPATH document is:

"Formal review for the multidisciplinary team (MDT) by the pathologist who will present and discuss the case at the local MDT meeting."

- 6.6** Therefore, a histopathologist could rely on the RCPATH document to support their claim that histology review at MDT meetings constitutes "double reporting".
- 6.7** At some MDT meetings only the histopathology reports, not the slides, were reviewed. With the possible exception of cases in which the biopsy being discussed has been "double reported" according to our recommended definition, we believe that the histological slides should be available for review and presentation at the MDT meeting. That does not mean to say that the histopathologist at the MDT meeting should examine and project every slide from every case.
- 6.8** Our findings in the Inquiry lead us to recommend that there should be a national protocol or standard for "double reporting", much narrower and more specific than the five alternatives (a–e) mentioned in the College document. The need for standardisation is important to avoid and, if necessary, resolve rival claims about whether a case has been double reported.
- 6.9** In summary, we recommend that, for a case to be regarded as double reported, two histopathologists should examine and discuss the case and then issue a diagnostic report in their joint names.
- 6.10** While double reporting, as defined in our recommendation, might be seen as the ideal arrangement to minimise the risk of diagnostic errors, it cannot be mandated without a very substantial increase in the number of consultant histopathologists nationally.

7. PAEDIATRIC PATHOLOGY

- 7.1** Prior to the public Inquiry into children's heart surgery at the BRI chaired by Professor Ian Kennedy, the paediatric pathology department in Bristol was internationally acknowledged as world-class. The department had 4 consultant paediatric/perinatal pathologists as well as registrars and specialist technicians. It was situated in St Michael's Hospital (within UHBT).
- 7.2** The old Children's Hospital had been at the top of the hill adjacent to St Michael's Hospital where the paediatric pathology department was. The new Children's Hospital is at the bottom of the hill, adjacent to and with connecting corridors to the BRI. The paediatric pathology department at St Michael's therefore became removed from the surgeons and clinicians working at the new Children's Hospital.
- 7.3** The Interim Report of the Kennedy Inquiry (which dealt with organ retention) had a devastating effect on the paediatric pathology department and ultimately resulted in one of the consultant paediatric pathologists, Professor Jem Berry, taking early retirement and another, Dr Michael Ashworth, leaving Bristol within months. One of the 4 consultants, Dr Adrian Charles, had left before 2001 to take up a post in Australia. The remaining consultant, Dr Helen Porter, a highly respected perinatal pathologist, struggled on for a further year before resigning and obtaining a post elsewhere.
- 7.4** The 'final straw' for Dr Ashworth had been when he heard of a proposal to move the paediatric pathology department from St Michael's Hospital to the BRI. Neither he nor Dr Porter had been consulted about the intention to move and he wrote to the then Chairman of the Division of Children's Services in Bristol:

"Matters came to a head when Helen Porter and I stumbled across a minute of the meeting referring to the move of this department the BRI site. This intention to move us has now been denied but it was not so initially and indeed the offending minute has not yet been corrected. I am conscious that there is a move nationwide, in part fuelled by the lack of trained paediatric pathologists, to amalgamate departments of paediatric pathology with their larger parent laboratories. The important point, however, is not whether it was intended to move our Department. What that particular episode highlighted was the lack of communication, and of consultation in the directorate of Pathology.

It was my sense of frustration with this episode coming as it did on top of the others and the inability to get any proper dialogue with the management that made me question whether my future lay in Bristol..."

7.5 This failure to consult those clinicians who had most knowledge about what was important and/or necessary for the paediatric pathology service became a recurring theme throughout the next decade.

7.6 On 16 July 2001, Professor Peter Fleming, Head of Division of Child Health, wrote to Mr Hugh Ross, the then Chief Executive of UHBT:

"Despite the impending departure of Mike Ashworth and the long-term (and possibly permanent) sick leave of Jem Berry, I believe we do have the potential to salvage the Department of Paediatric Pathology in Bristol but it will require wisdom, insight, consultation and determined action by the Trust and the University acting together..."

With the agreement of the Trust and University that the redevelopment and immediate support of Paediatric Pathology will be a high priority and will include investment in support of the salaries and facilities, I believe it may still be possible to attract to Bristol appropriate senior staff to revitalise the Department.

I think it is very important that the Trust and University recognise that without an appropriate size and quality of Paediatric Pathology service in Bristol, then many of the tertiary services currently being built up as joint NHS and University developments ... are all seriously threatened.

May I urge you, as a matter of extreme importance, to establish a small joint UBHT and University Working Group to address these issues immediately to provide a short-term solution to take effect at the beginning of October and a medium to longer term solution as soon as possible."

7.7 Mr Ross responded by saying that he had suggested that Nick Bishop, the then Medical Director of UHBT, should quickly work on an action plan with the Chairman/Clinical Director of the Division of Children's Services, Dr Morgan Moorghen and Professor Massimo Pignatelli.

7.8 In August 2001, the adult pathologists at the BRI offered to report any paediatric work which could not be dealt with by the sole remaining paediatric pathologist, Dr Porter. Dr Moorghen then the Clinical Director of the adult histopathology service at UHBT wrote to Mr David Frank, Chairman of the Division of Children's Services explaining that, in terms of replacement for Dr Berry and Dr Ashworth, the proposed arrangements were that advertisements for two NHS Consultant posts (11 sessions each) would appear in the press soon. He wrote:

“In the meantime as from 13th October Helen Porter will be the only consultant paediatric/perinatal histopathologist in Bristol. As we have discussed previously we need to put in place interim arrangements to support the service where we can, pending the appointment of more staff. The proposed interim arrangement subject to agreement by all clinicians will be:

- 1. Paediatric histopathology work will be looked after by the BRI-based adult histopathologists as from 1st October*
- 2. Perinatal post-mortems will remain the responsibility of Helen Porter with possibly some cover from Southmead (there are ongoing discussions about this)*
- 3. Paediatric post-mortems and SIDS cases: these are still under discussion.*

I have had some discussion with histopathologists in the adult Department and I have also chatted with Richard Spicer and Tony Oakhill but I have not had the opportunity to speak to the other Clinicians in the Children's Hospital who also use histopathology services. It is clear from these meetings that there are serious reservations by all concerned. The adult histopathology Department is busy and grossly understaffed (currently running at about half the recommended number of consultants for the present workload); therefore although everyone is willing to help, we are not actively seeking more work. In terms of specialist expertise everyone in the Department has long-standing interests in specific areas of histopathology and we all handle significant numbers of tertiary referrals either directly or via our clinicians. There is a certain amount of overlap between paediatric histopathology and adult histopathology in some areas; but we do recognise that there are specific areas of paediatric histopathology practice which differs significantly from adult practice. Therefore although we are offering to provide cover for paediatric histopathology as an interim

measure we do recognise our limitations and there has to be an understanding that we would seek an external opinion as and when required..."

- 7.9** A meeting to discuss paediatric pathology services was held on 22 August 2001 following which a letter was sent to the UHBT Chief Executive, Mr Ross, stating:

"On 1st October Michael Ashworth, Consultant Paediatric Pathologist, is leaving the Bristol Royal Hospital for Children to take up a similar post at the Alder Hey Children's Hospital in Liverpool. As you know Professor Jem Berry has already taken early retirement due to ill-health. This means that, with the loss of these Consultants, the Paediatric Pathology Service at the Children's Hospital is severely understaffed. The Clinicians at the Children's Hospital are worried that they will be unable to give their patients the necessary expert advice and treatment without this service.

The two vacant Pathology posts will be advertised immediately. The problem for Bristol is that there is a national shortage of suitably trained Paediatric Pathologists. Professor Fleming is part of a working party set up by the Colleges to look into this problem in more detail. At the moment, until and unless these posts are filled, the standard of care that the children receive will be below the previous exemplary standard of the paediatric pathology service.

A meeting was held on 22nd August attended by involved members of the profession to discuss these problems and try to solve them. The Adult Pathologists have agreed to help as much as they can but the Paediatric Clinicians continue to be concerned about the standard of the service and level of expertise that their patients will receive. There is no easy way to solve this problem. Clinicians and Pathologists will endeavour to minimise the risks to our patients but we think it is important that the Trust Board is aware of our concerns and the increased risk of successful legal action if problems should arise."

- 7.10** The paediatric pathology service was transferred to the BRI in October 2001 but the perinatal pathology service and Dr Porter remained at St Michael's Hospital. The adult pathologists at the BRI therefore reported paediatric cases as well as their own cases.
- 7.11** Some of the paediatric surgeons and clinicians made it quite clear that they were concerned that the adult pathologists did not have the requisite expertise in reporting paediatric cases,

especially the more complex cases such as Hirschsprung's Disease and Wilms tumours. They openly voiced their concerns at meetings and in writing.

7.12 In early 2002 a non-UK trained consultant paediatric pathologist, Dr Consolato Sergi was appointed by UHBT. As far as we are aware he had never practised in the UK before he came to Bristol. No representative from the paediatric services was involved in his appointment. Professor Michael Stevens, Professor of Paediatric Oncology, described to us his view of Dr Sergi's appointment to this single-handed post:

"(The appointment) certainly struck me and a number of other clinical colleagues as a relatively high risk strategy. He was a relatively inexperienced pathologist from another country, who didn't seem to have very strong support mechanisms in place".

7.13 The perinatal pathologist, Dr Porter, resigned at the end of 2002, feeling unsupported, undervalued and undermined. Dr Sergi continued as the sole consultant paediatric pathologist, now covering both paediatric and perinatal cases, and the UHBT adult pathologists continued to report paediatric and perinatal cases in his absence and when there were too many cases for him to handle single-handedly.

7.14 In October 2002 Mr David Frank, Chairman Division of Children's Services and Mr Richard Spicer, Lead Clinician Children's Surgery wrote to Mr Graham Nix, then Acting Chief Executive of UHBT:

"...We feel that decisions made by the Directorate of Pathology were taken without consultation or agreement with the paediatric pathologists and have led to the resignation of initially one and now two of the consultant paediatric pathologists. We do not feel that either the Directorate of Pathology or Trust management have taken our concerns seriously and have failed to act upon them. It is our view that if the paediatric pathology service had been managed as part of the Directorate of Children's Services this situation would never have been allowed to happen. This now exposes both ourselves as clinicians and our patients and the only remaining paediatric pathologist to unreasonable risks and pressures which we feel you as Acting Chief Executive, the Medical Director and the Trust Board should be aware of. We wait to hear your views."

7.15 In October 2002 a Paediatric Pathology Strategy Group (PPSG) was set up led by Professor Michael Stevens. Their first meeting took place on 31 October 2002. Their remit was to

recommend ways in which paediatric pathology should be developed in the short-term and the medium-term, and then report to the Medical Director and Chief Executive. It was acknowledged that a strategic plan to rebuild paediatric and perinatal pathology in Bristol would need to address both specific local factors in the aftermath of the Kennedy Inquiry and the wider generic issues such as the shortage of paediatric pathologists and trainees and national issues created by the response to organ retention.

7.16 When the PPSG met in January 2003 it was minuted that two particular concerns had emerged following a visit by a senior pathologist from Germany who had expressed interest in exploring opportunities to work in Bristol. First, there was a lack of clarity about leadership and authority in the Department - how do the positions of Clinical Director, Professor and Lead Clinicians interrelate and what authority/autonomy would be given to a new paediatric pathologist(s)? Second, there was a very serious concern that the physical state of the pathology department environment (particularly at the BRI) was so poor that few, if any, individuals would be prepared to work there.

7.17 It was agreed that the Trust management team should be made aware that solutions to these issues were of great importance when considering any strategy to recruit to the Department.

7.18 On 17 February 2003, Dr Caroline Calder, Dr Chris Collins, Dr Morgan Moorghen and Dr Joya Pawade (the adult histopathologists at UHBT) wrote to Professor Stevens:

“Thank you for chairing the meetings of the above group. A lot has been discussed at these meetings. Owing to time constraints and a wish to avoid some of the controversial historical events, it was not really possible to examine some of the issues in any detail. We are all agreed on a wish to see the development of a first-class paediatric/perinatal histopathology service. Nevertheless there are still some areas where there is still a significant divergence of views both in regard to the background and the proposed solution. This letter provides a summary of the collective views of the signatories who are all BRI-based Consultant Histopathologists who have had a significant input in the provision of paediatric diagnostic pathology services for the past year....

Model as proposed by PPSG

Maintenance of a separate laboratory for processing paediatric/perinatal material at St Michael's.

- *We believe that this amounts to a waste of resources and we do not accept the analysis of costs as presented at the last PPSG meeting held on 5 February 2003.*
- *We also believe that within the coming months, there is a strong likelihood the separate facility will have to be closed down by default as the main laboratory finds itself in difficulty with regard to providing cover as staff go off on sick leave or annual leave...*

Appointment of a fourth consultant Paediatric/perinatal pathologist

- *We are not supportive of this proposal on the grounds that there is insufficient work for a fourth person. Some of us are even of the view that some of these individuals may not be able to secure revalidation with the GMC because the workload will be too thinly spread out. Furthermore it would be extremely unlikely for this post to attract a strong candidate. We are not in agreement with the idea that a large number of consultants equates with excellence and high quality. We do however need high-calibre individuals who can maintain and build their experience based on a good number of cases which are handled within the close clinico-pathological setting...*

Our proposed model

Management

- *The paediatric/perinatal pathology service should be managed as a sub-department of the Department of Histopathology in a model which is similar to the cytology service. The management accountability in effect remains unchanged from the present model. A Lead Paediatric MLSO will be identified; there will also be designated secretaries who will look after the delivery of the perinatal/paediatric service. One of the paediatric/perinatal pathologists will take a Lead Managerial role on a rotational basis...*

Paediatric surgical biopsy reporting

- *To be carried out in BRI level 9 by paediatric pathologist/s with input from other histopathologists*

St Michael's laboratory

- *To be closed down and re-developed as an academic research facility to support the new Chair, the other Paediatric Pathologists and the Department of the Obstetrics and Gynaecology*

Future appointments

- *Appoint one full-time NHS consultant in paediatric/perinatal histopathology who will share the workload with Consolato Sergi on a more or less equal basis.*
- *Appointment of one Professor of paediatrics/perinatal histopathology. This should only proceed after there has been clear communication involving Senior clinicians in the Children's Hospital, St Michael's Hospital, the UBHT Department of Histopathology, the Clinical Director of the Laboratory Medicine and Senior Colleagues in the University regarding a common strategy for this appointment*
- *The remaining 0.5 WTE Consultant funding to be used to backfill consultant workforce on level 9 who provide a significant input in paediatric surgical biopsy reporting...*

We understand that this proposed model differs considerably from the proposal which is about to be finalised by the Paediatric Pathology Strategy group which you chair. We urge you to take the above points into account along with the views of our Clinical Director and General Manager before you make a final submission to the Chief Executive."

7.19 On 22 February 2003 Professor Stevens e-mailed Mr Nix for his comment a draft copy of the proposed service model he intended to submit to the Trust and wrote:

"I recognise that the preservation of the laboratory at St Michael's is not supported by some of the adult histopathologists and that there is a perception that the suggested level of senior medical staffing is excessive. Nevertheless I think this proposal reflects the view of the users of the service and others engaged with (and potential recruits to) PPP. The major objection to the retention of the St Michael's laboratory is based on cost although the strategy group was not instructed to save money and should therefore take the previous configuration and staffing level as its baseline. A potential saving in closing the St Michael's lab was estimated to be equivalent to 1 wte MLSO. Clearly it will be for the Trust to decide whether it wishes to

seek to achieve this cost saving by closing the laboratory and in doing so the Executive will need to balance the financial gain against the preference of those who run and use the service. The objection to the staffing level for senior medical staff is apparently based on concerns about the adequacy of workload to support revalidation for the individuals concerned. It is important to note however that four positions were filled by clinicians in the past (when Adrian Charles was in post) and that the additional 0.5 wte salary referred to in the proposal would offer flexibility in creating the fourth post to support academic recruitment - this post could even be filled by a non clinical senior lecturer. This should be seen as a key element of a strategy to recruit to the chair which in turn would stabilise the NHS service... Of course the two are interdependent and I hope the proposal recognises this.

I am well aware that there are some equally important issues for the adult service at BRI and have tried to use this proposal to raise these with the Trust. I hope this project might be seen as a contribution to a wider agenda directed towards the development and overall improvement of pathology services in Bristol and the south-west....”

7.20 On 26 February 2003 Dr Moorghen wrote to Graham Nix, Acting Chief Executive, pointing out that the views set out in the draft report of the Paediatric Pathology Strategy Group were not shared by the entire group and that the views of the adult histopathologists were set out in the letter dated 17th February which had been sent to Professor Stevens by them (see above). The same day he wrote to Professor Stevens making suggestions to be incorporated in or appended to the PPSG’s recommendations.

7.21 Professor Stevens submitted the PPSG’s recommended Service Model in March 2003. It acknowledged that, whilst all members of the group supported the reconstruction of a strong Paediatric and Perinatal pathology (PPP) service within UHBT, important differences emerged in the way this could and should be achieved. Principally these differences arose in two areas: first, in relation to the importance of maintaining a separate laboratory presence at St Michael's Hospital, and second, to the status and identity of the paediatric and perinatal pathology service within the Histopathology Department as a whole.

7.22 The main recommendations were that there should be a clear identity for the Department of Paediatric and Perinatal Pathology but that it would function, managerially, within the Department of Histopathology as part of the Division of Laboratory Medicine. One of the consultant medical staff would be appointed as Head of Paediatric and Perinatal Pathology

and would act as the lead clinician of the service within the Department and the Directorate. The Head would be accountable to the Head of Histopathology and through him/her to the Clinical Director of the Division of Laboratory Medicine. All elements of Paediatric and Perinatal post-mortem work except tissue processing and all elements of fetal and perinatal (including placental) pathology except tissue processing would be provided from the St Michael's site with the support of designated technical staff and facilities while all elements of paediatric surgical pathology and tissue processing would be undertaken in the histopathology department at the BRI.

7.23 The Service Model proposed by the PPSG was never implemented. When we asked Professor Stevens what had happened he told us:

"The problem was that this report went to the executive level in the Trust, but I don't think anyone at the executive level ever ensured that the department, or ... the pathology directorate actually implemented these recommendations.... I never sensed that anyone thought this was really a problem that was theirs to solve. That probably summarises it best to me: no one really owned it. There wasn't the commitment at the head of pathology or within the directorate management, to see this as a priority... I did feel that people recognised there was an issue, it's just that no one took responsibility for addressing it. I also think that we were going through a very difficult time nationally in terms of the availability of paediatric pathologists, so it was very easy for people to say 'There is no solution to this; it doesn't matter what we do, we're not going to find anyone'."

7.24 This was perhaps yet another example of the relatively low priority given to paediatric pathology and the general lack of commitment to rebuild a strong paediatric pathology service in Bristol.

7.25 Concerns were gradually raised about the competence of Dr Sergi, the sole paediatric pathologist in Bristol, and following alleged serious errors by him including misdiagnosis of a child who died of Hirschsprung's disease, he resigned and left the Trust in early 2004.

7.26 In late 2003 two new Consultant histopathologists had been appointed, Dr Pramila Ramani (paediatric pathology) and Dr Margaret Evans (perinatal pathology).

7.27 On 1 October 2003, shortly before they took up their posts in November 2003, Professor Stevens wrote to Dr David Hughes:

“... All this leads me to express the strongest concern that plans for the integration of two new colleagues (Dr Evans and Dr Ramani) into the Department of Perinatal and Paediatric Pathology at UBHT should be scrutinised and implemented with the greatest care. The fact that the existence of the Report from the Paediatric and Perinatal Working Party was actually unknown to the Medical Director and the Executive Director chairing the selection process at the recent Appointments Committee suggests that little has actually been achieved in delivering the support needed for the restructuring of this important service. It will be disastrous if there is inadequate leadership at this time. If this cannot be provided within the Department of Histopathology, it must be introduced from outside. A useful first step would be to ensure a structure for the management of paediatric and perinatal pathology which engages the Directorates of Child Health and Obstetrics and Gynaecology in the manner suggested in the Report issued earlier this year.

The Trust has a responsibility to ensure that the diagnostic service providers the paediatric and perinatal pathology is of the highest standard. It also has a responsibility to ensure that those charged with the delivery of service are provided with the necessary leadership and resources to enable them to do so...”

7.28 It concerns us that the Medical Director and Executive Director chairing the selection process at the Appointments Committee were apparently unaware of the existence of the Paediatric Pathology Strategy Group’s report. The PPSG had been set up by the Trust management and yet its recommendations appear to have gone unheeded or at the very least (as acknowledged to us by Professor Stevens he was not sure that it ever gained much steam, but) “it certainly ran out of steam”.

7.29 By May 2004 Dr Evans was expressing her concern and frustration about the poor clinical service that she perceived was being achieved because the paediatric and perinatal pathology service was on a ‘split site’, resulting in delays to the reporting of specimens. In early October 2004 she tendered her resignation, repeating her concerns about delays and her feeling of being unsupported. Although she was persuaded for a while to withdraw her resignation, she went on sick leave for a considerable period of time in early 2005, and during her absence her work had to be covered by a private company, Medical Solutions Ltd and the Perinatal post-mortem service in Bristol had to be suspended. Dr Evans finally left the Trust in July 2005. Dr Evans’ perinatal pathology post remained empty until it was filled by Dr Craig Platt on 1 May 2009.

- 7.30** Dr Pramila Ramani, who is highly regarded by the paediatric surgeons and clinicians, soldiered on as the sole paediatric pathologist. In the summer of 2010 a second paediatric pathologist was appointed to start in September 2010, but unfortunately they decided to take up a post elsewhere shortly before they were due to start.
- 7.31** Significant problems arose at any time when Dr Ramani was absent (either on holiday or on study or sick leave). Until late 2008 her work was covered by the adult histopathologists. We were concerned when we were told that the paediatric surgeons felt obliged to change their clinical practice whenever Dr Ramani was away and pathological opinion was required for complicated cases such as Hirschsprung's disease. We were told that the accepted modern practice is to treat Hirschsprung's disease in a one-stage operation which depends on having frozen section diagnosis by a histopathologist during the operation, but that the paediatric surgeons would only carry out this one-stage operation when Dr Ramani was available. In her absence, the child would be treated with enemas and surgery would be postponed until she was available or alternatively the child had to be sent outside the region.
- 7.32** Her absence also meant that if a rectal biopsy was taken in order to find out whether or not a child was suffering from Hirschsprung's disease, the specimen had to be sent away with a turnaround time of 5 to 7 days, and in the meantime the child had to be kept in hospital and the parents kept waiting for the result, whereas Dr Ramani could usually provide the diagnosis within 24 hours. We were told by Miss Janet McNally, Consultant Paediatric Surgeon, that during one two-week period that Dr Ramani was on annual leave there were three babies with possible Hirschsprung's disease and the delays that were incurred because their specimens had to be sent elsewhere resulted in 15 neonatal intensive care days being taken up by those children remaining in the neonatal intensive care unit waiting for the results. This meant that those beds were not available for other very sick babies.
- 7.33** We were told also by Miss McNally that in Autumn 2008 she was invited to represent the paediatric surgeons' point of view when the histopathology service was inspected for CPA accreditation. She told us that she had to say that as a paediatric group they were very unhappy with the service that they were getting, not because they had any problems with Dr Ramani, but that when she was away or on study leave they had no specialist paediatric pathology service at all and they felt that this had significant governance issues. They did not consider that cover by adult histopathologists was appropriate or acceptable. As a result, this

was flagged up as a major non-compliance and full CPA accreditation was not given until the matter was addressed.

- 7.34** Accreditation was given following the appointment of Dr Platt in 2009, but Dr Platt is in fact not a paediatric pathologist but a perinatal pathologist who does not cover any of Dr Ramani's surgical and oncological work.
- 7.35** In the spring of 2010 advertisements were published for two histopathology posts, one for an adult histopathologist and the other for a paediatric/perinatal pathologist. We were told that once again the paediatric clinicians/surgeons were not consulted at all before the advertisements went out and therefore had no input into their wording. Also there had been a lot of discomfort from the Women and Children's division that nobody from their division had been invited to sit on the Interview Panel for the appointment of the paediatric/perinatal pathologist, which was perhaps surprising as they would be the main users of the services of the new pathologist. Apparently it was raised with the Trust and they subsequently ensured that someone from the Women and Children's division was on the Panel.
- 7.36** Once again the pattern was repeating itself that the people who had the most knowledge about what was needed in paediatric pathology were not being consulted on important issues relating to the service. This lack of communication goes right back to the concerns which led to the resignations of Dr Ashworth and Dr Porter in 2001 and 2002.
- 7.37** It appeared to us that there was a general feeling that there does not seem to have been a great deal of support for paediatric pathology in the past. It was acknowledged that paediatric pathology involves only a small part of histopathology in general and that the adult histopathologists may well have felt that because the numbers of cases actually being seen in paediatric pathology are much less than their workload, there was not any need for any more paediatric pathologists. However we believe that paediatric and perinatal pathology is extremely important and should be valued and supported by managers, other pathologists and clinicians. Bristol should be encouraged to rebuild its reputation as one of the leading centres in the UK - if not internationally - for paediatric and perinatal pathology.
- 7.38** We heard evidence of a potential opportunity of joint networking between the paediatric and perinatal pathology services in Bristol, Oxford and Southampton, firstly concentrating on providing clinical services and then perhaps collaborating on research.

We recommend that such proposal should be strongly encouraged and that management supports such networking between these three centres to promote a strong paediatric and perinatal pathology service for the south west of England.

8. PATIENT ADVOCACY

- 8.1** The Panel recognises the considerable value of patient advocacy and believes that it should therefore be encouraged. It can be of great benefit to patients if, properly channelled, it raises awareness of the need to improve clinical services and health care more generally.
- 8.2** We therefore welcome the involvement of patient advocates in the National Health Service and greatly admire and respect the work that they do.
- 8.3** Although many people in their lives experience being a patient, there is a heavy responsibility on patient advocates to ensure that they are genuinely representative of their constituency. Therefore, any information which is potentially damaging to the confidence of patients must be evaluated very carefully before it is publicised.
- 8.4** We appreciate that it is sometimes difficult for a lay person to fully understand the nuances of complex clinical issues. Consequently, we recognise that this may make a lay person vulnerable to people who do understand the clinical complexities but perhaps have their own agenda.
- 8.5** We heard and received a great deal of evidence from a patient advocate, Mrs Daphne Havercroft.
- 8.6** We do not doubt her motivation or sincerity and admire the hard work she does on behalf of patients. However, we have some concern that some information had been provided to her by individuals with their own agendas, the full context and significance of which perhaps she had not fully evaluated.
- 8.7** Her commitment to patient safety is admirable, but patient confidence is an important part of patient wellbeing, and it is therefore important not to lose sight of that fact when acting as a patient advocate.

9. MEDIA HANDLING

- 9.1** The Trust's 'knee jerk' reaction to the first *Private Eye* article is a good example of the reactive nature of its relationship with the media. What is more, the response – which was to commission an independent review of 3500 histopathological specimens and to set up this Inquiry — provoked several more articles in *Private Eye* as well as articles in the *Sunday Telegraph*.
- 9.2** We have not carried out a detailed analysis of the Trust's relationship with the media, however we believe that proactive media relations are even more important in Bristol because of the legacy of the Kennedy Report. A lack of openness can lead to suspicions or accusations of intentional concealment.
- 9.3** How it handles the publication of our Inquiry report will be a challenge for the Trust and we would recommend that it approaches it – and all future relationships with the media – proactively with an emphasis on openness and honesty and with the involvement of senior management, including the Chief Executive and clinicians. This strategy should reinforce positive relationships with the media and with patients and the public.

10. WHISTLEBLOWING

- 10.1** The Panel would deeply regret it if this Inquiry and/or our Report in any way deters people in the future from reporting any concerns which they may have about a colleague's practice or competence.
- 10.2** Although almost every witness we spoke to during the Inquiry process expressed their regret that matters had gone as far as the publication of articles in *Private Eye* and national newspapers detailing concerns about the histopathology department at UHBT, we would not wish it to be thought that we attach any blame to those who 'blew the whistle'. The blame must lie with those who failed to take any effective action when concerns were originally (and repeatedly) raised.
- 10.3** Although we have been critical of the way in which concerns were transmitted and have made recommendations as to how they should be dealt with in the future, we strongly believe that clinicians are in the best position to recognise deficiencies in the performance or competence of colleagues and that patient safety requires that any concerns relating to performance or competence should be reported promptly but appropriately. Anyone who reports their concerns should be treated with respect and discretion.
- 10.4** Although we know who it was who gave the information to Dr Phil Hammond which led to his various articles in *Private Eye*, we have deliberately not named them as we fully understand why they felt that such a step had become necessary.
- 10.5** Neither do we blame Dr Hammond for publishing his article. As we have said elsewhere in the Report, we strongly believe that this Inquiry (or any other sufficiently comprehensive and/or independent review) would never have taken place without the appearance of the first *Private Eye* article. Although we would have preferred to have been allowed to conduct and conclude the Inquiry without the intervention of further articles both in *Private Eye* and the Sunday Telegraph, we fully understood that the journalists were only doing their job and were attempting to ensure that we were kept 'on our toes'.

10.6 It can never be easy to be a ‘whistleblower’ of matters involving colleagues, and we would hope that in future it is made easier for people with genuine concerns to pass those concerns on to those who can investigate them and, where necessary, deal with them appropriately.

11. RECOMMENDATIONS

	Recommendation	Action
A	<p>A single Histopathology Service should be established for Bristol with the potential to be one of the leading service and academic centres.</p> <ol style="list-style-type: none"> 1. Consultant staffing levels should be reviewed in accordance with the Royal College of Pathologists' <i>"Guidelines on staffing and workload for histopathology and cytopathology departments"</i> (2nd edition) June 2005, and, if necessary, adjusted to ensure they are sufficient for a safe, timely and reliable service. 2. The service should for the time being remain on two sites. 3. The unified service should be managed by a lead Trust unless the two Trusts have been merged. 4. The unified service should have strong management and effective clinical leadership. 5. A Job Description for the post of Head of the new integrated department should be prepared with adequate sessional provision for their managerial responsibilities. 6. All future consultant appointments should be joint appointments between the two Trusts unless they have merged. The appropriate clinicians should be involved depending on the specialist interest[s] of the post. 7. Consultants should work across both sites when necessary to provide the optimum service to patients. 	<p>UHBT</p> <p>NBT</p>

	<p>8. Specialisation should be developed with full participation in appropriate EQA schemes and attendance at relevant CPD events.</p> <p>9. The MDTs in both Trusts should be reviewed to promote collaboration.</p> <p>10. An audit programme should be established for all specialties.</p> <p>11. The BRI histopathology department should be upgraded.</p> <p>12. Implementation of a unified histopathology service for Bristol should be carefully planned and should include direct involvement of all consultants and other staff, facilitation by an experienced external facilitator and the involvement of patient representatives.</p> <p>13. The histopathology service should place the provision of excellent services to patients at the centre of everything it does. Personal and organisational rivalries should not be allowed to stand in the way of the provision of excellent services.</p>	
B	<p>Management Structure</p> <p>If the current management structure for the Histopathology Department is to remain, there should be clarification of the roles and responsibilities of Head of Division, Clinical Lead and Head of Department.</p>	UHBT
C	<p>Relocation of Services</p> <p>Whenever services are re-located, careful consideration must be given to the consequences for histopathology. The histopathologists with the appropriate expertise should transfer with the services to the new location where suitable facilities for them should be</p>	<p>UHBT</p> <p>NBT</p>

	provided.	
D	<p>Double Reporting</p> <p>The term ‘double reporting’ is often used loosely.</p> <p>1. The Royal College of Pathologists should agree a national definition of double reporting which we suggest should be:</p> <p><i>“For a case to be regarded as double reported, two histopathologists should examine and discuss the case and then issue a diagnostic report in their joint names.”</i></p> <p>We suggest that the normal process should be as follows;</p> <p>(a) The pathologist examines the case. If the case is straightforward, and not involving the specialties where double reporting is mandatory, the pathologist should prepare the report.</p> <p>(b) If the case involves the specialties where double reporting is mandatory that should be arranged.</p> <p>(c) If the pathologist feels that it would be helpful to have the views of a colleague informally that should be arranged. Informal consultation of this kind should be encouraged in order to promote a learning culture.</p> <p>(d) If the case is doubtful or difficult, double reporting should be arranged.</p> <p>(e) If a second opinion is required from outside the department that should be arranged. An interim report should be prepared which should make it clear that a second opinion is being arranged.</p> <p>(f) Until the new integrated department is established second opinions from the ‘other’ Bristol department should be regarded as from ‘outside’ the department.</p>	<p>RCPATH</p> <p>UHBT</p> <p>NBT</p>

	<p>(g) Until the new integrated department is established, histopathologists should be encouraged to ask colleagues in the other Bristol department for a second opinion where appropriate.</p> <p>2. The histological slides should be available for review and presentation at the MDT meeting for any case involving histopathological interpretation.</p>	
E	<p>Raising Concerns</p> <p>1. Any concerns about the standard of pathology reporting should be thoroughly, rapidly and, where appropriate, independently investigated and the results made available to all those involved.</p> <p>2. Concerns should be dealt with at the lowest possible level and not escalated unnecessarily.</p> <p>3. The pathologist(s) involved should be consulted directly.</p> <p>We suggest that the process should be as follows:</p> <p>a) If a pathologist, or any other clinician, is concerned about a pathology opinion the first step should be informal discussion with the pathologist who prepared the report. The spirit of the discussion should be one of enquiry and learning.</p> <p>b) If the matter is not resolved the concern should be raised with the Head of Department of the person raising the concern who should discuss the matter with the Head of Department of the pathologist who prepared the report.</p> <p>c) If the concern is not resolved by the Heads of Department the issue should be raised with the Head of Division of the person raising the concern who should discuss the matter with the Head of Division of the pathologist who prepared the report.</p> <p>d) If the concern is not resolved by the Heads of Division the</p>	<p>UHB</p> <p>NBT</p>

	<p>matter should be raised with the Medical Director of the person raising the concern who should discuss the matter with the Medical Director of the pathologist who prepared the report.</p> <p>e) If the concern is not resolved by the Medical Directors the matter should be raised with the Chief Executive of the person raising the concern who should discuss the matter with the Chief Executive of the pathologist who prepared the report.</p> <p>f) The person raising the concern and the pathologist who prepared the report should be appropriately supported at all stages.</p> <p>Where appropriate, an audit of relevant specimens should be conducted.</p>	
F	<p>Whistleblowing</p> <p>The Department of Health should review advice on whistleblowing to ensure that local policies include clear guidance on raising concerns about the work of a pathologist or any other clinician who works for a different Trust from the Trust employing the person raising the concern.</p>	Department of Health
G	<p>Relationships with the Media</p> <p>Proactive media relations are even more important in Bristol because of the legacy of the Kennedy Report.</p> <ol style="list-style-type: none"> 1. Relationships with the media should be proactive with an emphasis on openness, honesty and the involvement of senior managers and clinicians including the Chief Executive. 2. Relationships with the media should reinforce positive relationships with patients. 3. Service change should be explained. 	UHB

	<p>4. The Trust website should be kept up to date.</p> <p>5. The handling of our Report will be the first challenge of the new approach to relationships with the media.</p>	
H	<p>Paediatric and Perinatal Pathology</p> <p>1. Paediatric and perinatal pathology should be valued and supported by managers, pathologists and other clinicians.</p> <p>2. The minimum level of staffing should be one paediatric pathologist, one perinatal pathologist and one pathologist trained in both paediatric and perinatal pathology.</p> <p>3. Joint working between the paediatric and perinatal pathologists in Bristol, Southampton and Oxford should be strongly encouraged.</p>	UHBT
I	<p>Patients and Histopathology</p> <p>1. The Department of Health and the Royal College of Pathologists should work together to improve further patients' understanding of the role of histopathology.</p> <p>2. The Trust should develop proactive and constructive relationships with patients and patient advocates.</p> <p>3. Where a patient's care is going to be discussed at a multidisciplinary team meeting, patients should not be given information contained in histopathology reports until the reports have been considered by the multidisciplinary team.</p> <p>4. Where errors of diagnosis are identified, patients should be promptly informed.</p>	<p>Department of Health</p> <p>RCPATH</p> <p>UHBT</p> <p>NBT</p>

J	<p>Specialist Pathology</p> <ol style="list-style-type: none"> 1. The Royal College of Pathologists should review its guidance on ‘specialist’ histopathology with the intention of making it more explicit where possible. 2. There should be at least two specialist histopathologists in each subspecialist area to allow proper review and to provide cover for meetings and periods of leave. 	<p>RCPATH</p> <p>UHBT</p> <p>NBT</p>
K	<p>Trainees</p> <p>Trainees should have supervised involvement in the full range of specimens, including the most complex cases, in accordance with their seniority and experience.</p>	<p>UHBT</p>
L	<p>The Aftermath of this Inquiry</p> <ol style="list-style-type: none"> 1. The histopathologists should be given whatever support they need to face the aftermath of this Inquiry including skilled facilitation. 2. Consideration should be given to inviting the Inquiry Panel to return within the next 12 months to review what steps are being taken to address these Recommendations. 	<p>UHBT</p> <p>NBT</p>

ANNEXE 1: Terms of Reference

University Hospitals Bristol



NHS Foundation Trust

Histopathology Inquiry: Terms of Reference

1. To inquire into the performance of the histopathology services across the trust.
2. To inquire into all matters which led to the concerns raised since 2004 about possible misinterpretation and/or misdiagnosis of histopathology specimens.
3. To establish what action was taken by the Trust to address any concerns raised about the performance of histopathology services and to draw conclusions as to whether such response was appropriate, timely and sufficient.
4. To consider the results of the independent review of histopathological specimens and to draw conclusions from those results.
5. To make recommendations on any action necessary to ensure provision of safe and effective services for patients.

Approved by the board of University Hospitals Bristol NHS Foundation Trust on 28th October 2009.

MEDICINE BALLS



Pathological Sickness

ON 1 2007 a letter was sent to Dr Martin Morse, medical director of North Bristol Trust (NBT), detailing 11 alleged serious diagnostic errors made by histopathologists at the Bristol Royal Infirmary, resulting in significant patient harm. These cases came to light when slides and samples were subsequently reviewed at NBT.

According to the allegations, one woman (now deceased) was told her breast biopsy was benign but later presented with metastatic cancer, and patients with malignant lymphoma, melanoma (twice) and vulval carcinoma were also initially told they did not have cancer. Conversely two other patients allegedly had treatment for cancer when review of their biopsies found no evidence of it.

Documented errors appeared most likely in patients with rare lung disease. Again, patients have allegedly been told they have cancer when they don't, and vice versa. Another was allegedly told he had tuberculosis when subsequent review found that he didn't.

Interpreting tissue slides is stressful and complex, and some mistakes inevitably happen. The Royal College of Pathologists (RCPATH) clearly states that when discrepancies in reporting occur, prompt independent review is required but some of these errors date back to 2000, and when the college was invited to do such a review, it apparently declined as it did not want to get involved in an "internal matter".

Bristol is blessed with some fine pathologists, including respiratory specialists based at NBT, and if they worked in teams, accepted the same quality control and shared difficult diagnoses, then doubtless some harm to patients could have been prevented or reduced.

Alas, the long-standing rivalry between Bristol hospitals has prevented this from happening. Until July 2008, NBT pathologists claim they were unable to access the slides for their patients who were treated at the BRI, though this has now been resolved. However, slides from other patients who

might benefit from the specialist service at NBT are still not being shared. Dr Morse has raised concerns with the Medical Director of University Hospitals Bristol (UHB), Dr Jonathan Sheffield, but – two years after the whistle was blown – an independent external review has not happened. Four additional cases of apparent lung misdiagnosis have now been documented, but Dr Sheffield has stated that there is "no evidence to confirm a significant error rate" in the service.

As well as the RCPATH, these concerns have been brought to the attention of the chief executives of both trusts, the medical director of the strategic health authority, the medical director of the Avon Somerset and Wiltshire Cancer Services and the National Clinical Assessment Authority, thus far without satisfactory investigation or resolution.

It seems extraordinary, given what happened previously in Bristol, that UHB staff would not accept they might have a problem in their pathology department and act quickly to get an outside assessment. An urgent external review and the assimilation of pathology services across Bristol into a network that encourages scrutiny and shared expertise is now vital for patient safety. Dr Sheffield and the RCPATH have been sent a detailed summary of the alleged misdiagnoses and M.D. has asked Barbara Young at the Care Quality Commission to investigate.

M.D.

ANNEXE 3 (i): Diagnostic Error in Histopathology, Sir James Underwood

Histopathology

Histopathology is a clinical specialty involving the diagnosis and assessment of disease by the examination of cells and tissues. The effective treatment of a wide range of diseases relies on the expert histopathological interpretation of tissue samples (i.e. biopsies) and surgically removed tissue (i.e. resections). Even in cases where the diagnosis is already known, histopathology can yield important information about the extent and aggressiveness of the disease.

The principal diagnostic instrument is the microscope. To enable tissue to be examined microscopically it first must be hardened so that very thin sections can be cut. This hardening is normally done by chemical fixation, dehydration and infiltration with wax; this takes about 24 hours. However, if a rapid diagnosis is needed (for example, during a surgical operation), the tissue is hardened by freezing; the tissue than then be cut thinly (i.e. frozen section). The cells and other structures in the tissue are rendered visible by staining.

When examining the tissue, the histopathologist will take account of the patient's clinical details provided on the request form accompanying the specimen. Having reached an opinion on the case, the histopathologist will then send a report to the clinician responsible for the patient's care. In many cases, the histopathologist's opinion is qualified by wording that indicates the degree of certainty. For example, if the histopathologist is absolutely certain of the diagnosis, phrases such as "diagnostic of [the disease]" will be used. Where there is doubt about the diagnosis, this may be expressed as "consistent with [the disease]" or "highly suspicious of [the disease]".

For many diseases, notably cancer, the final decision about diagnosis and treatment will be made at a meeting of the multidisciplinary team where all relevant information (surgical, radiological, histopathological, etc) about the patient can be reviewed and discussed. This can result in a refinement or even revision of the histopathological opinion. For example, the originally reported histopathological opinion could have been erroneous because vital information had been omitted from the request form.

Histopathology involves considerable knowledge, training, experience and expertise allied to judgement. However, there is a large element of subjectivity, particularly in complex,

borderline or doubtful cases. Consequently there is a risk of error in histopathology (although the diagnostic error rate in histopathology is significantly less than in many other specialties). While error-free histopathology would be desirable, it is probably unachievable except when dealing with the most simple and clear-cut diagnostic problems. Undetected errors in histopathology can have catastrophic consequences for patients: a potentially lethal disease can be misdiagnosed as a benign condition, resulting in insufficient or ineffective treatment; a relatively trivial disorder can be misinterpreted as a malignant neoplasm, prompting unnecessarily intensive and potentially harmful treatment.

Histopathologists engage in various activities to ensure high reliability and to minimise the risk of errors: laboratory accreditation (typically by CPA(UK)Ltd), external quality assurance schemes, continuing professional development and clinical audit. They should also work in histopathology services with an open culture of error awareness in which misdiagnoses are reviewed and discussed openly with the aim of reducing the likelihood of a recurrence. Theoretically, errors could also be reduced by double reporting, but doing this routinely would require a substantial increase in the consultant workforce; currently, it is regarded as mandatory only for dysplasia in Barrett's oesophagus and for dysplastic/malignant melanocytic lesions.¹

Like other branches of medicine, histopathology is becoming more complex and specialised. Especially in major teaching centres and university hospitals, consultant histopathologists concentrate on a small range of types of specimen (e.g. gynaecological, gastrointestinal, skin) rather than seeking to maintain competence across the full scope of the histopathology workload. In its guidance on the recognition of specialists in histopathology, the Royal College of Pathologists emphasises that there is no absolute distinction between "general" and "specialist" histopathologists. Nevertheless, the College lists the attributes expected of a "specialist" histopathologist.²

James Underwood

8 June 2010

¹ *Quality assurance in histopathology and cytopathology reporting practice*. Royal College of Pathologists. February 2009.

² *The recognition and roles of specialist cellular pathologists*. Royal College of Pathologists. June 2006.

ANNEXE 3 (ii): Diagnostic Error in Histopathology, Dr Ray McMahon

Independent Inquiry into Histopathology Services

Report prepared by Dr Ray McMahon, Consultant Histopathologist

2 June 2010

The nature of a histopathological diagnosis (e.g. whether it is a matter of fact or of opinion)

Histopathological diagnosis is a composite of many different factors which contribute to patient management. Unlike other aspects of pathology, it is not possible to provide absolute values and to a greater or lesser extent depending on circumstances, all histopathology reports provide an opinion rather than an absolute fact. The relative certainty of that opinion is variable and in the great majority of cases there is little or no dispute about that opinion. Nonetheless it is important to remember there is considerable variation in the difficulty of cases. Histopathological diagnosis is not a 'black and white' exercise and there are many recognisable, predictable 'grey' areas that should be appreciated.

The concept of a 'correct' histopathological diagnosis (e.g. the extent to which a reliable diagnosis can be achieved)

In many instances a 'correct' diagnosis can be achieved. Some diagnoses are absolutely clear cut and could (should) not be missed. Other diagnoses are less capable of certainty and in those circumstances, appropriate caution is required by the reporting pathologist. Much of the training in histopathology is geared to providing trainees with a framework for dealing with this level of uncertainty. Histopathological reports should convey the degree of certainty or otherwise that the reporting pathologist has in his/her report. The report forms part of the clinical record and is an integral part of clinical management.

The 'correctness' of a report depends on many factors, which can be separated into 3 distinct phases: pre-analytical, analytical and post-analytical. Of these, the pathologist only fully has control of the analytical phase. The pre-analytical phase includes the preparation of the biopsy or resection material including fixation and the transport of that material to the laboratory. It also involves the provision of clinical information and the 'question' being asked of the pathologist for that particular biopsy or resection. The post-analytical phase is what happens after the pathologist has reported and the report is back in the domain of the requesting clinician. The pathologist can pre-empt many difficulties in the pre-analytical areas by the provision of appropriate advice and guidance on specimen preparation and the use of standardised request cards. Similarly in the post-analytical phase there is increasing participation by pathologists in multi-disciplinary team meetings (MDTMs) and in

clinicopathological conferences (CPCs), where potential confusion on the significance of elements of reports can be clarified.

In the analytical phase, there may be problems in the preparation of specimens relating to selection of blocks at the gross pathology of specimens. There may also be difficulties with failure to recognise typographical errors in the final report which may have the effect of changing the meaning or emphasis of a report.

Most issues arise in the microscopy phase. Occasionally pathologists will make a completely unexpected diagnosis, whereby an obvious cancer will be missed but this is very unusual and often points to issues outwith the diagnostic process. These include workload pressures, problems with colleagues and personal difficulties. In microscopy there may be problems associated with a relatively small number of pathologists missing obvious diagnoses, converting a benign diagnosis to a malignant one. Some diagnoses in histopathology are known to be difficult where there is large inter-observer variability, including melanocytic skin lesions, breast pathology and gynaecological pathology. In this situation, pathologists should develop alternative strategies including consultation with local or other colleagues.

There is wide variability in the reported 'error' rate on a national and international basis, partly related to the definitions as previously discussed and also to the inherent complexity of particular case types. These range from under 2% to up to 40%. What is clear is that, like other branches of medicine, pathologists are human and fallible and are not always capable of providing the absolutely correct diagnosis every time.

The impact of 'incorrect' histopathological diagnoses on patient care and welfare (e.g. are some diagnostic 'errors' more grave than others?)

There is great variability in the impact of 'incorrect' diagnoses. The Royal College of Pathologists (RCPATH) has a scheme by which these variations in diagnosis are categorised. Initially, these were Category 1: a diagnostic error likely to have a definite influence on clinical management and possible outcome; Category 2: a misinterpretation or oversight, with the potential to affect clinical management or outcome; and Category 3: a minor discrepancy of disease categorisation, likely to be of little clinical significance. This initial categorisation was reviewed and further developed by elaborating on the difference between a discrepancy (a difference of opinion between the original and review interpretations) and an error (when the discrepancy is confirmed by two independent reviewers). It also emphasised the distinct purposes of such evaluations, whether in response to concerns about an individual doctor's performance or as part of a duty of care review, looking at patients whose care may have been sub-optimal, usually after establishment of poor performance.

The refinement of these two distinct areas has led to the separation of these categories.

- Where concern has been expressed about a pathologist's performance, Category A reflects issues with regard to gross specimens, Category B to discrepancies in microscopy, Category C to discrepancies in clinical correlation, Category D to lack of recognition of difficulty in a particular case

leading to failure to seek a second opinion, and Category E to discrepancies in the final report such as typographical errors or ambiguities.

- In duty of care reviews, Category 1 discrepancies result in no impact on care; Category 2 where there is minimal harm without morbidity; Category 3 where there is minor harm and morbidity; Category 4 where there is moderate harm or morbidity; and Category 5 where there is major harm or morbidity. These relate to delays in diagnosis, further unnecessary investigations, delays in therapy or unnecessary therapy.

The frequency of diagnostic disagreements as revealed by EQA schemes

The expected level of agreement in external quality assurance (EQA) schemes in discussion meetings to reach consensus for scoring purposes is in the order of 75-80%, with some variation depending on the type of scheme whether general or specialist. Many pathologists belong to both types of scheme, especially those working in district general hospitals with those working in teaching hospital and supra-regional or national centres more likely to belong to their appropriate specialist EQA scheme. These exist for the great majority of specialist areas in pathology. The primary purpose of EQA activity is educational but there is also an important secondary role in the identification of poor performance by an individual. For this reason there is currently dual oversight of these schemes by the RCPATH Steering Committee for Interpretive EQA Schemes and the Histopathology Panel of the National Quality Assurance Advisory Panel. All schemes use standard operating procedures (SOPs) in their governance practice, reviewed annually by both groups. These vary slightly from scheme to scheme but shown here is the form of words used by the National (Specialist) Gastrointestinal Histopathology EQA for dealing with substandard performance:

“Scores in the bottom 2.5% should be considered substandard performance. An 'Action Point' is a score within the bottom 2.5% of the scores of the group in two out of three consecutive circulations in which the individual participates.

If an action point is reached a 'Dear Colleague' letter should be sent by the Scheme Secretary (anonymously on behalf of the Organiser) inviting an explanation, offering assistance and explaining the next steps.

After the first action point has been reached the Scheme Secretary (on behalf of the Organiser) should record the event against the participant's PIN and subsequently ignore the past record of substandard performance so that it does not mask any future improvement. A form of surveillance should then be continued for three circulations after which the conditions of participation should return to those applied to all other Pathologists in the scheme. The second action point would then be defined exactly the same as the first, i.e. an average score falling in the bottom 2.5% for two out of three successive circulations. Failure to respond to a circulation will be recorded as score in the bottom 2.5% in these circumstances.

When the second action point has been passed, the Scheme Organiser via the Scheme Secretary will inform the Chairman of the Histopathology National Quality Assurance Advisory panel who will then initiate an appropriate investigation. It is envisaged that these procedures should be activated only in exceptional circumstances and should cause no more concern to EQA participants than the current possibility of being reported for

incompetence by a colleague. The main purpose of EQA schemes should remain educational, as it has remained in other disciplines.”

The standard of cases used in EQA schemes is expected to reflect routine practice at the appropriate level (general or specialist) and cases submitted for scoring purposes should be capable of being reported on a single stained section, along with which is provided the clinical information and ancillary investigations available to the reporting pathologist at the time of formulation of the final report. The majority of pathologists (usually far in excess of the 75-80% required for consensus) are capable of recognising the ‘correct’ diagnosis which is agreed at consensus meetings. Occasionally outlying diagnoses will be seen, which may reflect a poor choice of case material or an absence of the diagnostic features in the case material received by an individual or group of pathologists. It may also indicate an area of pathology with which the participant is not currently familiar or in which they have a ‘blind spot’. The feedback provided to all participants after each circulation allows the individual pathologist to reflect on their practice (even before reaching an action point as defined above), so that they may decide to withdraw from reporting in a particular aspect of pathology or to seek retraining or further guidance on this area from a local or national expert. The extent to which this occurs is also variable, with the selection of cases for inclusion being particularly crucial. Circulations usually involve 10-14 cases and after consensus has been achieved, most schemes will include 8-13 cases for scoring. Some schemes recognise ‘serious errors’ and emphasise these in the discussion meetings and in the written feedback provided. The discussion meetings are an opportunity for peer groups to meet to consider the proffered diagnoses but also to provide educational opportunities for scheme participants. Organisers typically target the educational component at areas which have in the past identified difficult diagnostic areas or dilemmas. The number of referrals to the Histopathology NQAAP for reaching the second action point defined above is extremely low (single figures per annum nationally). Scheme organisers report more frequently in their annual reports of individuals triggering the first action point, after which remediation is usually developed locally.

Further Reading

Bryant SJ, Davies DJ. Diagnostic error in anatomical pathology: the uncertainty of its measurement? *Pathology* 2006; 38: 487-489.

Leong ASS, Braye S, Bhagwande B. Diagnostic errors in anatomical pathology: relevance to Australian laboratories. *Pathology* 2006; 38: 490-497.

Raab SS, Grzybicki DM. Quality in cancer diagnosis. *CA Cancer J Clin* 2010; 60: 139-165

RCPATH. Review of the categorisation of discrepancies in histopathology. November 2008

RCPATH. Concerns about performance in pathology: guidance for healthcare organisations and pathologists. February 2006

ANNEXE 4 (i): Reviews of the 26 cases, review by the Royal College of Pathologists

Report on the review of 26 index cases

This supplementary report is written by Professor Peter Furness, President of The Royal College of Pathologists (RCPath). It represents a supplementary report to that provided in June 2010 pertaining to the independent audit of 3500 cases commissioned by University Hospitals Bristol NHS Foundation Trust (UHBT).

Instruction

This supplementary report is provided at the request of Mr Ed Marsden, Inquiry Secretary, on behalf of Verita, as summarised below:

Brief for the Royal College of Pathologists

University Hospitals Bristol NHS Foundation Trust has commissioned the Royal College of Pathologists to undertake a review of the 26 index cases. The Trust has been advised by the Inquiry Panel regarding the specific brief for the review.

Terms of reference

1. To obtain independent opinions from two appropriate specialists on each of the 26 cases.
2. For each case, to assess whether these opinions indicate an error or discrepancy in relation to the original report from the UHBT histopathologist.
3. For each case of error or discrepancy, to provide a short commentary on the nature of the error or discrepancy.
4. To provide a report on any specific or general conclusions that can be drawn from the review of the 26 cases.

Conduct of the review

Regarding term of reference 1, the specialist histopathologist reviewers should be provided with the clinical information that was written on the request form accompanying the specimen when originally reported at UHBT. The reviewer should not be provided with the original UHBT report before they submit their opinions on each case; they should be sent the UHBT report only after they have submitted their opinions so that they can then make the assessment to fulfil term of reference 2.

The College will select appropriate specialists who, ideally, will have not seen these cases in the Pathlore/Medical Solutions review.

The Royal College of Pathologists was provided by UHBT with slides and original reports for 26 cases for review. We are informed that these include only 25 cases of the 26 that were originally brought to the attention of the review panel. We have since been informed that the original 26 cases included a lung biopsy taken at a private hospital in Bristol. Sections and reports from that case have not been supplied to the College.

This report also includes the review of an alleged misdiagnosis that came to light during period of the Panel's Inquiry (second case on page 6, identified as BH 09-10810 and BH 09- 19076).

Term of reference 1 having been fulfilled, this report pertains to terms of reference 2, 3 and 4.

Qualifications and experience

As set out in my report of June 2010.

Independence

As set out in my report of June 2010.



Review of cases

The text in the following tables represents my attempt to summarise and sometimes to interpret the often lengthy comments made by the reporting pathologists and the reviewing pathologists. For detail, the original reports should be read. A total of 12 reviewing pathologists were commissioned by the Royal College of Pathologists. They are identified below by a reviewer ID number.

The text labelled 'Comment' after each case represents my attempt to identify features of each case that I regard as important in relation to assessing the competence of the reporting pathologists.

Section 1

Pulmonary pathology cases

Bristol case number:	BH07-12183
Bristol pathologist:	Dr Collins
Original diagnosis:	Localised process, not suggesting chronic interstitial lung disease. Supplementary report (dated October 2007, delay not specified) gives Dr Ibrahim's opinion.
Reviewing pathologist 1:	Reviewer ID 1
Review diagnosis:	Non-specific interstitial pneumonia, not localised disease.
Categorisation of discrepancy:	B2
Reviewing pathologist 2:	Reviewer ID 2
Review diagnosis:	Non-specific interstitial pneumonia.
Categorisation of discrepancy:	B2 and D

Comment:

Both reviewers comment on the presence of pleural changes making the diagnosis difficult. Reviewer ID 2 believes that a second opinion should have been sought.

Bristol case number:	BH 02/00347 BH 04/09520
Bristol pathologist:	BH 02/00347: Dr Moorghen BH 04/09520: Dr Pawade
Original diagnosis:	BH 02/00347: Interstitial lung disease, ? extrinsic allergic alveolitis. BH 04/09520: Extrinsic allergic alveolitis. Reviewed November 2004; Focal interstitial pneumonitis, no evidence of lymphoma.
Reviewing pathologist 1:	Reviewer ID 1
Review diagnosis:	BH 02/00347: Mild non-specific inflammation. No error. BH 04/09520: Extrinsic allergic alveolitis.
Categorisation of discrepancy:	BH 02/00347: No error. BH 04/09520: B3 (on basis of amended report).
Reviewing pathologist 2:	Reviewer ID 2
Review diagnosis:	BH 02/00347: Non-specific inflammation. BH 04/09520: Hypersensitivity pneumonitis.
Categorisation of discrepancy:	BH 02/00347: No error. BH 04/09520: No error (on basis of first report).

Comment:

All seem to agree that the findings in these biopsies are relatively non-specific; possible explanations are suggested with varying degrees of confidence but no convincing error is identified.

Bristol case number:	BH08/6855
Bristol pathologist:	Dr Pawade
Original diagnosis:	Ill-defined granulomas; various possible explanations proffered, including infection.
Reviewing pathologist 1:	Reviewer ID 1
Review diagnosis:	Strongly suggestive of extrinsic allergic alveolitis.
Categorisation of discrepancy:	B2
Reviewing pathologist 2:	Reviewer ID 2
Review diagnosis:	Granulomatous interstitial pneumonitis, consider infection or drug reaction.
Categorisation of discrepancy:	A (Inadequate dissection, sampling or macroscopic description).

Comment:

None of the pathologists offers a definite diagnosis. In view of the different opinions of the expert reviewers I do not believe that the original report can be regarded as being proven to represent a diagnostic error.

Bristol case number:	BH08/7816
Bristol pathologist:	Dr Pawade, also seen by Dr Collins
Original diagnosis:	Malignant mesothelioma of epithelioid type. Supplementary report after external review by Prof Nicholson (26/6/2008); atypical mesothelial proliferation, not definitely mesothelioma.
Reviewing pathologist 1:	Reviewer ID 2
Review diagnosis:	Indeterminate for malignancy.
Categorisation of discrepancy:	B3
Reviewing pathologist 2:	Reviewer ID 3
Review diagnosis:	Likely to be mesothelioma. Not definite.
Categorisation of discrepancy:	B3

Comment:

This is clearly a very difficult case. If an error can be identified in the original report it is not unequivocally in the diagnosis, but in the apparent confidence with which the diagnosis is proffered, apparently initially without consideration of obtaining a second opinion.

Bristol case number:	BH08-5922
Bristol pathologist:	Dr Calder
Original diagnosis:	Desmoplastic malignant mesothelioma. Supplementary report issued 3 months later after review with Dr Morgan, seen by Dr Pawade: Chronic inflammation and fibrosis, no evidence of mesothelioma.
Reviewing pathologist 1:	Reviewer ID 1
Review diagnosis:	Reactive pleural fibrosis with entrapped mesothelial cells.
Categorisation of discrepancy:	B2
Reviewing pathologist 2:	Reviewer ID 2
Review diagnosis:	Highly suspicious of desmoplastic malignant mesothelioma.
Categorisation of discrepancy:	B3 (on the basis of initial report)

Comment:

The difference of opinion between the experts illustrates the difficulty of this case. Consequently the main error in the initial report should be regarded as in proffering a diagnosis in which no suggestion of uncertainty is expressed and without having obtained a second opinion.

Bristol case number:	BH07-15546
Bristol pathologist:	Dr Pawade
Original diagnosis:	Suggestive of extrinsic allergic alveolitis, possible co-existing connective tissue disorder. No evidence of malignancy. Supplementary report after external review by Prof Nicholson: Lymphoid interstitial pneumonia, several possible underlying causes discussed, lymphoma is a possibility.
Reviewing pathologist 1:	Reviewer ID 3
Review diagnosis:	Difficult case, could be reactive but might be lymphoma. Seek further opinion.
Categorisation of discrepancy:	B2
Reviewing pathologist 2:	Reviewer ID 2
Review diagnosis:	Lymphoid interstitial pneumonia, but with features raising a suspicion of underlying malignancy.
Categorisation of discrepancy:	B2

Comment:

This is clearly a difficult case; the main error in the original report is not in the diagnosis, but in the confident assertion that there is nothing at all present to suggest malignancy, and the failure initially to seek a second opinion.

Bristol case number:	BH04/14787 and BH04-15096
Bristol pathologist:	Dr Pawade reporting the opinion of Dr Ibrahim
Original diagnosis:	BH04/14787: Pleural plaques. BH04-15096: Chronic non-specific inflammation, no evidence of malignancy. Subsequent external opinion from Professor Lucas 'confirms' a diagnosis of leishmaniasis as the underlying cause. The supplementary report states that the patient is known to have cutaneous leishmaniasis; it would appear that this information was not available when the original report was produced.
Reviewing pathologist 1:	Reviewer ID 1
Review diagnosis:	BH04/14787: Pleural plaques. BH04-15096: Inflammation probably due to leishmaniasis (this diagnosis suggested without prior knowledge of the cutaneous leishmaniasis).
Categorisation of discrepancy:	BH04/14787: No error. BH04-15096: B2
Reviewing pathologist 2:	Reviewer ID 2
Review diagnosis:	BH04/14787: Pleural plaques. BH04-15096: Visceral leishmaniasis.
Categorisation of discrepancy:	BH04/14787: No error. BH04-15096: B1-2

Comment:

The identification of leishmaniasis depends on the identification of tiny organisms within the cytoplasm of infiltrating inflammatory cells. These are easily missed, especially if the clinical information gives no hint of the possibility of a rare tropical infection. It is relevant that in this case the leishmania were initially missed despite the sections being viewed by two Bristol pathologists. The underlying error appears to have been a failure to inform the pathologists that the patient had leishmaniasis in the skin.

Bristol case number:	04/08093
Bristol pathologist:	Dr Calder
Original diagnosis:	Fibrosis, no evidence of malignancy. Supplementary report after MDT review and seen by Dr Sohail: Desmoplastic malignant mesothelioma.
Reviewing pathologist 1:	Reviewer ID 1
Review diagnosis:	Sarcomatoid mesothelioma with desmoplastic features.
Categorisation of discrepancy:	B2, D
Reviewing pathologist 2:	Reviewer ID 2
Review diagnosis:	Biphasic, predominantly sarcomatoid, malignant mesothelioma.
Categorisation of discrepancy:	B1

Comment:

The original report clearly represents a benign/malignant error.
Reviewer ID 2 is of the opinion that the error simply should not have been made;
Reviewer ID 1 regards the incorrect diagnosis to be understandable, but it should not have been made with such confidence, so the serious error is not to have sought a second opinion.

Bristol case number:	BN06/00400 and BH 06/02482
Bristol pathologist:	BN06/00400: Dr Calder BH 06/02482: Dr Pawade
Original diagnosis:	BN06/00400: Cytology – no malignant cells seen. BH 06/02482: Lymphocytic interstitial pneumonitis with features raising a possibility of underlying measles.
Reviewing pathologist 1:	Reviewer ID 1
Review diagnosis:	BN06/00400: Cytology – no malignant cells seen. BH 06/02482: Granulomatous inflammation consistent with but not diagnostic of extrinsic allergic alveolitis.
Categorisation of discrepancy:	BN06/00400: No error. BH 06/02482: B2 (NOT suggestive of measles), C (clinical suggestion of external allergic alveolitis, incorrectly abbreviated to EEA, not considered).
Reviewing pathologist 2:	Reviewer ID 2
Review diagnosis:	BN06/00400: Cytology – no malignant cells seen. BH 06/02482: Granulomatous inflammation, several possible causes suggested.
Categorisation of discrepancy:	BN06/00400: No error. BH 06/02482: B2. The features are not those of viral infection.

Comment:

All pathologists agree on the description and none offer a definite diagnosis of the underlying cause, but the original report is in error for its strong suggestion that the underlying cause is likely to be a viral infection (Measles). This was proffered as a possible explanation, not a definite diagnosis.

Bristol case number:	BH 09-10810 and BH 09- 19076
Bristol pathologist:	BH 09-10810: Dr Sohail BH 09- 19076: Dr Pawade
Original diagnosis:	BH 09-10810: Squamous cell carcinoma, stage pT2 pNX BH 09- 19076: Necrosis, cause not evident; ? necrotic tumour ? old tuberculosis. Subsequent report – AFB negative.
Reviewing pathologist 1:	Reviewer ID 1
Review diagnosis:	BH 09-10810: Squamous cell carcinoma, stage pT1 pN0 BH 09- 19076: Tuberculosis. AFB stain is positive.
Categorisation of discrepancy:	BH 09-10810: B2, error in staging. BH 09- 19076: B1
Reviewing pathologist 2:	Reviewer ID 2
Review diagnosis:	BH 09-10810: Squamous cell carcinoma, stage pT2 pN0. BH 09- 19076: Tuberculosis. AFB stain is positive.
Categorisation of discrepancy:	BH 09-10810: A (should have requested EVG stain to assist staging). In a subsequent note reviewer ID 2 subsequently recognises that she had incorrectly staged the tumour, thus repeating the mistake of the Bristol pathologist. BH 09- 19076: B1

Comment:

BH 09-10810: The fact that one expert shared the 'error' in staging indicates that despite the B2 categorisation this is an understandable and common mistake.
BH 09- 19076: Failing to detect the tuberculosis bacilli appears to be a serious mistake.

Section 2

Gynaecological pathology cases

Bristol case number:	SH06-4596 BH07-16491
Bristol pathologist:	SH06-4596: Dr Sen BH07-16491: Dr Pawade
Original diagnosis:	SH06-4596: Right - Micropapillary serous borderline tumour with microinvasion. Left – endometriosis, benign serous adenofibroma. BH07-16491: Adenocarcinoma, consistent with primary serous carcinoma of the ovary.
Reviewing pathologist 1:	Reviewer ID 4
Review diagnosis:	SH06-4596: Right - Encysted low grade serous adenocarcinoma arising from micropapillary serous borderline ovarian tumour. Left; endosalpingiopsis, chronic salpingitis, normal ovary. BH07-16491: Adenocarcinoma.
Categorisation of discrepancy:	SH06-4596: B2 BH07-16491: No discrepancy.
Reviewing pathologist 2:	Reviewer ID 5
Review diagnosis:	SH06-4596: Right: High grade serous carcinoma, Left: normal ovary, chronic salpingitis. BH07-16491: Adenocarcinoma.
Categorisation of discrepancy:	SH06-4596: B2 BH07-16491: No discrepancy.

Comment:

The two expert reviewers both conclude that a B2 error has been made, based on the assessment of the invasion ('micro' or not), but they differ between each other on whether the tumour is high grade or low grade.

Bristol case number:	BH06-10483
Bristol pathologist:	Dr Pawade
Original diagnosis:	Adenocarcinoma, metastatic, similar to previous endometrial primary.
Reviewing pathologist 1:	Reviewer ID 4
Review diagnosis:	Metastatic adenocarcinoma.
Categorisation of discrepancy:	A (inadequate immunohistochemistry)
Reviewing pathologist 2:	Reviewer ID 5
Review diagnosis:	Metastatic adenocarcinoma, probably from endometrial primary but previous slides not available to allow assessment of suggested endometrial primary.
Categorisation of discrepancy:	Unable to comment because of absence of previous slides for comparison.

Comment:

I do not think this case represents an error.

Bristol case number:	BH06-14135
Bristol pathologist:	Dr Wong (after consultation with Dr Moorghen, Dr Pawade and two external specialist opinions)
Original diagnosis:	Adenocarcinoma in caecum/appendix, probably representing spread from a gynaecological primary.
Reviewing pathologist 1:	Reviewer ID 4
Review diagnosis:	Mucinous adenocarcinoma, primary site uncertain.
Categorisation of discrepancy:	Unable to comment as the previous sections (of gynaecological specimens).
Reviewing pathologist 2:	Reviewer ID 5
Review diagnosis:	Mucinous adenocarcinoma.
Categorisation of discrepancy:	A (on the basis of incomplete documentation of sampling). Diagnosis appears to be correct but assessment limited by lack of slides from previous specimens.

Comment:

I do not believe that a diagnostic error has been demonstrated in this case. Initial consultation before the primary report was issued appears to have been extensive.

Bristol case number:	BH07-7964
Bristol pathologist:	Dr Pawade
Original diagnosis:	Squamous cell carcinoma of the cervix FIGO stage 1B1. Subsequent report from Southmead pathology department (May 2007, pathologist not identified) confirms squamous cell carcinoma. Supplementary report after external review by Dr Ganesan (August 2007): Large cell neuroendocrine carcinoma.
Reviewing pathologist 1:	Reviewer ID 4
Review diagnosis:	Small cell (neuroendocrine) carcinoma.
Categorisation of discrepancy:	B2
Reviewing pathologist 2:	Reviewer ID 5
Review diagnosis:	Poorly differentiated carcinoma with features suggestive of neuroendocrine differentiation.
Categorisation of discrepancy:	A (due to incomplete block identification) and B2.

Comment:

This appears to represent a moderately serious error in tumour classification, making a diagnosis of the commonest type of malignancy at this site without adequately considering the possibility of a rare variant.

Bristol case number:	BH07-11538
Bristol pathologist:	Dr Pawade
Original diagnosis:	Complex hyperplasia of the endometrium modified by progesterone therapy. No evidence of malignancy. Benign multilocular ovarian cyst, exact pathogenesis not evident. Also a report identified as BH07-17862 from the same patient; report available only represents an external opinion from Professor Wells making a diagnosis of atypical polypoid adenomyoma.
Reviewing pathologist 1:	Reviewer ID 4
Review diagnosis:	Atypical polypoid adenomyoma.
Categorisation of discrepancy:	B2
Reviewing pathologist 2:	Reviewer ID 5
Review diagnosis:	Atypical polypoid adenomyoma.
Categorisation of discrepancy:	B2

Comment:

The expert reviewers are unanimous about the nature of this error in the original report, but reviewer ID 5 comments that 'atypical polypoid adenomyoma is an uncommon lesion, with which non-specialist pathologists might not be familiar'. Hence the consistent classification as B2.

Bristol case number:	BH07-12593
Bristol pathologist:	Dr Pawade
Original diagnosis:	Grade 2 endometrioid adenocarcinoma; malignant glands identified in cervix. Also a benign stromal nodule.
Reviewing pathologist 1:	Reviewer ID 4
Review diagnosis:	Grade 2 endometrioid adenocarcinoma. Glands in cervix are benign (hence error in staging). Also stage 1a stromal sarcoma (difficult diagnosis).
Categorisation of discrepancy:	B3 - Endometrial cancer staging. B3 - Stromal nodule diagnosis.
Reviewing pathologist 2:	Reviewer ID 5
Review diagnosis:	Grade 1 endometrioid adenocarcinoma. Endocervical gland involvement confirmed. Cellular leiomyomata, no stromal nodule.
Categorisation of discrepancy:	A (inadequate block identification) B3 (endometrial cancer grade) B2 – stromal nodule diagnosis.

Comment:

The expert reviewers both believe that they have identified minor errors in the original report, but it is remarkable that they have identified different errors, and thereby disagree with each other. Consequently I cannot conclude that the presence of a diagnostic error has been proven in this case.

Bristol case number:	BH07-14878 BH07-17027
Bristol pathologist:	Dr Pawade
Original diagnosis:	BH07-14878: Grade 1 endometrioid adenocarcinoma. BH07-17027: Grade 2 endometrioid adenocarcinoma, stage pT1b. Subsequent supplementary reports after MDT review discuss the extent of infiltration in the lower uterine segment, with the conclusion (after review by 3 pathologists) that the upper endocervical canal is involved, hence stage 2b rather than 1b.
Reviewing pathologist 1:	Reviewer ID 4
Review diagnosis:	BH07-14878: Grade 1 endometrioid adenocarcinoma. BH07-17027: Grade 2 endometrioid adenocarcinoma. With involvement of the endocervix (stage 2b).
Categorisation of discrepancy:	BH07-14878: No discrepancy. BH07-17027: B1 (incorrect staging).
Reviewing pathologist 2:	Reviewer ID 5
Review diagnosis:	BH07-14878: Grade 1 endometrioid adenocarcinoma. BH07-17027: Grade 2 endometrioid adenocarcinoma. Assessment of cervical involvement is difficult. Quote: "In my view invasive carcinoma is not present in the endocervix but there is evidence of endocervical gland involvement". Discussion with colleagues is justified.
Categorisation of discrepancy:	BH07-14878: No discrepancy. BH07-17027: A (incomplete block identification) and B2 (incorrect staging).

Comment:

Both experts agree that the stage of the tumour has been incorrectly assessed. But reviewer ID 5's original report discusses at some length the difficulty of assessing the presence or absence of cervical involvement by tumour in this case. This makes his subsequent classification of a B2 discrepancy somewhat surprising, as it is a discrepancy based on an incorrect evaluation of precisely this difficult point. If reviewer ID 5's initial comments on the difficulty of staging are correct, then this makes reviewer ID 4's evaluation of the same point as a B1 discrepancy even more surprising.

Bristol case number:	SH05-11309 (also identified as 05-180145) BH07-8838
Bristol pathologist:	SH05-11309: Dr Sen BH07-8838: Dr Pawade
Original diagnosis:	SH05-11309: Serous borderline tumour with non-invasive implants. BH07-8838: Moderately differentiated serous adenocarcinoma arising in a background of borderline ovarian tumours. Invasive omental metastases.
Reviewing pathologist 1:	Reviewer ID 4
Review diagnosis:	SH05-11309: Serous borderline tumour with invasive implants. (The distinction between invasive and non-invasive implants is noted to be difficult and subjective). BH07-8838: Serous borderline ovarian tumour with non-invasive implants. Omentum contains invasive and non-invasive implants.
Categorisation of discrepancy:	SH05-11309: B3 BH07-8838: B3, D
Reviewing pathologist 2:	Reviewer ID 5
Review diagnosis:	SH05-11309: SH05-11309: Serous borderline tumour with implants some of which are non-invasive but one of which is probably invasive. (The distinction between invasive and non-invasive implants is noted to be extremely difficult). BH07-8838: Serous borderline ovarian tumour. Small bowel biopsy shows low-grade serous carcinoma; omentum shows non-invasive and invasive implants (low grade serous carcinoma).
Categorisation of discrepancy:	A (no block codes) SH05-11309: B2 BH07-8838: No discrepancy.

Comment:

Both experts comment on the difficulty of distinguishing between invasive and non-invasive implants in this context. Consequently reviewer ID 4 characterises the discrepancies he identified as B3. Despite acknowledging that “this distinction can be extremely difficult”, reviewer ID 5 subsequently classifies the discrepancy as B2. However, in the accompanying text he seems to suggest that this higher classification is based on a belief that the report should have acknowledged the uncertainty, which in the RCPATH classification should arguably be regarded as a Category D discrepancy rather than a higher grade of Category B.

Bristol case number:	SN07-513 (Peritoneal lavage), SH07-2315 (clot from cytology) SH07-2172 (Uterus, tubes and ovaries)
Bristol pathologist:	Cytology - Dr Sen Histology – Dr Sutak
Original diagnosis:	Cytology - No malignant cells seen. Histology - Left ovary - Mucinous adenocarcinoma, grade 2-3, probably primary but consider possibility of metastasis from gastrointestinal tract. FIGO stage 1A. No malignancy detected in the omentum. Subsequent external review by Dr McCluggage is described as supporting these conclusions.
Reviewing pathologist 1:	Reviewer ID 4
Review diagnosis:	Mucinous adenocarcinoma. The morphology suggests possible metastasis from a GI primary; further investigations are needed. Metastatic adenocarcinoma in the omentum.
Categorisation of discrepancy:	No discrepancy. (No comment made on discrepancy re. tumour in omentum).
Reviewing pathologist 2:	Reviewer ID 5
Review diagnosis:	Mucinous carcinoma in left ovary (cannot confidently distinguish whether primary or metastatic). Omentum shows reactive changes but no evidence of malignancy.
Categorisation of discrepancy:	No discrepancy.

Comment:

This case appears to have been appropriately investigated and reported, including an evaluation of the difficulty of the case and the use of an expert opinion.

The opinion of reviewer ID 4 that there is tumour in the omentum is noted but as reviewer ID 5 disagrees this cannot be regarded as identification of an error in the original report.

Section 3

Breast pathology cases

Bristol case number:	BH06-15770 BH06-16908
Bristol pathologist:	BH06-15770: Dr Sohail BH06-16908: Dr Calder
Original diagnosis:	BH06-15770: No abnormality detected. BH06-16908: Grade 1 tubulo-lobular carcinoma with lobular carcinoma in situ. B5b.
Reviewing pathologist 1:	Reviewer ID 6
Review diagnosis:	BH06-15770: Normal, minor involutional changes. BH06-16908: Invasive carcinoma of no special type, grade 1. Intermediate grade DCIS/LCIS is present. B5b.
Categorisation of discrepancy:	BH06-15770: No significant discordance. BH06-16908: No significant discordance.
Reviewing pathologist 2:	Reviewer ID 7
Review diagnosis:	BH06-15770: Normal (repeat biopsy may therefore be advised). BH06-16908: Lobular in situ neoplasia and sclerosing adenosis (difficulty in interpretation noted due to faded slides).
Categorisation of discrepancy:	BH06-15770: No discrepancy. BH06-16908: B2

Comment:

Reviewer ID 7 reports a B2 discrepancy, but as reviewer ID 6 agrees with the original report I cannot conclude that this case represents a proven diagnostic error.

Bristol case number:	BH04-11333
Bristol pathologist:	Dr Calder
Original diagnosis:	Grade 2 invasive ductal carcinoma.
Reviewing pathologist 1:	Reviewer ID 6
Review diagnosis:	B4, suspicious of metaplastic carcinoma.
Categorisation of discrepancy:	B3
Reviewing pathologist 2:	Reviewer ID 7
Review diagnosis:	B3, of uncertain malignant potential.
Categorisation of discrepancy:	B3

Comment:

Both experts comment on the difficulty of interpreting this small biopsy. The implication is that the original report, which is short and appears to make a confident diagnosis of malignancy, represents over-confidence.

Bristol case number:	BH01/06137
Bristol pathologist:	Dr Calder
Original diagnosis:	B2 – benign.
Reviewing pathologist 1:	Reviewer ID 7
Review diagnosis:	Low grade ductal carcinoma in situ (B5).
Categorisation of discrepancy:	B2
Reviewing pathologist 2:	Reviewer ID 8
Review diagnosis:	Probable intermediate grade ductal carcinoma in situ; immunohistochemistry needed for confident diagnosis.
Categorisation of discrepancy:	B2

Comment:

The expert reviewers concur that the original report represents a diagnostic error, but it is one that (to quote reviewer ID 8) ‘a small proportion of histopathologists might make’. It is notable that the original report gave no hint of uncertainty.

Section 4

Dermatopathology cases

Bristol case number:	BH02-10518
Bristol pathologist:	Dr Weir/Dr Pawade
Original diagnosis:	Probable keratoacanthoma.
Reviewing pathologist 1:	Reviewer ID 9
Review diagnosis:	Probably pseudoepitheliomatous hyperplasia (difficult case).
Categorisation of discrepancy:	B3
Reviewing pathologist 2:	Reviewer ID 10
Review diagnosis:	Squamous papilloma, probably HPV induced.
Categorisation of discrepancy:	B2/3

Comment:

Both expert reviewers comment on the difficulty of this case and the need for more clinical information. Both consider the possibility that this could be a squamous cell carcinoma, though both regard that as unlikely. Both believe that a diagnosis of keratoacanthoma is unlikely to be correct, but as keratoacanthoma is a localised squamous proliferation, classification as a B3 rather than a B2 discrepancy seems reasonable.

Bristol case number:	BH00-12216 BH04-01518
Bristol pathologist:	BH00-12216: Dr Calder BH04-01518: Dr Collins
Original diagnosis:	BH00-12216: Basal cell carcinoma, completely excised. BH04-01518: Metastatic poorly differentiated malignant melanoma.
Reviewing pathologist 1:	Reviewer ID 9
Review diagnosis:	BH00-12216: Nodular melanoma. BH04-01518: Not reviewed.
Categorisation of discrepancy:	B2
Reviewing pathologist 2:	Reviewer ID 10
Review diagnosis:	BH00-12216: Invasive spindle cell melanoma. BH04-01518: Not reviewed.
Categorisation of discrepancy:	B1

Comment:

This is a serious error.

Bristol case number:	6005356 (Bristol Nuffield Hospital)
Bristol pathologist:	Dr Pawade
Original diagnosis:	(1) Basal cell carcinoma. (2) In-situ eccrine porocarcinoma.
Reviewing pathologist 1:	Reviewer ID 9
Review diagnosis:	Slides not initially available; on arrival, labelling changed. Therefore not clear which is (1) and which is (2). One lesion is a basal cell carcinoma, probably corresponding to (1). The other is a nodular melanoma, not an in-situ eccrine poroma/porocarcinoma.
Categorisation of discrepancy:	B1
Reviewing pathologist 2:	Reviewer ID 10
Review diagnosis:	(Slides labelled BH10/3463, but this may represent re-labelling; see original documentation. The name corresponds to the case identified as 6005356). Sections include a nodular malignant melanoma and a basal cell carcinoma.
Categorisation of discrepancy:	B1 The discrepancy between the slides and the report is so great that reviewer ID 10 would have preferred to re-check that he and the reporting pathologist were reporting the same sections.

Comment:

The uncertainty about slide labelling in this case is a matter for concern. On the face of it this seems to be a serious error. But one has to wonder whether this might be an error of slide identification rather than diagnosis.

Section 5
Haematopathology case

Bristol case number:	BN06-00109 BN06-00686
Bristol pathologist:	BN06-00109: Dr Banu/Dr Lott BN06-00686: Dr Calder
Original diagnosis:	BN06-00109: Lymph node aspirate – lymphocytes, no epithelial elements detected. BN06-00686: Inflammatory lymph node, no evidence of malignancy.
Reviewing pathologist 1:	Reviewer ID 11
Review diagnosis:	BN06-00109: Lymphoid aspirate. Epithelial cells not detected. BN06-00686: Suspicious of follicular lymphoma, grade 1.
Categorisation of discrepancy:	BN06-00109: E (Microscopy states 'accurate assessment is not possible' but conclusion includes 'Reactive'). BN06-00686: B2 and D
Reviewing pathologist 2:	Reviewer ID 12
Review diagnosis:	BN06-00109: Lymphoid aspirate suggestive of follicular lymphoma. BN06-00686: Probable follicular lymphoma, immunohistochemical confirmation needed.
Categorisation of discrepancy:	BN06-00109: B2 BN06-00686: B2

Comment:

This case represents a failure to identify a follicular lymphoma on aspirate and on biopsy (by two different pathologists). Although this is a benign/malignant distinction it is one where mistakes are commonly made, hence the B2 classification.

Discussion

In evaluating this set of 26 cases I believe that it is very valuable to have the opinions of two experts on each case, delivered independently and without knowledge of the content of the original report. Comparison of the two independent expert opinions on each case demonstrates that there is a considerable divergence of opinion between the experts in many of these cases – including some benign/malignant disagreements (see BH07-12593, SH07-2172, BH06-16908). This emphasises that:

- a) most of these are difficult cases
- b) histopathology reports represent professional opinions, not measurements; uncertainty and differences of opinion are to be expected, especially when difficult cases are being reported.

In seven of these cases I do not believe that there is convincing evidence that a diagnostic error has been made, largely because of disagreements between the two expert reviewers but in two cases because both reviewers agree that no error had been made. It is not clear to me why these cases were included in this set.

At the other end of the spectrum, I would identify four cases as representing serious errors (BH04/8093, BH09/19076, BH00-12216, 6005356, Nuffield Hospital) that could raise concern about the competence of the reporting pathologist (Category B1). One of these (BH09/19076) was apparently brought to the attention of the Review after the Review had started its work.

In one of these serious errors (6005356) the discrepancy between the report and the slides is so great that one reviewer suggested that the identity of the slides should be checked. The labelling of the slides in this case was reported to be unclear. One possible explanation is that the reporting pathologist was actually examining the wrong microscope slides when the report was dictated. If so, the error would be one of diligence rather than diagnostic competence. This possibility emphasises the importance of designing systems so that (a) such human errors are made less likely (b) errors are identified before they cause harm to patients.

Any competent pathologist can make a serious error on rare occasions. The frequency of such errors therefore has to be considered.

In interpreting the overall significance of these results it is essential to consider how these cases were selected. I do not have detailed information on this but I note that the dates extend from 2000 to 2009 and I understand they were identified in a non-systematic manner.

It is, therefore, inappropriate to draw conclusions about the frequency of errors and discrepancies from this group of cases. The previous systematic review of 3500 cases is the valid way to assess the frequency of discrepancies. I note that Dr Pawade's name is associated with some of the more serious discrepancies, but I do not regard this as an adequate sample for the assessment of a pathologist's competence and I would refer to the systematic audit of 3500 cases for that purpose. Having made that point, I do not believe that the identification of only four serious (B1) errors from the workload of a department of this size over the years from 2000 to 2009 can reasonably be considered to be surprising. To that extent, I am not convinced that these cases, when considered in isolation, justify the concerns about the performance of the department that have been repeatedly expressed in the media.

Similarly, the method of selection means that caution should be exercised in evaluating the nature of the errors and discrepancies identified in this group of cases. However, I believe that some valid observations can be made.

It is striking that in many of these cases the expert reviewers expressed uncertainty and a desire to undertake further investigations, whereas the original report admitted no uncertainty at all. Most of these are clearly difficult cases; but the difficulty of the cases is often not at all evident from reading the original reports.

The previous systematic review of 3500 cases led me to suggest that in the pathology department at UHBT there seemed to be an insufficient use of consultation and second opinions in the reporting of difficult cases. A few of the present 26 cases were the subject of internal and/or external consultation with other pathologists before a report was issued, but the majority of cases seem (from the documentation provided) to have been reported initially by a single pathologist with no consultation. This applies to several cases where the two expert pathologists obviously found the case difficult and a few where one of the expert pathologists explicitly suggested that a second opinion should have been sought. This therefore reinforces my previous suggestion that the department as a whole should make more liberal use of internal and external consultation on difficult cases.

Overall, the nature of the discrepancies identified here provides no reason to doubt the conclusions of my previous report.

Conclusions

Study of these 26 cases does not alter the conclusions I previously drew from the systematic review of 3500 cases, and to some extent those conclusions are reinforced.

The most important message remains that the pathologists at UHBT should be more willing:

- to describe in their reports the presence of uncertainty in some histopathological diagnoses
- to make much greater use of consultation and second opinions in such cases
- to establish systems (such as double reporting and systematic MDT review of critical diagnoses) that will, as far as possible, identify diagnostic errors (which will inevitably occur occasionally) before they cause harm to patients.

However, in my opinion these 26 cases do not in isolation justify serious concern about the overall competence of the pathologists in the histopathology department at UHBT.

Professor Peter Furness
2nd October 2010

ANNEXE 4 (ii): Reviews of the 26 cases, Panel's Overview

The 26 cases

This analysis of the 26 cases is not intended to establish the “correct” diagnoses, but to consider what conclusions the Panel can draw from them within its remit under the terms of reference.

In assessing the 26 cases the Panel has relied on: 1) a tabulated summary of the anonymized cases submitted to the Panel jointly by Dr Jonathan Sheffield (Medical Director, UHBT) and Dr Christopher Burton (Medical Director, NBT), including copies of the reports from the review by Source Bioscience; 2) contemporaneous histopathology reports on the cases issued from the histopathology departments at UHBT and NBT; 3) correspondence copied to the Panel referring to any of the cases; 4) remarks made by witnesses on any cases or case categories; and 5) a review of the cases conducted by the Royal College of Pathologists. The case numbers used in this appendix are derived from the tabulated summary from Drs Sheffield and Burton; this is referred to subsequently as the Sheffield/Burton table. The Panel has relied on laboratory accession numbers when cross-referencing between the case numbers in the Sheffield/Burton table, the Source Bioscience review and the report of the review by the Royal College of Pathologists.

Respiratory cases (1, 4, 7, 9, 12, 14, 20, 22, 23 and 26)

The respiratory cases comprise pleural biopsies from patients with suspected pleural disease (cases 1, 9, 20 and 23) and lung biopsies for the investigation of interstitial lung disease (cases 4, 7, 12, 14, 22 and 26 [case X in the Sheffield/Burton table]).

Cases 1 and 9 are pleural biopsies both reported at UHBT as “*malignant mesothelioma*”, but subsequently diagnosed as reactive pleura with no malignancy. The latter interpretation was confirmed by Source Bioscience review, although the difficulty of case 9 is acknowledged by the comment that “*if clinical suspicion remains I would rebiopsy*”. The College’s review concludes that both cases are “*difficult*” and that the main error was “*in proffering a diagnosis in which no suggestion of uncertainty is expressed and without having obtained a second opinion.*”

The pleural biopsy from **case 20** was reported at UHBT as, in summary, *"fibrosis"*. According to the Sheffield/Burton table, the patient was told of this reassuringly benign diagnosis. However, following MDT review, the biopsy was double reported as *"malignant mesothelioma"*; the patient was then given appropriate treatment. The Source Bioscience review declared it to be unequivocally malignant mesothelioma. The College's opinion is that this case *"clearly represents a benign/malignant error"*.

Case 23's pleural biopsy was referred by a UHBT histopathologist to Dr Ibrahim for his opinion; this was apparently quoted in full in the UHBT report which concludes *"chronic non-specific inflammation ... no evidence of mesothelioma"*. However, the Sheffield/Burton table implies that prior to this, and before the case was considered at the MDT meeting, a verbal report from the UHBT histopathologist of malignant mesothelioma resulted in the patient being given intra-pleural fluorouracil — a cytotoxic agent. It seems that the reporting histopathologists were not informed initially that the patient had leishmaniasis (a parasitic infection, uncommon in the UK). The presence of pleural leishmaniasis was diagnosed by an external expert (Professor Sebastian Lucas, London) and endorsed by the Source Bioscience reviewer, although the latter comments *"Leishmaniasis bodies noted in one section but I could easily have missed them"*. The College review concludes that *"The underlying error appears to have been failure to inform the pathologists that the patient had leishmaniasis in the skin"*.

The lung biopsies for the investigation of interstitial lung disease (**cases 4, 7, 12, 14, 22 and 26**) are complex and appear mostly to involve diagnoses and refinements of opinions that arguably could only be made, and invariably were made eventually, after full discussion of each case by the MDT. The College review (which did not include case 26) concluded that none of these cases represents a diagnostic error, although some reports conveyed an erroneously high level of confidence in the diagnosis offered — for example, a strong suggestion of viral infection in case 7.

In the Sheffield/Burton table, only one case (**case 14**) is considered to represent a *"misdiagnosis"* by the UHBT histopathologist who reported it. This was initially reported in summary as *"These features suggest a diagnosis of extrinsic allergic alveolitis ..."*. Subsequently, Dr Ibrahim reviewed the biopsy and wrote (letter of 26 November 2007) to Dr N Maskell stating that *"The appearances are those of lymphoid interstitial pneumonia"*, an opinion then confirmed both by Professor Andrew Nicholson (London)

to whom the biopsy was referred and, more recently, by the Source Bioscience reviewer. The College concludes that *“This is clearly a difficult case”* and that *“the main error in the original report is not in the diagnosis, but in the confident assertion that there is nothing at all present to suggest malignancy, and the failure initially to seek a second opinion”*.

Gynaecological cases (2, 5, 6, 8, 11, 15, 18, 21 and 25)

A vulval biopsy (case 19) is considered under skin cases.

None of the gynaecological cases involves a discrepancy, error or misdiagnosis of benign versus malignant tumour. There are disagreements about tumour stage (**cases 5 and 8**) and about tumour type and differentiation (**cases 2, 18, 21 and 25**) with varying degrees of clinical implications, some possibly affecting treatment. The Royal College of Pathologists’ review concludes that no error was committed in some cases (e.g. case 21), while in other cases (e.g. case 15) a category B2 error occurred (defined as *“a diagnosis which is fairly clearly incorrect, but which one is not surprised to see a small percentage of pathologists suggesting”*).

In **case 6**, Dr Lynn Hirschowitz (NBT) reported endometrial curettings as *“atypical glandular hyperplasia”* with some areas *“suspicious of invasive carcinoma”*. The subsequent hysterectomy was reported at UHBT as *“complex hyperplasia of the endometrium modified by progesterone therapy. No evidence of atypical hyperplasia or adenocarcinoma seen”*. Dr Hirschowitz disagreed (letter of 21 October 2007) and considered that the appearances were *“highly suggestive of atypical polypoid adenoma”*. Two months later (letter dated 20 December 2007), UHBT referred the lesion in the hysterectomy specimen to Professor Mike Wells (Sheffield) who agreed that the appearances were those of atypical polypoid adenoma, an opinion confirmed by the Source Bioscience reviewer and by both College reviewers. Although one of the College reviewers commented that *“atypical polypoid adenoma is an uncommon lesion, with which non-specialist pathologists might not be familiar”*, it is notable that gynaecological pathology is one of the specialties of the UHBT histopathologist who reported the lesion.

Disagreements in **cases 11 and 15** concern the distinction between borderline ovarian tumours and ovarian adenocarcinomas. The Sheffield/Burton table does not include

either case 11 or case 15, but histopathology reports labelled “case 11” and “case 15” are included in the bundle of 26 cases submitted to the Panel. The patient in case 15 had a right ovarian tumour removed in April 2006. This was reported at UHBT as “*serous borderline tumour with a micropapillary pattern*”. The patient subsequently developed enlarged lymph nodes around the abdominal aorta and, in November 2007, a biopsy of these revealed “*adenocarcinoma ... consistent with primary serous carcinoma of the ovary*” according to the UHBT report. The Source Bioscience reviewer’s opinion on the original ovarian tumour was “*serous cystadenocarcinoma of the ovary*” and the College’s reviewers also diagnosed the lesion as serous adenocarcinoma (although they gave different opinions on the grade of malignancy). By letter dated 23 December 2009 from Mr John Murdoch, the patient was informed her clinical history “*prompted a review of the original pathology from your ovary by our pathologist and, in fact, she thought there was cancer there all along*”.

Skin cases (13, 19 and 24)

Based on evidence available to the Panel, **cases 13 and 24** — both confirmed malignant melanomas — are clear examples of misdiagnosis. Case 13 was reported as basal cell carcinoma, a much less aggressive and localised skin cancer, and case 24 as a porocarcinoma. The Source Bioscience reviewer commented that the latter was an “*obvious diagnostic error*”. The College review regards case 13 as a “*serious error*”. The College review reaches a similar conclusion about case 24, and suggests “*this might be an error of slide identification rather than diagnosis*”; in other words, the pathologist could have picked up and examined a slide associated with another patient who may genuinely have had malignant melanoma. If so, case 24 reflects a serious lack of diligence rather than a histological misinterpretation and would imply that another patient, who did have malignant melanoma, was also misdiagnosed. However, this is only speculation.

In **case 19**, a vulval lesion, the Source Bioscience and College reviewers’ opinions support the original benign diagnosis by the histopathologist at UHBT. While more than one NBT histopathologist was convinced that the lesion was squamous cell carcinoma, in contrast to the UHBT opinion that it was a keratoacanthoma, the Source Bioscience and College experts regard it as a squamous cell papilloma or pseudoepitheliomatous

hyperplasia. If any diagnostic error was committed in this case, it is attributable to the NBT histopathologists who regarded the lesion as malignant.

Breast cases (3, 10, 16 and 17)

In **case 3** (included under the heading of “Haematopathology case” in the report of the College’s review), no evidence was forthcoming to support the claim in the Sheffield/Burton table that *“review of the initial biopsy suggested to show signs of NHL [non-Hodgkin’s lymphoma]”*. In a letter (21 May 2010) to the Panel, Dr Burton conceded that he *“made an inaccurate presumption on the basis of the Private Eye letter”*. Review of the initial biopsy by Source Bioscience mentions no discrepancy. The College’s experts regard the biopsy as *“suspicious of follicular lymphoma”* and *“probable follicular lymphoma”*, in contrast to the original UHBT report which stated categorically that there is *“no evidence of malignancy”*. The College’s comment is that *“this is a benign/malignant distinction ... where mistakes are commonly made”*.

The breast biopsy in **case 10** was reported initially at UHBT as ductal epithelial hyperplasia with no evidence of in-situ or invasive malignancy; but when invasive breast carcinoma was subsequently diagnosed, it is claimed that the slides of the original biopsy *“were re-reported as DCIS by Nassif Ibrahim”* (email from Mr Simon Cawthorn to Dr Christopher Burton, 4 December 2009). The Source Bioscience reviewer’s opinion was *“indeterminate epithelial proliferation ... may be ADH [atypical ductal hyperplasia] or even low-grade DCIS [ductal carcinoma in situ]”*, but commented that the slides were faded which made assessment difficult. In a letter (21 May 2010) to the Panel, Dr Burton stated *“Dr Sheffield and I took the view that this report [from the Source Bioscience reviewer] neither supported the original benign diagnosis, nor fully supported the subsequent MDT diagnosis of DCIS”*. The College’s specialist reviewers’ opinions were *“low-grade ductal carcinoma in situ”* and *“probable intermediate-grade ductal carcinoma in situ”* and concluded that the original report *“represents a diagnostic error”*. The College’s review report also comments that *“It is notable that the original report gave no hint of uncertainty”*.

Case 16’s biopsy was double reported at UHBT as *“The features are interpreted as Grade 2 invasive ductal carcinoma”*. Irrespective of whether the wording “are interpreted as”

(rather than, for example, “are diagnostic of”) implies a slight degree of uncertainty, the inclusion of “grade 2” in the report could be regarded as tending to reinforce the assumption that malignancy is present. In an undated letter to Mr Cawthorn, Dr Ibrahim gave his opinion that the biopsy *“may well represent part of an intracystic papillary carcinoma”*. However, a report dated 25/10/2004 and attributed to “NI.EH” concludes that *“There is no evidence of malignancy”* and gives a diagnosis of *“Sclerosed benign intracystic papilloma”*; this opinion was shared by the Source Bioscience reviewer. In this case, Dr Ibrahim stated initially that the lesion was possibly malignant, thus tending to lend some support to the UHBT opinion while not fully endorsing it. The comment in the College’s review is that *“Both experts comment on the difficulty of interpreting this small biopsy. The implication is that the original report, which is short and appears to make a confident diagnosis of malignancy, represents over-confidence”*.

The salient biopsy from **case 17** was reported as a *“grade 1 tubulo-lobular carcinoma”* at UHBT. The patient was referred to NBT for surgery, but apparently only the report, not the slides, was considered at the MDT prior to wide local excision of the lesion and lymph node sampling. No malignancy was found in the excised tissue. According to the Sheffield/Burton table, this case was settled in litigation, implying that a misdiagnosis of the biopsy at UHBT was conceded. However, one of the College’s expert reviewers regarded the biopsy as *“invasive carcinoma of no special type”* and thus agreed that carcinoma was present as stated in the UHBT report; consequently, the College *“cannot conclude that this case represents a proven diagnostic error”*.

Conclusions

These 26 cases fall into three broad categories.

1. Cases in which significant misdiagnoses (e.g. benign versus malignant) occurred that either were corrected by MDT review or were not detected before inappropriate treatment was given.
2. Cases in which the histopathology cannot be reliably and fully interpreted without comprehensive consideration of all aspects (clinical, radiological, histopathological) such as occurs typically at MDT meetings.

3. Cases in which the diagnosis is regarded generally as difficult and is frequently associated with a high degree of inter- and intra-observer disagreement, even between experts.

These categories are not mutually exclusive. For example, in case 23 there was an initial significant misdiagnosis (malignant mesothelioma) resulting in the patient being told they had cancer and a cytotoxic drug injected into the pleural cavity. Furthermore, it seems that the reporting histopathologist was not informed initially that the patient had leishmaniasis, a rare condition in the UK; this information might have led to a different interpretation of the histological appearances. Finally, the interpretation of pleural biopsies, particularly the distinction between malignant mesothelioma and reactive pleural disease is generally regarded as one of the more challenging areas of histopathology. Therefore, this case falls into all three categories.

In contrast, case 24 is an example of significant misdiagnosis in which an aggressive skin tumour (malignant melanoma) was misinterpreted. On review this was regarded as an obvious error.

Finally, in a few cases (e.g. case 19) it is notable that the expert opinions from Source Bioscience and College reviewers suggested that the opinion given by an NBT histopathologist, alleging error by the UHBT histopathologist who originally reported the biopsy, was incorrect.

The report of the College's review concludes that only three of the 26 cases represent "*serious errors*" — cases 13, 20 and 24. In many other cases no error (as defined by the College) is considered to have occurred, either because the expert reviewers agree with the UHBT pathologist's opinion or they disagree between themselves as to the correct diagnosis.

Perhaps the most striking conclusion, echoed by Professor Furness in his discussion of the College's review of these cases, is that many of these cases represent intrinsically difficult diagnostic problems, but the inevitable uncertainties are often not reflected in the wording of the original reports.

ANNEXE 5: Statistical Analysis of the 3,500 cases, Ian White

University Hospitals Bristol Foundation Trust pathology review: Independent review of the statistical analysis

Ian White, 4th June 2010

Scope of this report

I was asked to review the data and their statistical analysis. I received

- notes of two meetings planning the study,
- a spreadsheet containing the data as entered,
- a Stata file containing the data,
- a Stata analysis program and the output from that program, and
- a document summarising the results.

Aims of the statistical analysis

Errors were classified technically ("Expression of concern"). Where a technical error was found, it was further classified by its clinical impact ("Duty of care").

Based on the summary of results, the aims of the statistical analysis were:

1. To compute the error rate (with confidence interval) for the following definitions of error:
 - a. Any error (technical)
 - b. Minor/moderate/major harm (clinical)
 - c. Moderate/major harm (clinical)
 - d. Major harm (clinical)
 - e. B1 error (technical)
 - f. B1 or B2 error (technical)
2. To explore whether the error rate varies significantly between physiological systems, and if it does, to compute the error rate (with confidence interval) for each system.
3. To explore whether the error rate varies significantly between pathologists, and if it does, to compute the error rate (with confidence interval) for each pathologist.

These aims don't appear to have been written down explicitly before the data were collected, but they are consistent with the notes of the planning meetings, and they seem sensible aims. It would have been better for the definitions of error to have been selected before the data were analysed, but it is hard to see how this could have introduced any bias.

Data processing

I am unable to comment on how the data were collected and entered into the spreadsheet. However, I note that the data appear to be of good quality, because they are very complete, with just two missing values for sex and four for “Duty of Care” out of 3508 records, and because there are no obvious discrepancies.

I can confirm that the data entered on the spreadsheets were correctly transferred into the statistical analysis.

Data analysis

Major harm

Major harm was not observed in the data. This could have been reported as an error rate of 0% with 95% confidence interval from 0 to 0.1%.

Statistical methods

The analysis used tests for heterogeneity on the log odds scale and 95% confidence intervals computed on the log odds scale. These methods are sensible, but could be improved on when error rates are very low (as for example for moderate errors). Specifically, greater accuracy might be gained by testing heterogeneity using a Pearson chi-squared test for heterogeneity (based on a contingency table), and by computing 95% confidence intervals using “exact” methods.

Subgroups with no errors (e.g. Breast for Minor/moderate error) were excluded from the analysis. The modifications proposed above would allow them to be included. In particular, it makes sense to give a 95% confidence interval even when the observed error rate is 0.

I repeated the analysis with the proposed modifications for the errors with overall rate below 2%, and I obtained very similar results (see appendix). Thus, I think the results reported are appropriate.

Calculations

I have checked most of the calculations and in each case they have been done correctly.

Graphs

I would have liked the graphs to include

- the overall error rate (and ideally its 95% confidence interval);
- 95% confidence intervals when the observed error rate is 0.

The graphs in the appendix fill this gap; they do not alter the overall interpretation.

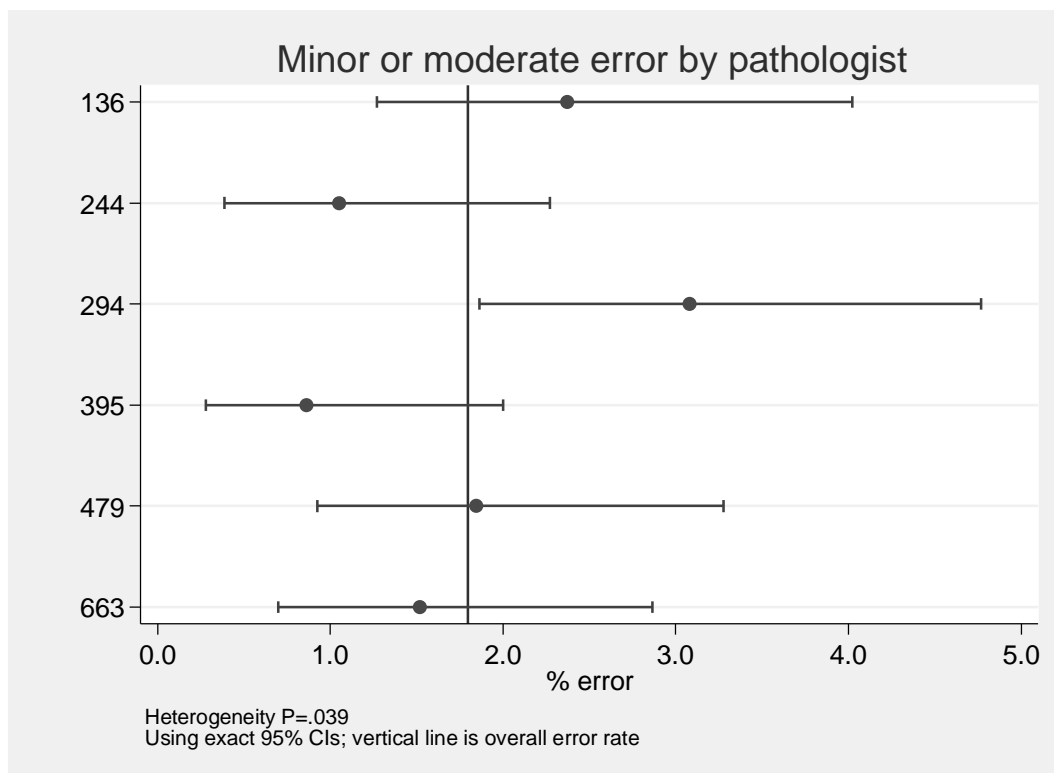
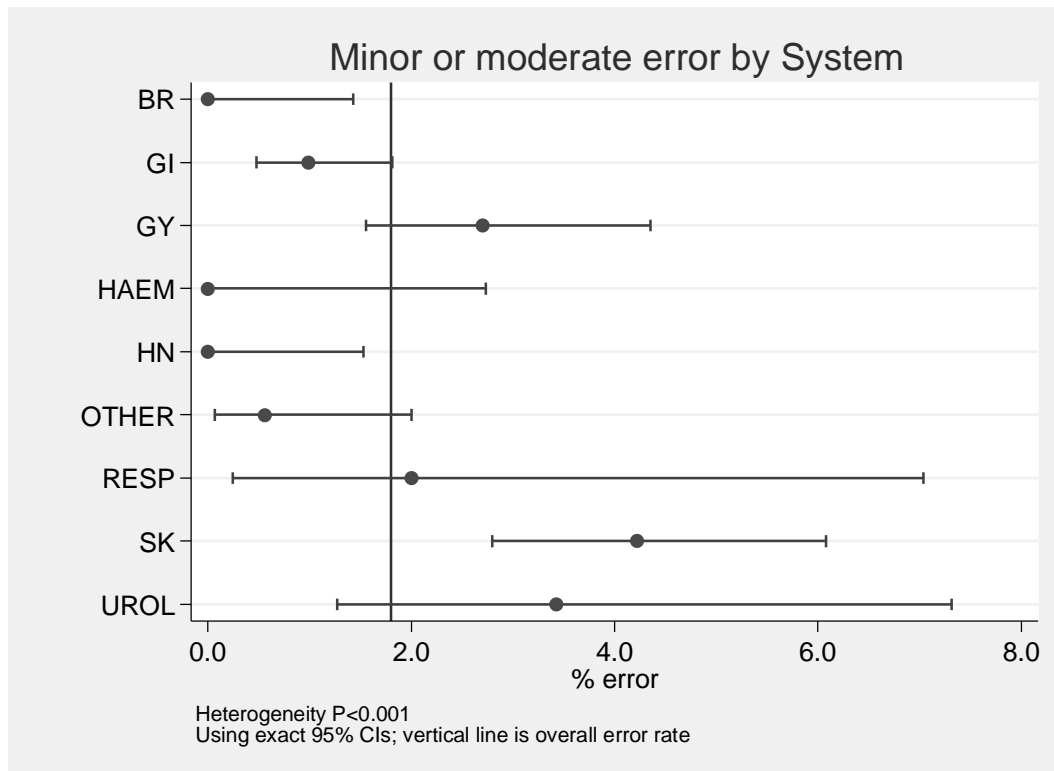
Conclusions

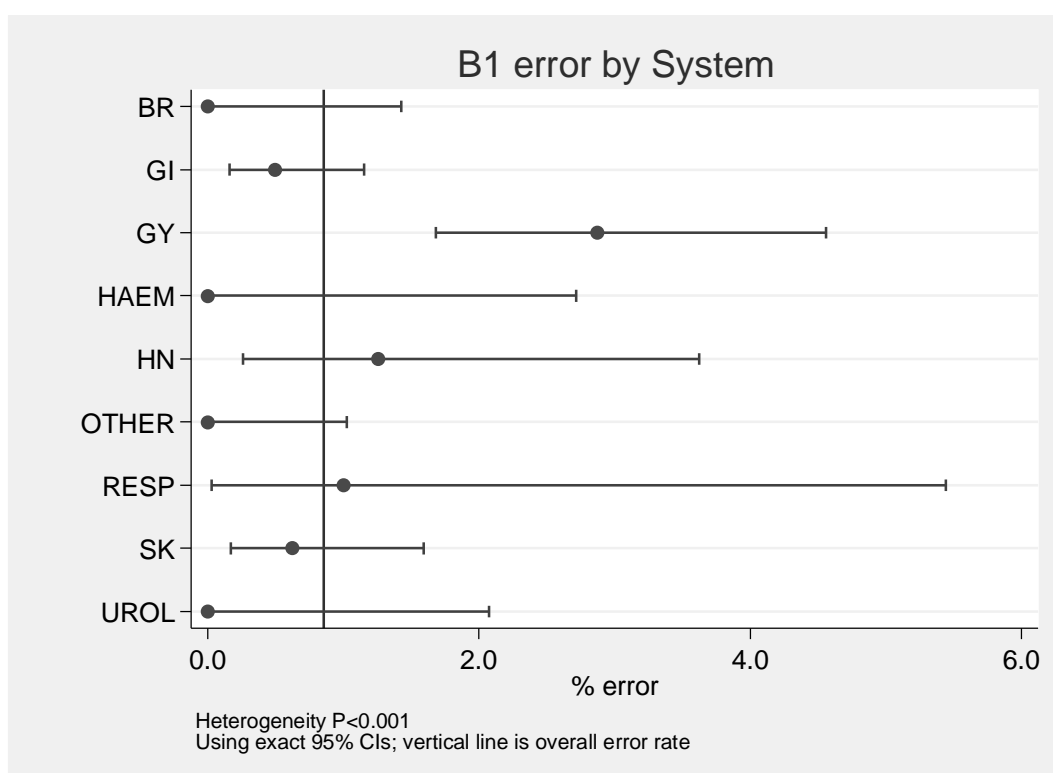
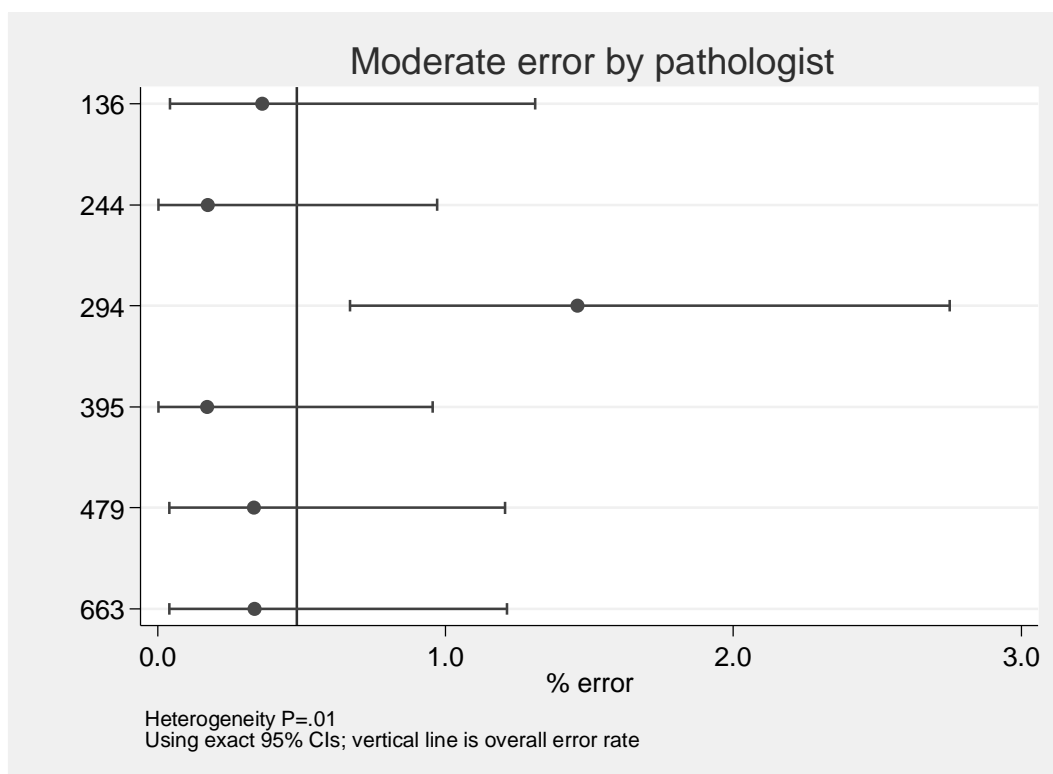
The analyses done were appropriate and correctly implemented.

I have not touched on interpretation of the results. In particular, any differences between pathologists might possibly be explained by differences in the spread of their workload across systems.

Appendix: graphs from alternative analyses

These cover the errors with overall rate <2%.





ANNEXE 6: Report on the Assessment of the Results of the Independent Audit, Professor Peter Furness



CONFIDENTIAL

Report on the assessment of the results of an independent audit of histopathology cases

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1. Report Author

This report is written by Professor Peter Furness, President of The Royal College of Pathologists (RCPATH).

1.1 Qualifications and experience

I hold the degrees of MA (Cantab) BM, BCh (Oxon) PhD (Nottingham) and I am a Fellow of the Royal College of Pathologists, by examination in histopathology. I am currently employed as a consultant histopathologist by University Hospitals of Leicester NHS Trust. I am also Honorary Professor of Renal Pathology at the University of Leicester.

I have a long interest in quality in the histopathology laboratory, having established the first UK national external quality assessment (EQA) scheme in diagnostic histopathology in 1990. I was Chair of an RCPATH Working Group on interpretive EQA and was the principal author of the College's guidance on running interpretive EQA schemes. I have been Clinical Advisor in Pathology to the National Patient Safety Agency. From 1990 to 2008 I ran the UK National External Quality Assessment Scheme in renal histopathology. I have been a member of Executive of United Kingdom National External Quality Assessment Schemes Ltd (UKNEQAS), a member of the Board of Clinical Pathology Accreditation Ltd (CPA) and Chair of the RCPATH Steering Committee for External Quality Assessment. I was elected to Council of the RCPATH in 2002 and was elected vice President of the RCPATH in 2005. In that role I became a member of the Professional Performance Panel of the RCPATH and was principal author of a revision of the College guidance on the classification of diagnostic discrepancies/errors in histopathology. That revised guidance was used to classify diagnostic discrepancies in this review. I was elected President of the RCPATH in 2008 and *ex officio* I am now Chair of the Professional Performance Panel of the RCPATH.

1.2 Independence

I have never worked in Bristol and I have no professional or financial association with any hospital or pathologist in Bristol. I have in the past undertaken work for PathLore plc but I ceased to do such work on election as vice-President to the College in 2005 and I have had no involvement with PathLore since then. I have had no previous involvement with Verita.

1.3 Instruction

This report is provided at the request of Mr Ed Marsden, Inquiry Secretary, on behalf of Verita, in relation to a contract agreed between Verita and The Royal College of Pathologists to provide an assessment of the audit of 3500 cases commissioned by University Hospitals of Bristol NHS Foundation Trust (UHBT) from the perspective of an independent histopathologist, specifically to consider the questions set out in the Conclusion of this report. I do not claim expertise in statistics.

2. Background to the report

In brief, my understanding of the background is that concerns were expressed about the standards of diagnosis and reporting in the histopathology department of the University Hospitals of Bristol NHS Foundation Trust (UHBT). These concerns were largely expressed by agents external to the Trust and achieved some publicity in the media. They centred on a relatively small number of cases where it was alleged that serious diagnostic errors had been made. However, it was apparent that most of these cases represented difficult diagnoses. As they were not identified systematically from a defined time period or series of cases it was not possible to estimate the frequency of errors.

To address these concerns and to identify and correct any problems with the histopathology service the Trust management commissioned an audit of 3508 cases that had been reported by the UHB histopathology department. The original microscope slides and histopathology reports from these cases were reviewed by consultant pathologists from outside Bristol, through the agency of Medical Solutions plc (also known as 'PathLore'). The reviewers were

asked to identify any points of disagreement with the original reports and to classify such discrepancies according to the system published by the RCPATH at www.rcpath.org/resources/pdf/reviewofcategorisationofdiscrepanciesfinal.pdf

For reasons explained in that document, this classification has two parts. In one, an opinion is expressed on the seriousness of the discrepancy in relation to the reporting pathologist's performance. In the second an opinion is given on the possible impact on patient care, should the discrepancy in opinion be confirmed to be a genuine error. The justification for this approach is given in the document.

The management of UHB commissioned an independent panel, managed by Verita, to review the histopathology service at UHB, including evaluation of the results of the review of cases by PathLore. Verita has asked the RCPATH to assist with that analysis in accordance with the contract between Verita and the RCPATH dated 20 April 2010.

In order to deliver the requirements of that contract I have been asked, as a senior histopathologist with experience of the work of the RCPATH Professional Standards Unit, to address the following specific points:

- a) to what extent the results of the audit are consistent with a histopathology service of acceptable reliability and to identify areas of improvement;
- b) to comment on whether error or discrepancy rates give cause for concern about either individual pathologists or specific organs/systems (e.g. breast, gynaecology);
- c) whether the audit reveals any systematic pattern of diagnosis or error;
- d) to consider the reported discrepancies on a case by case basis and report on patterns as seems appropriate; and
- e) to provide a written report to the Inquiry and, if necessary, to explain the findings.

These matters overlap, so I propose to provide a report of my observations first, which will address item 5. I will then return to the specific questions in items 1 to 4 at the end.

2.1 Materials provided

I have been supplied with four lever arch files containing copies of the original histopathology reports of 377 cases where a discrepancy of any type was identified by the PathLore reviewers. Each report is accompanied by a report from a named PathLore reviewer, indicating the nature of the discrepancy identified and classifying that discrepancy according to the RCPATH system identified above.

I have also been provided with sheets of paper listing the laboratory number of each case, the sex of the patient, the organ system of the specimen, the specimen type, the pathologist who issued the original report, and the classification of any discrepancy in relation to the competence of the pathologist and in relation to any duty of care issues that may arise due to potential impact on patient care.

The number of the first case where a discrepancy is identified is BH07-30 and the number of the last is BH07-18756. My understanding is that the cases for review were selected from cases reported in 2007, after elimination of those cases where serious errors had already been identified and investigated, by a method designed to produce a random selection of cases with a sample size of approximately 3,500.

I have not been provided with any reports relating to the 3131 cases that were reviewed but where no discrepancy was identified.

I have not been supplied with any of the microscope slides associated with these cases; this report is based exclusively on my examination of the paper documentation.

I have been supplied with tabulated data extracted from these records of discrepancies indicating the numbers and percentages of discrepancies broken down by type of discrepancy, organ system and reporting pathologist. I have not personally checked all these figures but the few that I have checked myself (see below) concur with the figures as stated so I have assumed that these figures are accurate.

3. The report

3.1 Design and analysis

The case review study is extensive and I am satisfied that it exceeds the recommendations of the RCPATH as set out during initial discussions between the Professional Standards Unit of the RCPATH and the Medical Director of UHBT. However, because the audit was not selective the number of cases reported by each pathologist in each organ system is relatively small, especially in specialties where relatively few specimens are received by the laboratory (e.g. respiratory system). This needs to be considered if statistical analysis of such small sub-groups of cases is attempted.

3.2 Case-mix

The types of cases examined represent a broad spread of types of specimen from a variety of different organ systems, as I would have expected. I do not have an analysis of the normal casemix of the histopathology department at UHBT but I have assumed that the sample examined is representative. It contains specimens from all the areas of principal concern (breast, gynaecology, respiratory and skin). The analysis provided to me includes a numeric breakdown of cases examined in each organ system (breast 257, gynaecology 592, respiratory 100 and skin 641).

3.3. Comments on the frequency and nature of the discrepancies

Differences of opinion between histopathologists are not uncommon and when a reviewer disagrees on the interpretation of the features in the original report it does not prove that the original report is incorrect. As a result the RCPATH makes a distinction between a 'discrepancy' and an 'error' as set out in the RCPATH publication at www.rcpath.org/resources/pdf/reviewofcategorisationofdiscrepanciesfinal.pdf :

- a **discrepancy** can be defined as a difference of opinion between the original interpretation and the interpretation at review;
- a discrepancy can only be considered an **error** when the discrepancy is confirmed by two independent reviewers.

It should be noted that the discrepancies in microscopy identified in this audit have not, to my knowledge, been evaluated by a third pathologist and therefore in accordance with RCPATH guidance it remains appropriate to describe them as 'discrepancies' rather than 'errors'.

There are a small number of exceptions, where the original report documents input from a specialist pathologist external to the department. In two, the original pathologist and external expert agree with each other, but the PathLore reviewer disagrees; it seems illogical to regard these as diagnostic discrepancies (BH07-9826; BH07-10494). In another case the reviewer seems to agree with the external expert, who had corrected the local pathologist's original diagnosis; in this case, as the original pathologist recognised that an expert opinion was needed I do not believe that this should be regarded as a discrepancy, because in seeking an expert opinion the correct course of action was taken (BH07-15546). These are obviously difficult cases. It is a matter of concern that two of them were categorised as B2 rather than B3. The consistency of classification by the reviewers is further considered below.

Most of the PathLore reviewers are pathologists who will be known to most UK histopathologists as specialists with a national reputation for diagnosis of the organ systems they are reviewing. Consequently it seems reasonable, for the purpose of analysis, to assume that the external reviewer's opinion is more likely to be the correct one.

It must also be borne in mind that a specialist reviewer, whose routine work is limited to one organ system, may have a different concept of what is an 'understandable' mistake to that of a generalist whose work covers all human disease.

The RCPATH document on the classification of discrepancies acknowledges that it is often difficult for a pathologist to estimate the impact of an error on patient care, as the pathologist

is not necessarily aware of how the original report influenced treatment nor of the other relevant clinical features of each case. This point is evident in many of the comments of the reviewers, where considerable uncertainty is often expressed in this part of the classification of discrepancies. As a result I regard the 'duty of care' part of the analysis as being of value to the clinical governance systems in UHBT, facilitating review of patient care; but it is not helpful in assessing the competence of the pathologists nor in assessing the safety of the pathology department. I therefore propose to consider only the 'Expression of concern' categorisation of the discrepancies in this report.

For ease of reference, the RCPATH's current definition of each category is as follows:

Category (Expression of concern)	Description
A	Inadequate dissection, sampling or macroscopic description Where relevant, this should be assessed against guidance such as the College datasets and tissue pathways. It should be remembered that the pathologist issuing the final report may not have dissected, described and sampled the specimen.
B	Discrepancy in microscopy 1. A diagnosis which one is surprised to see from any pathologist (e.g. an <i>obvious</i> cancer reported as benign) 2. A diagnosis which is fairly clearly incorrect, but which one is not surprised to see a small percentage of pathologists suggesting (e.g. a moderately difficult diagnosis, or missing a small clump of malignant cells in an otherwise benign biopsy) 3. A diagnosis where inter-observer variation is known to be large (e.g. disagreements between two adjacent tumour grades, or any very difficult diagnosis) (Note: In deciding where a specific discrepancy lies in this classification, consideration should be given to the range of responses that might be expected if the case was used in a relevant interpretive external quality assessment scheme. (1) would be a surprising diagnosis even from one participant; (2) would be unsurprising from a small minority of participants; (3) would generate diagnoses so varied that the case could not be used for scoring purposes.)
C	Discrepancy in clinical correlation This would represent a failure to answer the clinical question (if clearly expressed on the request form), despite that answer being evident from the material available; or a failure to indicate that a specimen is clearly inadequate to answer the clinical question.
D	Failure to seek a second opinion in an obviously difficult case This could imply over-confidence
E	Discrepancy in report This would include typographical errors and internal inconsistencies or ambiguities in the report which should have been corrected before authorisation

The numeric analysis provided to me demonstrates that all six pathologists whose work is being reviewed undertake primary responsibility for reporting specimens from all organ systems examined in the department. There is some evidence of specialisation; for example, the large majority of haematological cases are reported by JP and a large proportion of breast specimens are reported by CJC and MS. But for the other organ systems the numbers suggest that the workload is shared between all the consultants.

That being the case, it is notable that the frequency of each type of discrepancy attributable to each pathologist is relatively similar. Expressed as a percentage of cases reviewed:

Category	Pathologist					
	CC	CJC	MM	JP	NW	MS
A	0	0.3	1.3	0.7	0.3	0.2
B1	1.3	0.7	0.6	1.2	0.8	0.7
B2	3.8	2.6	4.2	2.1	0.3	2
B3	5.1	4.4	5.8	4.6	4.2	4.2
C	0.7	1.0	1	1.4	0.8	0.5
D	0.7	0	0.2	0	0	0.2
E	0.5	0.7	1.8	0.9	0.3	1.9
Unclassified	0	0	0	0.2	0	0

I have not attempted a statistical analysis of this data, but it seems self-evident that differences between pathologists in the frequency of the most important category (B1) are small and are probably not statistically significant. **If this is confirmed by a statistician, the results do not identify any one pathologist as justifying specific concern in relation to skills of microscopic diagnosis.**

NW seems to have fewer B2 discrepancies than the other pathologists; I find this difficult to explain in the absence of any corresponding difference in rates of B1 or B3 discrepancies but I will discuss the possible significance of B2 discrepancies below.

MM has the highest rate of type A discrepancies. This appears to be largely due to a failure to find the recommended number of lymph nodes in colonic resections for cancer, and a failure to examine sections cut at deeper levels in circumstances where the reviewers think this is appropriate. These possible weaknesses should be investigated further by systematic audit.

MM and MS may have higher rates of category E discrepancies. This suggests that they might need to be more diligent in checking the content of their reports before they are authorised. However, my examination of the individual discrepancy reports indicates that some of the reviewers have been extremely assiduous in identifying very small typographic errors. The most trivial example I detected was a report identified as a Category E discrepancy because it described a classification of colon cancer stage as a 'Duke's Stage' rather than a 'Dukes' Stage' (BH07-7405). This misplaced apostrophe is a common mistake; indeed, as it occurred in the 'clinical information' section of the report it is quite possible that it represented an accurate transcription of the information provided by the surgeon. Bearing in mind the nature of the typographic errors reported I was not concerned that the number of Category E discrepancies associated with any pathologist was excessive.

A table was provided to me (not reproduced here) showing the number and rates of discrepancies attributable to each pathologist by organ system. At this level the number of discrepancies per pathologist in each organ system is small, so the data have to be interpreted with caution and a statistical opinion should be sought on the power of the study to provide a reliable result. Beyond the statistical analysis, in those areas where the pathologists in the department do have some specialisation the distribution of difficult cases may have had an effect on the reported rate of discrepancies. For example, the largest number of discrepancies in the haematological system is attributed to JP; but JP reports almost all the haematological specimens, and as the local specialist in this type of specimen JP presumably reports all the difficult cases. A similar comment may be made about breast pathology, where most of the reports and most of the discrepancies are attributable to CJC and MS.

It is self-evident that comparisons between pathologists are not possible where essentially all the work is done by one pathologist, as in haematology. Furthermore, review of the haematological discrepancies shows the majority to be category B3, most of them representing a disagreement with the reviewer on difficult interpretations of whether or not a marrow sample contains a small population of cells from a previously diagnosed haematological malignancy. I will discuss the potential significance of this type of discrepancy below. **Overall, and subject to the need for statistical analysis, this**

tabulation does not suggest to me that any one pathologist has a significantly higher rate of discrepancies in any single organ system.

The comparisons discussed above, made between one pathologist and all the other pathologists in the department, would fail to detect a problem in performance that affected all the pathologists in the department to a similar extent. I therefore turn to consider whether the histopathology service as a whole is generating discrepancies at a rate which gives cause for concern.

In this context, the most important category to consider is **category B1** – a report which one is surprised to see from any pathologist. The overall rate of B1 discrepancy is 0.9%, which I would regard as worrying. But any pathologist will occasionally generate a category B1 discrepancy. Systems should be in place that are designed to identify such reports before they cause patient harm. I was presented with authorised reports identified as B1 discrepancies without any subsequent supplementary report providing a correction. This suggests that systems to identify errors before they cause patient harm were not in place. I will turn to the matter of ‘double reporting’ important or difficult cases in the discussion of B2 discrepancies, below.

In some organ systems the rate of B1 discrepancies is much higher. A total of 17 such discrepancies were reported in gynaecological pathology; equivalent to 2.9% and by far the highest rate of B1 discrepancies in any organ system. *Prima facie*, this appears to be unacceptable and suggests a specific problem with this organ system.

However, examination of the B1 discrepancies leads me to suspect that the high rate of B1 discrepancies within gynaecological pathology is due to the approach of a single PathLore reviewer. The gynaecological pathology specimens were reviewed by three pathologists; SM, MW and AH. As I have not personally examined the microscope slides, it is not possible for me to comment with any confidence on the classification of category B discrepancies offered by the reviewers. However, I noted that SM was repeatedly reporting category B1 discrepancies on the basis of disagreements with the tumour grade, notably in cervical biopsies. On enquiry I have been informed that SM reviewed 464 of the 690 gynaecological cases that were reviewed, so one would expect SM to have identified more discrepancies than the other reviewers. However, it is striking that all 17 category B1 discrepancies were reported by SM, with no B1 discrepancies reported by MW or AH. If the cases for review were distributed amongst the reviewers by a random process, and if the reviewers all use the same criteria for the identification of B1 discrepancies, my calculations suggest that the probability of this distribution arising by chance is less than 1%. I am therefore led to question the work of reviewer SM in this regard, and to suggest that PathLore should be asked to seek another opinion on all the cases where SM reported a B1 discrepancy.

Indeed, having identified such a difference in the criteria for the identification of B1 discrepancies by one reviewer it would seem reasonable to suggest to the review panel that all cases identified as B1 discrepancies should be re-reviewed ‘blind’ by a second reviewer. Furthermore, it is of course possible that cases initially identified as a B2 discrepancy could be reclassified as B1 on review. This suggests that to obtain a full and accurate record of B1 discrepancies, all B2 discrepancies should also be re-reviewed. Obtaining a second reviewer’s opinion would also allow the identification of ‘errors’ rather than ‘discrepancies’, according to the RCPATH definitions of those words as set out above.

The interpretation of the rate of B1 discrepancies should be reconsidered after that work has been done.

The overall rate of **category B2** discrepancies is 2.5%. In contrast to the B1 discrepancies, examination of the original reports and the reviewers’ comments did not cause me to question the validity of this figure, but it did reveal a number of contributory factors.

First, in accordance with the RCPATH definition, many of the B2 discrepancies are genuinely difficult diagnoses, such that one would expect a proportion of discordant diagnoses from a group of competent pathologists. However, it is notable that remarkably few of the original reports record any mention of seeking a second opinion from another pathologist. The reporting software used in Bristol includes a field identified as ‘*Additional reporting pathologists:*’ – but it is almost invariably empty, even where the report identifies and discusses an area of diagnostic difficulty. This might be because the department has chosen

not to use this facility; I did notice a tiny number of reports where the text of the report mentioned the involvement of another pathologist, but the '*Additional reporting pathologist*' field was nevertheless empty (e.g. BH07-7234). But such reports are rare.

There are some circumstances where there is national guidance indicating that two consultant opinions should always be obtained; for example, suspected epithelial dysplasia in distal oesophageal biopsies. Even in these circumstances the reports are almost invariably attributed to and authorised by a single pathologist.

I have noted above that three cases include an opinion from a specialist pathologist from outside the department. I am unable to draw conclusions on whether the frequency at which external opinions are sought is appropriate, because it is likely that such cases would not be included in those where external review identified a discrepancy.

I note that the cases under examination were reported in 2007. Since that date the Royal College of Pathologists has published specific guidance on the use of 'double reporting' in its document '*Quality assurance in histopathology and cytopathology reporting practice*', available at www.rcpath.org/resources/pdf/g082_qahistoreporting_feb09.pdf. I suggest that it would be of value to audit whether the department is now complying with this guidance.

Second, a proportion of category B2 discrepancies relate to the use of diagnostic terms or classification systems that the reviewers regarded as obsolete, and I agree. Many of the reports are remarkably short, and it is not unusual to find reports where important items of information are missing – such as ones identified in the RCPATH 'cancer dataset' documents (e.g. BH07-11969, BH07-12129). These are matters that are readily amenable to audit. Reading the original reports, many are in a style reminiscent of reports one reads when reviewing cases that were reported ten or twenty years ago. A subjective impression is gained of a department that has not shown enthusiasm to keep up with modern developments. It would be relevant to evaluate the participation of the consultants in national educational meetings and other external CPD activities.

The overall rate of **category B3** discrepancies is 4.8%. Examination of the reports indicates that the reviewers have correctly interpreted the RCPATH guidance and have used this code in situations where it is well known that pathologists show very poor inter-observer reproducibility. For example, the high rate of B3 discrepancies in urological pathology (15%) is largely attributable to disagreements about the Gleason scoring system for grading adenocarcinoma of the prostate.

In this context, the reported rate of discrepancy for an individual pathologist is not surprising. But examination of the individual discrepancies is again revealing. First, the low frequency of any documented second opinion being sought is striking, as is discussed above in the context of B2 discrepancies. Second, in the context of the 15% B3 rate in urological pathology, the commonest disagreement is for the original report to describe an adenocarcinoma of prostate as having a Gleason score of 3+3=6 whereas the reviewer regards the tumour as Gleason 3+4=7. This is a small difference, and a high rate of disagreement is not surprising. However, it is a distinction which can very often have a dramatic influence on prognosis and therapy, and (as noted above) none of these cases show any evidence of a second opinion having been sought. Furthermore, there is anecdotal evidence of 'grade inflation' in Gleason scoring of prostatic cancer, with older pathologists tending to score tumours lower than young pathologists and Gleason patterns 1 and 2 now being reported only very rarely, if at all.¹ Whether such a 'drift' in grading over time is to be welcomed or derided, it might again suggest that lower Gleason scores might be generated by a group of pathologists who have not maintained a close interaction with current trends in their subject.

In view of my comments above, I am slightly surprised that the reviewers report relatively few category D discrepancies (failure to seek a second opinion). In part this can be explained by an approach where, if a Category B discrepancy is identified, that is regarded as the more important point to document, so the failure to seek a second opinion is not mentioned by the reviewer.

I am unable to draw any further conclusions from the data on discrepancies of other types.

4. Conclusions

In the light of the above observations I turn to the specific questions put to me by Verita.

a. To what extent the results of the audit are consistent with a histopathology service of acceptable reliability and to identify areas of improvement

The overall rate of discrepancies identified by the audit suggests that, in 2007, there is some cause for concern about the overall performance of the histopathology department, in respect of areas discussed in my report above. The underlying causes cannot be identified with certainty from the material available to me but I suggest that the broader Inquiry currently being undertaken should examine the working practices in the department, particularly in relation to the sharing of difficult cases, the incorporation of second opinions into reports and checking of particularly significant or unexpected diagnoses, for example through the system of cancer multidisciplinary team meetings. The procedures used by the pathologists to keep up to date should also be scrutinised.

b. To comment on whether error or discrepancy rates give cause for concern about either individual pathologists or specific organs/systems (e.g. breast, gynaecology)

I was unable to detect evidence of any one pathologist giving cause for concern beyond the overall concerns about the function of the department, as discussed above.

In respect of individual organ systems, interpretation is made difficult by the small sample size in some organ systems (e.g. respiratory), uncertainty about the criteria applied by the reviewers (e.g. gynaecological pathology, for reasons discussed above) or by specialisation within the department (e.g. breast and haematological specimens). Some categories of discrepancy are, by their nature, confined to one organ system (e.g. lymph node sampling in colonic cancer resections) but I have gained the impression from reading the original reports and the reviewers' comments that there is not a major problem that is limited to one organ system; rather, all organ systems are affected by matters discussed under question (1) above.

c. Whether the audit reveals any systematic pattern of diagnosis or error

I do not believe that a systematic pattern of error is identified, beyond the problems discussed in (1).

d. To consider the reported discrepancies on a case by case basis and report on patterns as seems appropriate

I have reviewed the reports and the reviewers' reports of 377 cases and I have set out my conclusions above. I do not believe that it would be of value for me to make 377 separate comments on the individual cases.

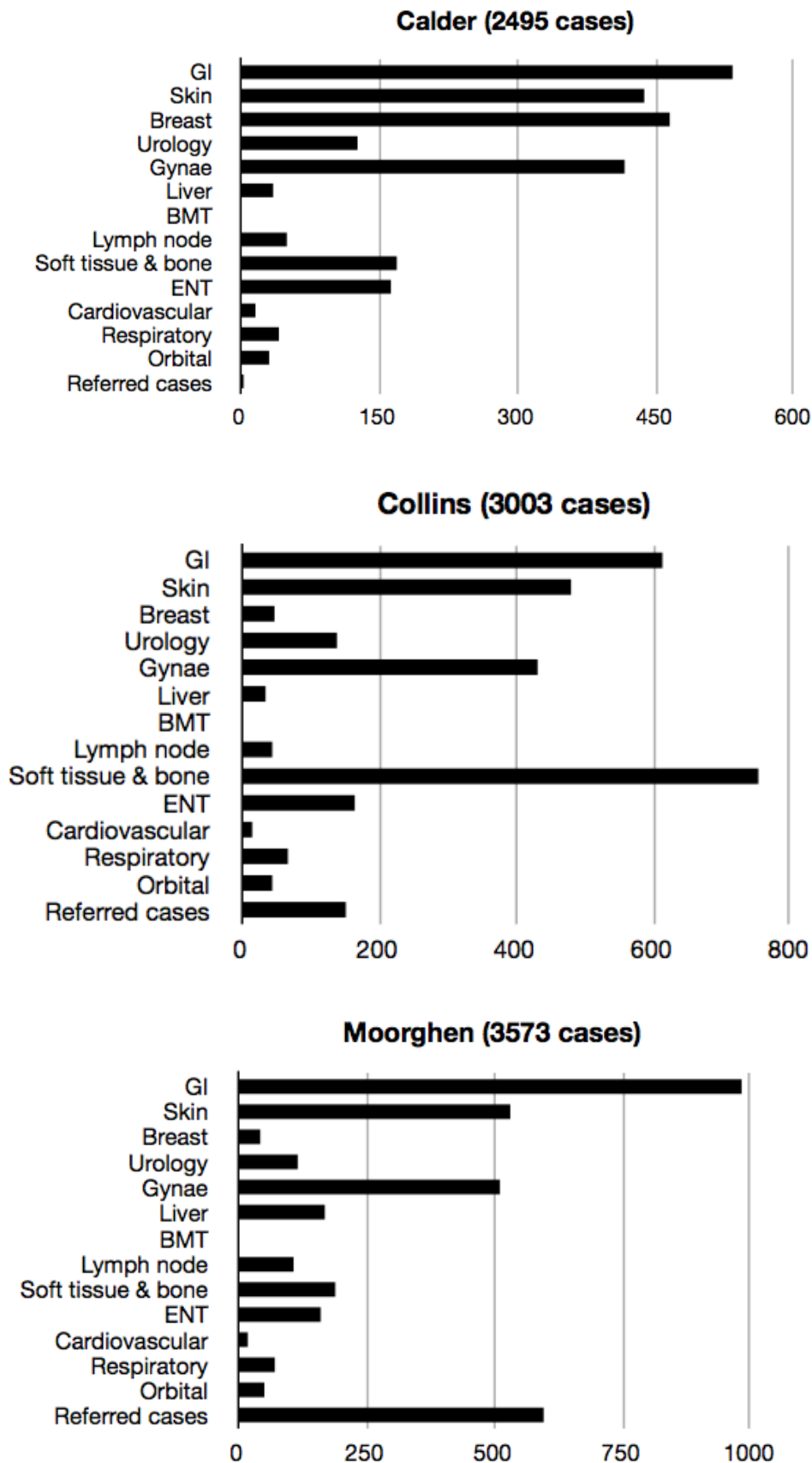
I have identified some patterns of discrepancy as set out above, but my firm impression is of a broader problem with the working patterns of the department, as discussed in (1).

5. Reference

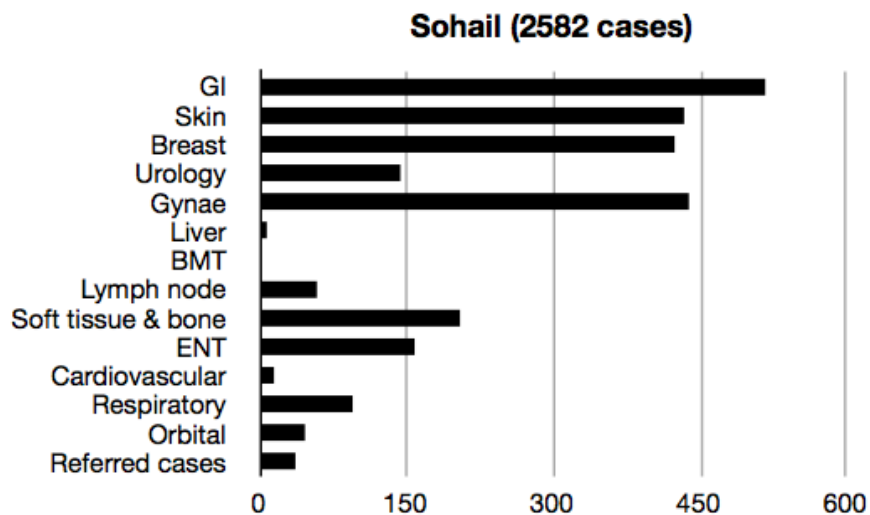
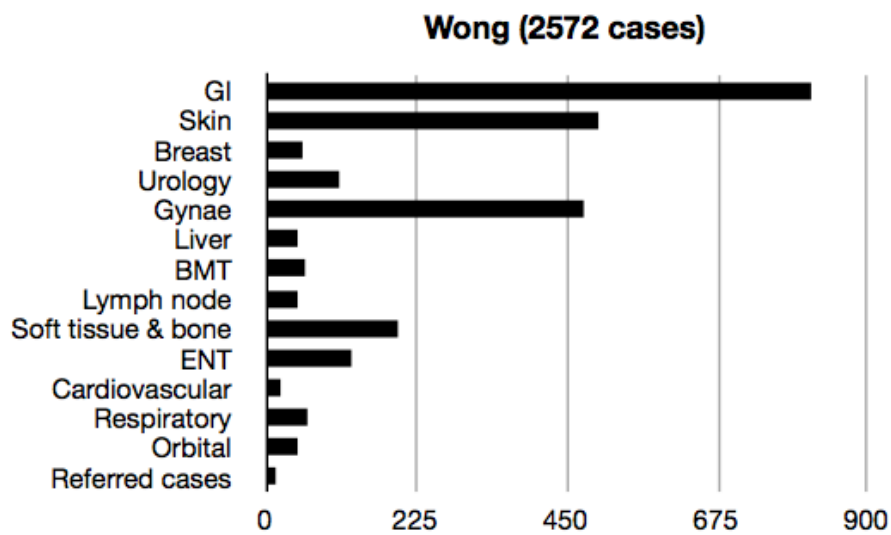
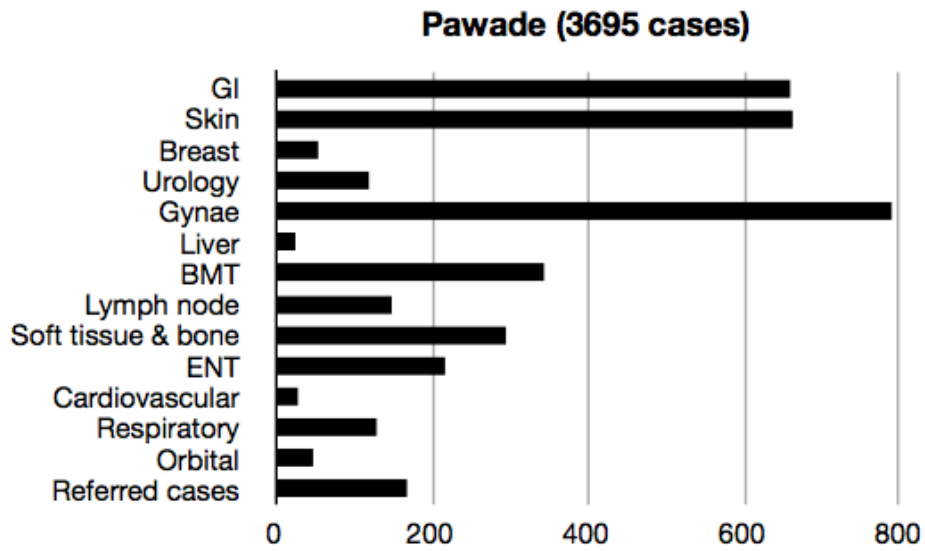
1. BJU Int. **100**:1240-44, 2007, Histopathology **50**:683-90, 2007.

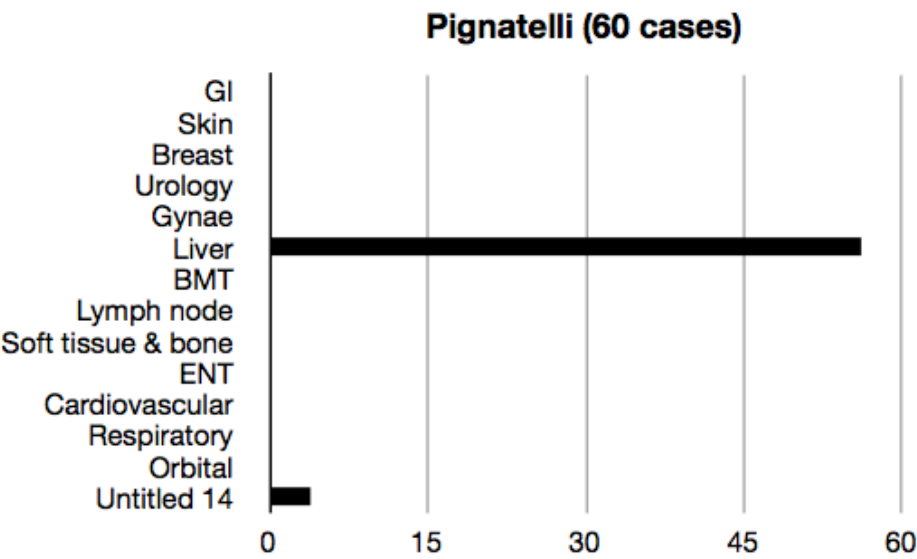
Professor Peter Furness MA BM BCh PhD FRCPath

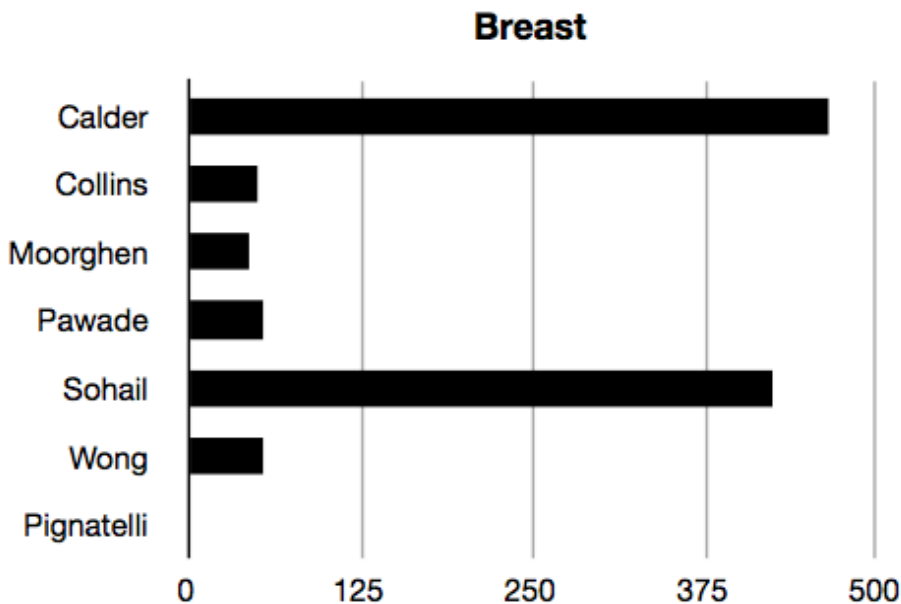
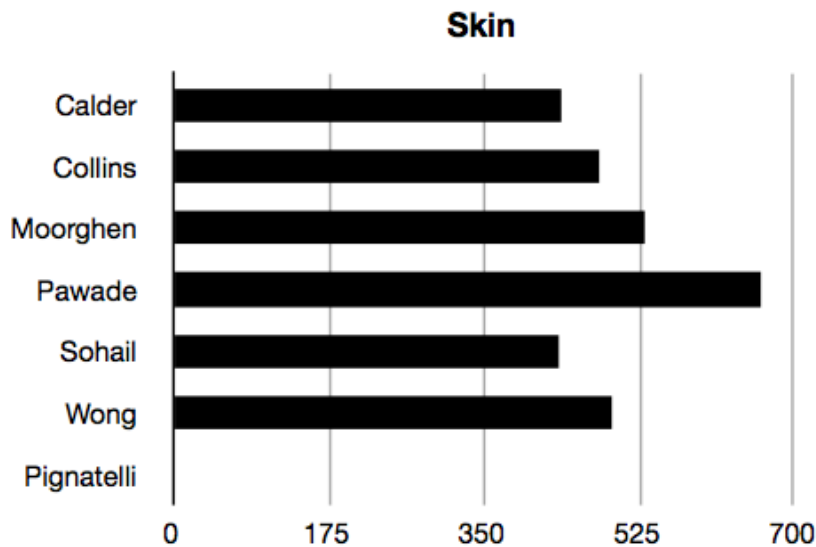
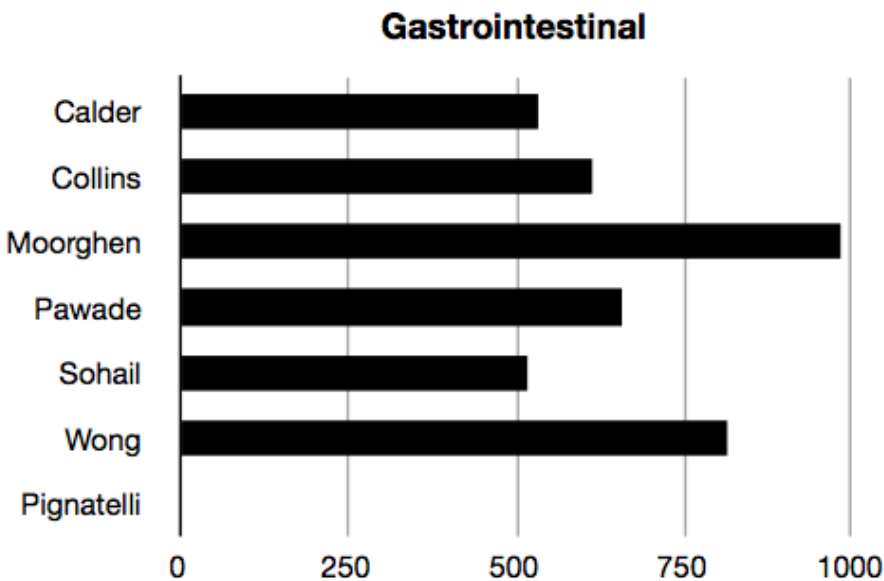
ANNEXE 7: UHBT Workload Graphs for 2007 and EQA Participation



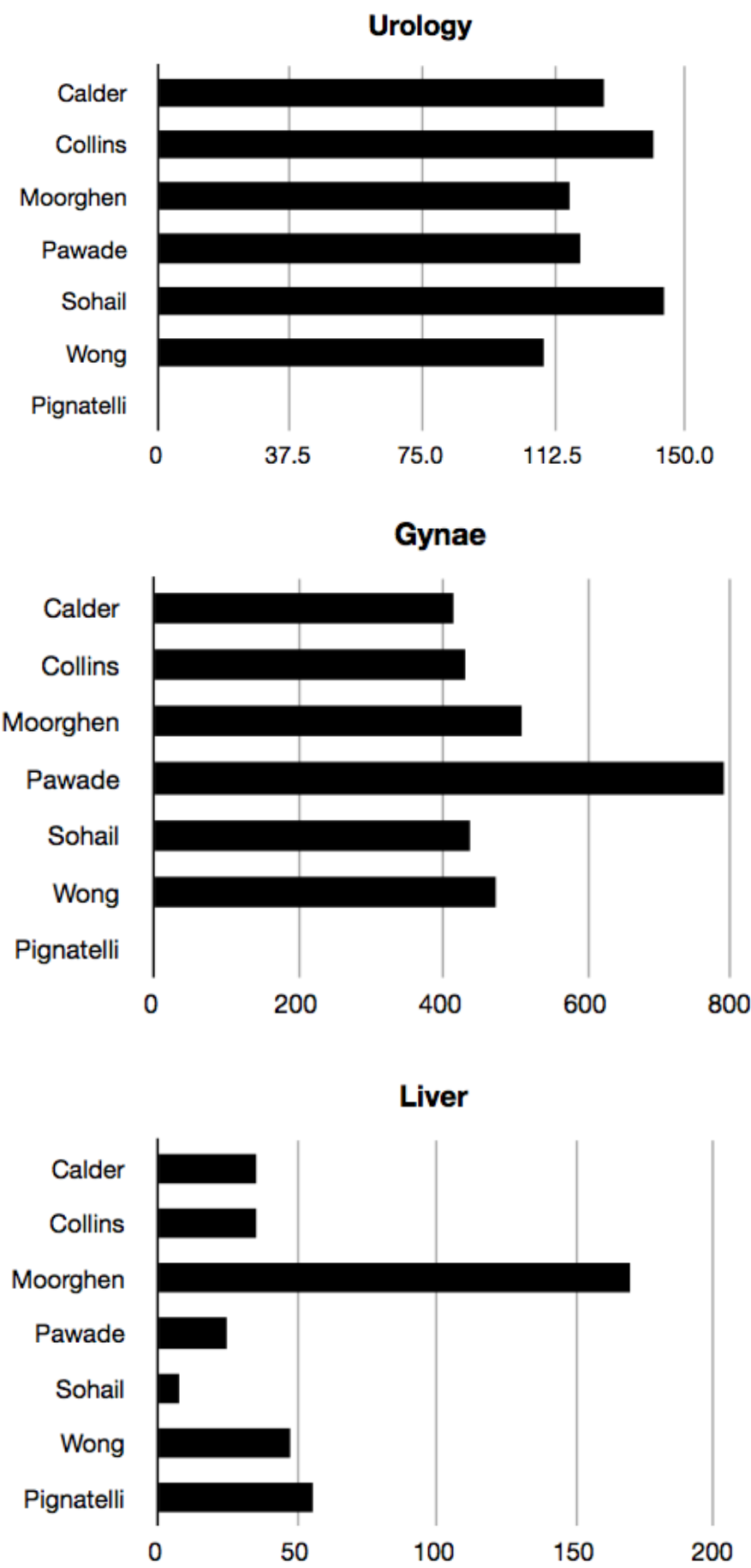
UHB histopathology workloads in 2007

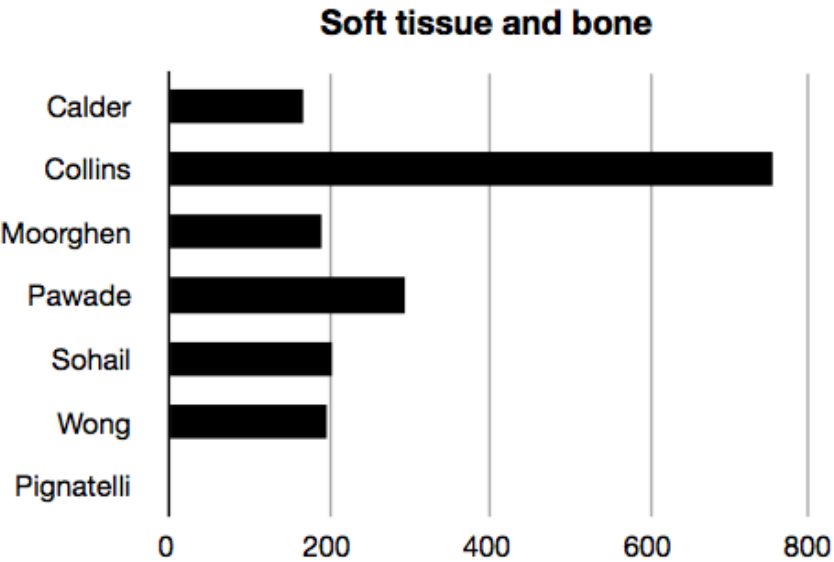
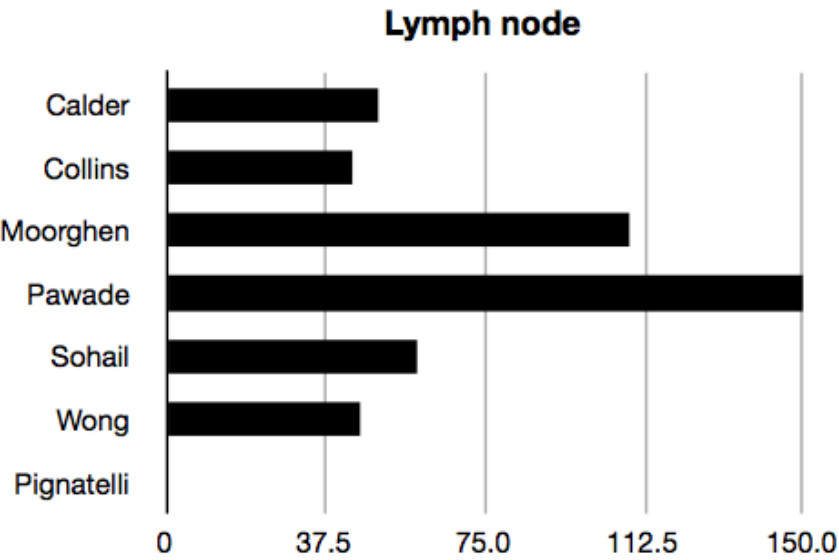
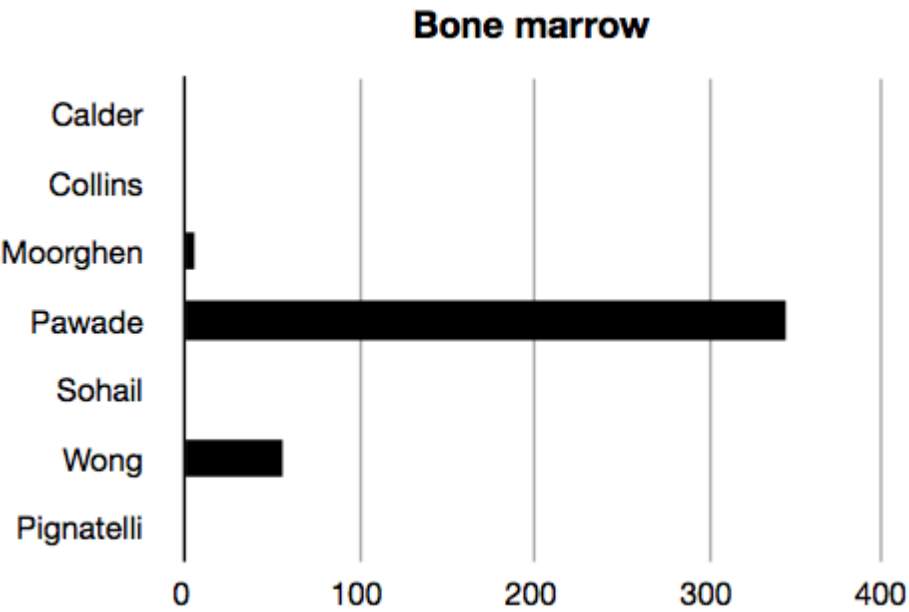


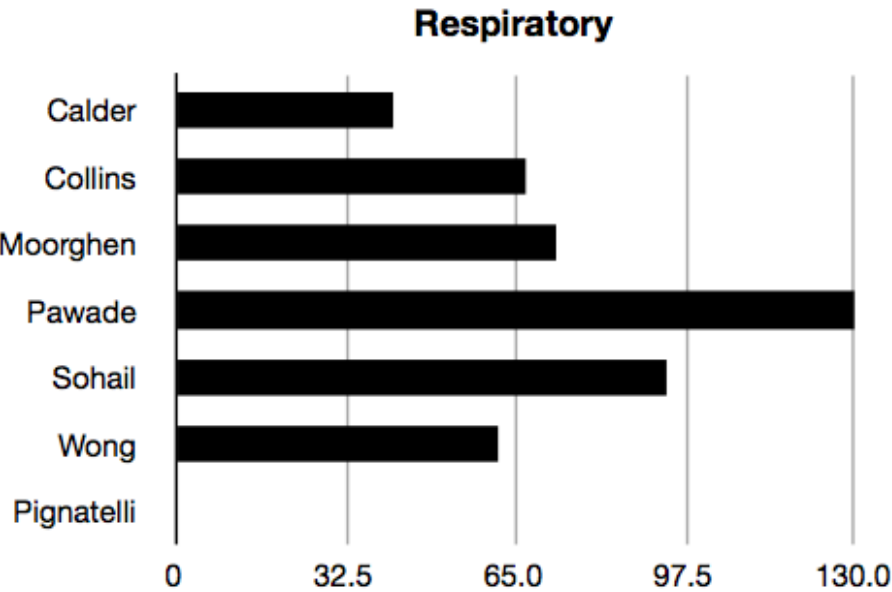
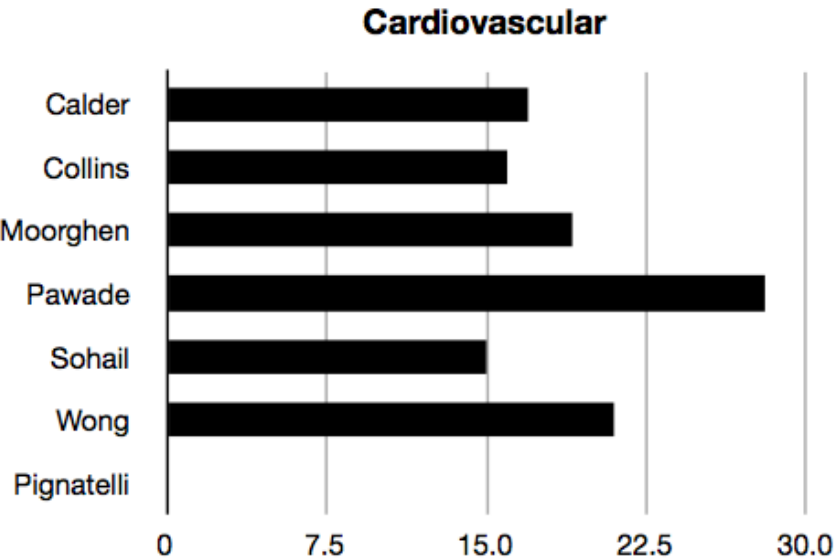
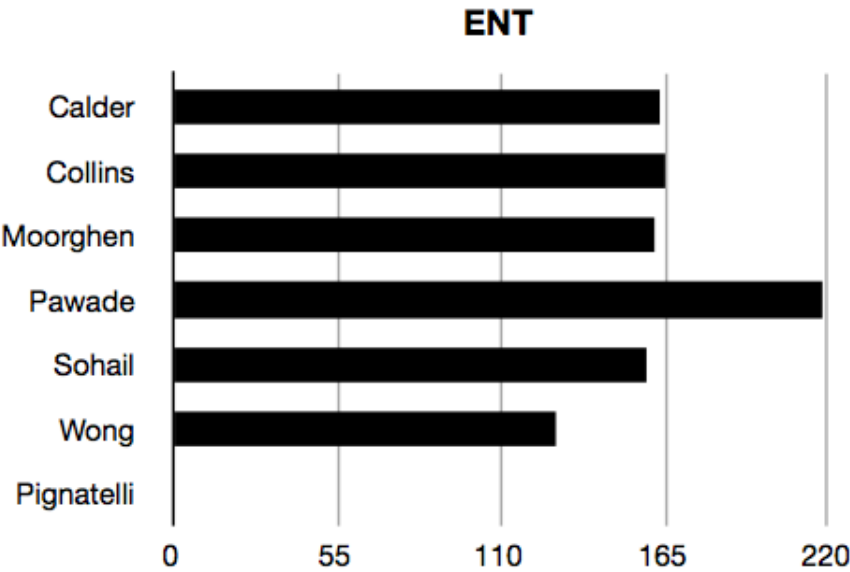


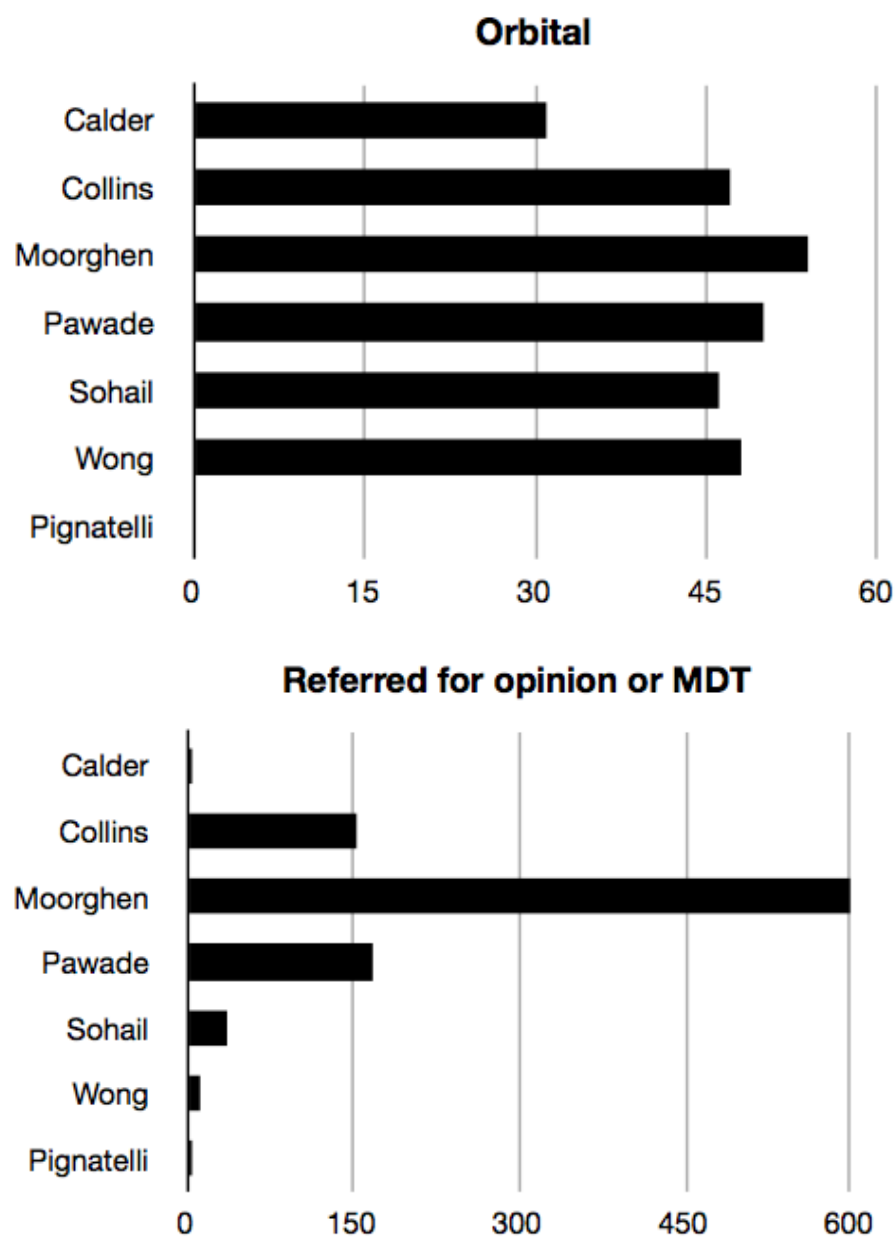


UHB histopathology workloads in 2007









External Quality Assurance scheme participation

Consultant	General EQA	Specialist EQA
Calder	Wessex & SW England	Breast
Collins		Musculoskeletal
Pawade	Wessex & SW England	Gynaecological
Sohail	Wessex & SW England	Breast Gynaecological
Moorghen	Wessex & SW England	Liver Gastrointestinal
Wong	Wessex & SW England	Gastrointestinal
Pignatelli		
Ramani		Paediatric