

Review of the Response of Heart of England NHS Foundation Trust to Concerns about Mr Ian Paterson's Surgical Practice; Lessons to be Learned; and Recommendations

**Kennedy Review** 

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\*I should declare that, although I have never previously had any formal contact with the Trust or its constituent Hospitals, my brother Stuart was a surgeon at two of the Hospitals. He ceased to operate after contracting hepatitis from a patient around 1990 and died of liver disease in 1999. It was partly in honour of his memory that I agreed to take on this Review.

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## **EXECUTIVE SUMMARY**

- 1 This is a tragic story. It is not a story about the whole of the NHS. It is about something that happened in one corner of one hospital Trust in one part of the NHS. But, it has lessons for the whole of the NHS.
- 2 It is a story of women faced with a life threatening disease who have been harmed. It is a story of clinicians at their wits' ends trying for years to get the Trust to address what was going on. It is a story of clinicians going along with what they knew to be poor performance. It is a story of weak and indecisive leadership from senior managers. It is a story of secrecy and containment. It is a story of a Board which did not carry out its responsibilities. It is a story of a surgeon who chose on occasions to operate on women in a way unrecognised by his peers and thereby exposed them to harm.
- 3 The Review was commissioned by the Board of Heart of England NHS Foundation Trust (HEFT, the Trust). It is specifically concerned to identify the lessons which the Trust can learn from the way in which it responded to the concerns raised over time about Mr Ian Paterson's surgical practice. It is informed by the papers received from the Trust and the interviews held with patients, staff and others. Special thanks are due to the many patients whom I spoke to and who wrote to me. I learned much from their experiences and insights. They deserve to have the opportunity to understand what was happening in the breast unit while they were receiving treatment. I hope that this Review provides that opportunity.
- 4 The Review seeks to set out the facts as clearly as possible and to comment on them. The aim is to allow those who read it to come to an informed and considered view and reach their own conclusions. If there is to be any real understanding, so that lessons can be learned, it is important to avoid focussing on the "name and shame" approach. When things go wrong, it is mistaken and naive to imagine that one person or group was solely responsible. Instead, the focus must be on the systems in place which brought about what happened.
- 5 In this Review I draw attention to features of the system which contributed to what happened. They include: the role of the Board; the approach and way of working of the Executive; the culture of the Trust; the ability to voice concerns and be heard; the level of communication within the Trust and between the Trust and others; the role of confidentiality; and, perhaps most crucially, the place of the patient's perspective. It is these factors which must be addressed if anything is to be learned.
- 6 The Review begins with the appointment by the Trust of Mr Paterson as a surgeon in March 1998. He had been the subject of an investigation and suspension two years previously by his then employer, Good Hope Hospital and had been required to undergo a period of supervised practice before recommencing laparoscopic surgery. The Trust was advised of this prior to his appointment. On his acceptance of the appointment to the Trust, his relations with his colleagues at Good Hope became increasingly difficult. Matters came to head and he was asked by the Chief Executive of Good Hope Hospital to leave without completing his period of notice.
- 7 He is described as charismatic and charming and was much-liked by his patients. He was not, however, a team-player in an area of care which is absolutely dependent on clinicians working efficiently and effectively as a team. The team suffered as a

consequence, as did, inevitably, the care of women with breast cancer. In July, 2011, Mr Paterson's registration with the GMC was made subject to conditions for eighteen months. In October, 2012 he was suspended by the GMC and the suspension remains in effect. He was suspended by the Trust in May 2011. His pay was stopped in November 2012.

- 8 Women with breast cancer undergo surgery as the principal form of treatment. Depending on their condition, they have some form of localised surgery, not amounting to a mastectomy, or they have a mastectomy. A mastectomy is defined as the removal of breast tissue so as to leave a flat chest wall.
- 9 Fellow clinicians and nurses in the breast care team became concerned about Mr Paterson's surgical practice. One of the particular concerns was the amount of tissue left behind on occasions after what was described as a mastectomy. Concerns were such that, towards the end of 2003, one clinician carried out an audit of 100 patients. The audit called into question Mr Paterson's clinical competence and suggested that women on occasions may have been exposed to an increased risk of a recurrence of their cancer. The Trust's senior managers responded by asking a senior clinician, Mr Wake, to carry out an investigation. A Report was prepared and submitted in January 2004. It made a series of recommendations. It was taken to be principally concerned with making the Multi-Disciplinary Team (MDT) work better. In fact, it made a number of other recommendations about Mr Paterson's surgery which were not acted upon. Surprisingly, it only referred in passing to one of the central concerns – that, on occasions, Mr Paterson was leaving behind tissue after carrying out what was supposed to be a mastectomy – and made no recommendation on the matter.
- 10 The Report overlooked a crucial issue: the issue of consent. Women were giving their consent to a mastectomy. But, on occasions, a variation of a mastectomy was being carried out; what became known later as a "cleavage sparing mastectomy". This was not a recognised procedure. Women did not consent to it in any properly informed way. Whenever Mr Paterson intentionally chose to leave behind tissue, while saying that he was carrying out a mastectomy, he was in breach of his obligation to obtain consent from his patient. Had this lack of proper consent been identified and dealt with properly by senior managers in 2003 or earlier, as it should have been, events would probably have taken a different course. But, despite being referred to by concerned clinicians in 2003 and again by an external expert in 2007, the question of lack of consent was not formally raised by senior managers until mid-2011.
- 11 The Trust's response to the Mr Wake's Report was to seek to improve the working of the MDT. The concerns over Mr Paterson's clinical competence went unaddressed. Mr Paterson continued to operate as before for nearly four years. The oncologists who were based in another Trust felt ignored. They had expressed their concerns and supplied evidence. They felt that no-one at Mr Paterson's Trust was listening. Like many clinicians who spend their time looking after patients, they regarded the management of the Trust as remote. They had little understanding of it or contact with it. As a consequence, their attempts to provoke action from those able to take action were ineffectual.
- 12 They were faced by an awful ethical dilemma: what to do about the patients whom they were seeing who were supposed to have had a mastectomy but had not, in fact, had one, but, rather, had only had a "partial mastectomy" (a contradiction in terms). The dilemma was resolved on occasions by compensating for the "partial

mastectomies" that some women were receiving. Some patients were referred back to the surgeon for more surgery, (which, of course, should not have been necessary had a mastectomy been performed). But, as regards other women, the decision was taken, on occasions, to depart from standard practice and treat them as if they had not had a mastectomy (which they had not had).

- 13 The alternative course open to the oncologists and other members of the team would have been to down tools and refuse to treat those patients who had not been operated on correctly. They did not feel able to do this. They had raised concerns already and been told that the procedure raised no increased risk and that only fatty tissue was being left behind. (The breast care nurses, who had also expressed concern, received the same assurance from Mr Paterson). The culture in the Trust was not conducive to raising concerns about a leading surgeon, particularly as the oncologists were not surgeons and were from another Trust. Their desire to do the best for the patient in front of them prevailed over making a stand. The result was less than optimal care for women and a festering sense of frustration and anger among the clinicians in the breast care team.
- 14 They could have raised the issue with the senior managers of their Trust, but did not do so. They could, when all else failed, have reported their concerns to the professional regulatory body, the GMC. They did not do so. In the circumstances, they should have done.
- 15 The QA (Quality Assurance) Visit of 2004 led to concerns being expressed about the MDT and surgical practices. In a follow-up meeting, three months later, concerns were reiterated. But, the QA team can only recommend. Action is for the Trust. The Chief Executive rightly pressed managers for reassurance about the matters raised and was given such reassurance. The National Cancer Peer Review in 2005 painted a picture of a harmonious MDT delivering a good service. It is hard to reconcile the two opinions. Staff may have been seeking to put on a good "show", though that is unlikely. It is more likely that the Review simply lacked rigour.
- 16 Senior managers saw Mr Paterson at the time as a highly effective surgeon performing efficiently, enabling the Trust to meet its targets. The memory of what the 2004 Report had been about faded. It became the received wisdom that it just concerned matters of man- management. The Board, which is responsible for the care and welfare of all patients in the Trust, was not at this time made aware of any of the concerns raised, nor responses to them. They were told the good news from the Report of the Peer Review in 2005. They were not told of Mr Wake's Report, nor the less favourable views expressed by the initial and follow-up QA Visits in 2004, and the recommendations which followed. Good news was preferred to true news.
- 17 A further QA Visit took place in 2007. It reported that progress had been made. The Report was only four months before the Trust launched an investigation into Mr Paterson's surgical practice. The discrepancy can be explained, in part, by the absence of input from oncologists and the concentration of the Visit on technical problems confronting the holding of an MDT across three sites. That said, the Director of the West Midlands Cancer Intelligence Unit (WMCIU) who led the QA Visit, continued, at the same time, to raise concerns that had reached her concerning Mr Paterson's surgery.
- 18 Relations between Mr Paterson and other surgeons were unsatisfactory. A longserving fellow-surgeon left. Another surgeon left within a few months of her

appointment. Potential new recruits had been put off by Mr Paterson's behaviour, save for one appointment in 2003. It appeared that Mr Paterson wanted the lion's share of the work for himself. When the Trust decided to make a new appointment in 2007, Mr Paterson was excluded from the process of selection, despite his being the leading surgeon, for fear that he would again put off any applicant. This is just one example of how senior managers behaved, towards Mr Paterson. Rather than confront him, they preferred to work around him.

- 19 The culture of the organisation at the relevant time was hierarchical and seen by some as oppressive. Inappropriate behaviour by consultants went unchecked. Speaking out about concerns was not easy, particularly for younger members of staff. The Board was passive, responding to what it was told by the Executive rather than actively exercising effective governance.
- 20 The new surgeon appointed in 2007 soon began to raise concerns about Mr Paterson's surgery after seeing some of Mr Paterson's patients, under the newlyintroduced system of cross-cover. The senior managers decided to launch an investigation. They did so using the Department of Health's disciplinary procedures, working through the HR Department. This decision was to have profound implications for years to come. Principal among them was that, thereafter, everything relating to the management of the concerns about Mr Paterson was covered in a blanket of confidentiality. Communication within the Trust was impeded. Patients were unaware of concerns about the surgeon in whose hands they were placing their hopes for the best possible care. Mr Paterson's colleagues did not know what was going on. Others, including those responsible for managing staff working in and around the breast unit, could not answer the questions these staff put to them, because they could not get answers themselves. They felt undermined. Rumour, gossip and speculation filled the gap left by the lack of information. Members of the Board were in the same position. They did not see any of the Reports commissioned by the Executive and received only one formal briefing between 2007 and 2010. When there was a report to the Board in November 2010, it was triggered by the imminent publication of a story in the media.
- 21 The second important implication of pursuing an investigation through the disciplinary procedures was that senior managers worked within the approach adopted by the Department of Health's National Clinical Assessment Service (NCAS). This approach concentrated on identifying the measures necessary to reintegrate Mr Paterson into the team and make sure that his surgery met appropriate standards. The perspective, therefore, was that of the clinician and his needs, all set out in an Action Plan.
- 22 There was another perspective which could and should have been adopted: that of the patient. Had that perspective been adopted, the question would have been: how can we act in the best interests of patients. This may have caused senior managers to require Mr Paterson to cease operating on women with breast cancer until the concerns that had been swirling around for several years could be calmly analysed. This perspective did not appear to be understood, far less adopted.
- 23 The Board was informed that an investigation had been launched but received no further formal notice of progress. There is a device under the disciplinary procedures whereby a Non-Executive member of the Board is appointed to "oversee" the investigation. If it was intended to provide it, this device failed to provide the Board with any assurance concerning the investigation. The Non-Executive did not once

report back to the Board. Thus, the Board was entirely in the hands of the Executive. As a consequence, the Board could not effectively hold the Executive to account as to the conduct or outcome of the investigation or any action taken.

- 24 The senior management established a two-part investigation: matters of interpersonal relations were investigated by a physician from the Trust. An external, independent expert investigated Mr Paterson's surgery. Both Reports made a series of recommendations. The most important was that Mr Paterson must cease immediately from carrying out two surgical procedures: the so-called cleavage sparing mastectomy (csm) and "shaves after mastectomy". Mr Paterson agreed to do so at the end of December, 2007.
- 25 An Action Plan was drawn up for Mr Paterson in consultation with NCAS. One element of the Plan was that Mr Paterson's surgery be observed by a distinguished external surgeon. This expert made his observations unaware that there had been a series of previous Reports, and that concern had been expressed about breast tissue being left behind after what was described as a mastectomy. He should have been told. What had already been said would have provided a context in which to carry out his observations, but the claims of confidentiality meant that he was denied it. Nonetheless, he submitted a Report which was critical of aspects of Mr Paterson's surgical practice. The critical comments went beyond Mr Paterson's previous performance of "partial mastectomies" to include his surgical technique more generally. In particular, it referred to Mr Paterson's surgery as needing to be "less rushed" on occasions.
- 26 The receipt of this Report could have served as another opportunity to require Mr Paterson to cease operating while the concerns being expressed were even more closely examined. This is what at least one outside expert thought should have been done. It was not done. Mr Paterson continued to operate until mid-2011, subject to the conditions placed on him at the end of 2007. He did not observe these conditions on occasions and was eventually excluded from the Trust.
- 27 Having decided not to require Mr Paterson to cease operating, senior managers had to turn their minds to the patients whom he had already operated on. Their view appeared to be that, while Mr Paterson may have been carrying out an unrecognised procedure, it was not clear that the procedure was harmful. (This view overlooked the fact that the absence of consent, in the case of csm, already harmed patients, as did the need for further operations in the case of "shaves after mastectomy".) Given that it was an unrecognised procedure and involved leaving behind tissue on the chest wall, the view taken was that the procedure known as csm could pose a risk. This led to a pursuit of data to determine whether there was, in fact, a risk of harm, and, if so, what that risk was. At the same time, senior managers also sought to address a second question: if there might be a greater risk of a recurrence of their cancer, should any of Mr Paterson's patients, and, if so, which, be recalled by the Trust. In response to this second question, senior managers embarked on an approach which involved identifying those patients whom they thought might be most at risk and recalling only them.
- 28 This approach was hopelessly flawed. First, any woman who had had tissue left behind was necessarily exposed to an increased risk of recurrence. So, at the very least, all patients who had had csm or "shaves after mastectomy" had to be recalled. But, there was no means of telling who had had csm. It was proposed to identify patients by examining their records and notes. But, the records did not identify who

had had a csm: the operation was always recorded as a mastectomy. Photographs and other records equally would not identify the relevant patients. Three independent experts brought in to advise said as much. Their advice was not heeded. The only plausible approach was to recall all the patients who had been operated on by Mr Paterson for breast cancer. This was the view expressed by a number of clinicians. It was not accepted by senior managers. They embarked on a limited recall.

- 29 The reasons why senior managers chose the route of a limited recall, despite the fact that it was misbegotten, are complex and not entirely clear. They include:
  - a failure, initially, to appreciate the scale of the issues involved
  - the tendency to approach the concerns about Mr Paterson's surgery as being technical, requiring an analysis of data about outcomes (even though such an analysis was impossible: the number of csm operations performed was unknown, as was the total number of patients Mr Paterson had operated on, in both the NHS and the private sector, and without a total number it is not possible to calculate a rate of recurrence and compare it with the rate of other surgeons).
  - the sheer managerial implications of a mass recall of patients, and
  - a desire to contain and control the fallout from the concerns and thereby protect the reputation of the Trust. Containment became a dominant objective over time, but it became impossible, not least when stories began to appear in the media.
- 30 The selection of patients to be recalled, apart from being flawed as an approach, was also affected by the fact that Mr Paterson was involved in the process of selection. If all the patients had been recalled, there would have been no need to involve him. A process of selection, however, meant that he was consulted as to whether this or that patient had undergone a csm. Given Mr Paterson's refusal to accept that csm exposed patients to any greater risk of harm, the process of selection was fraught and led to an even greater worsening of relations in the MDT.
- 31 Initially, twelve patients were identified for recall. But, even as they were identified, patients began to present themselves at clinics who had not been selected for recall, but needed further examination. The period between 2009 and 2011 was a period during which the limited recall unravelled, as more and more patients needed to be examined.
- 32 The process of recalling patients was dogged by delay. Not enough resources were allocated to do the job properly. The burden of examining patients fell largely on the shoulders of one surgeon who already had a full clinical load. The delay meant that the some patients may have been put to even greater risk by having to wait before being recalled or seen. It also greatly added to the anxiety of women, many of whom thought they had been cured and now were plunged into the uncertainty of a possible recurrence.
- 33 Members of staff within the Trust remained largely in the dark about what was being done. Confidentiality, as a consequence of the HR process, was cited as the reason. Outside the Trust, Regulators were advised of the recall in 2009 and were updated in 2011. By contrast, other bodies, particularly the Cancer Screening Service responsible for referring patients to the Trust, were not aware of what was happening until alerted by the media in 2010.

- 34 A new leadership team took over at the end of 2010. The decision to recall all patients was made soon afterwards. It was the right decision. Again, not enough resources were allocated but it was successfully completed by early 2012.
- 35 The fact that the recall was managed and operated by staff who had previously looked after them at the Trust created difficulties for some patients, and for some nurses. Efforts were made to engage outside specialists, doctors and nurses, but with very limited success.
- 36 The Trust invited patients to complaints resolution meetings at which senior managers sought to set the record straight and apologise. The senior staff acted with commendable sensitivity. Despite the effort to be open, however, these meetings were dogged by the repeated assertion, in response to patients' questions, that concerns had surfaced in 2007 and that the Trust had acted promptly to require Mr Paterson to cease carrying out csm and "shaves after mastectomy". It was not accurate that concerns had only surfaced in 2007, but those advancing this view did so unaware of the full history. They had not been adequately briefed.
- 37 The way in which the Trust worked contributed to this inability to recall and uncertainty about the past. The Trust appeared to have worked informally for a good many years. There were serious gaps in the organisational memory of the Trust. This was a significant lapse in good governance. In particular, the Board, which is responsible for all that goes on in the Trust, was never adequately appraised formally of what was going on in relation to Mr Paterson's surgical practice until towards the end of 2010, seven years after concerns had been raised by some of the team caring for women with breast cancer. Nothing ever showed up on the Trust's Risk Register, a remarkable fact given what has subsequently occurred.
- 38 The new leadership has sought to correct this state of affairs, through regular updates. The Board cannot discharge its responsibilities if it is not properly kept informed. It should have been informed at least by 2004, after Mr Wake's Report of his internal investigation.
- 39 Alongside the process for recalling patients which they established, the second element of senior management's approach to the concerns about Mr Paterson's surgical practice centred for several years on the pursuit of data. The pursuit of data might be seen, at some point, as some sort of displacement activity: wrestling with the very human problem of the patient could be postponed while the technical issue of data, which the clinician-scientist is more comfortable with, can be resolved. One of the lessons of history from the many occasions when things have gone wrong in the NHS, it is that senior managers and doctors who are reluctant to confront what is actually happening, take refuge in the call for ever more data. The view was that data was needed to establish whether Mr Paterson's surgical practice exposed patients to an increased risk of harm. (The issue of consent, which did not require data, was simply overlooked and not pursued formally till mid-2011.)
- 40 Data was relevant to address two central questions: should Mr Paterson be required to stop operating on women with breast cancer; and which patients should be recalled. As regards recall, the only plausible strategy was total recall. As regards his continuing to operate, there was enough evidence to suggest that Mr Paterson should have been stopped at least by 2007, if not before. Indeed, if the issue of consent had been identified, as it should have been, a reason to require Mr Paterson to cease operating had existed for several years earlier. Equally, if Mr Wake's Report

had been taken seriously, a proper analysis of Mr Paterson's performance would have been instituted over the next six months. This analysis would have built on the Audit that Dr Stockdale had already carried out in 2003. It is very likely that the result would have been that Mr Paterson would have been required to stop operating on women with breast cancer by the end of 2004 at the latest. That did not happen. By 2007/8, in any event, data was emerging which appeared in the Report of the West Midlands Cancer Intelligence Unit (WMCIU) in 2009 to suggest that Mr Paterson's overall surgical performance was poorer than that of his peers as well as the fact that patients undergoing certain procedures were at a significantly higher risk of recurrence.

- 41 The WMCIU's Report, and subsequent iterations, were not received by senior management with the seriousness that they deserved. The Reports warned of significant risks to certain groups of patients who had been operated on and advised senior managers to act on this. They should have acted promptly. Instead, the Trust continued to state that the process of collecting and analysing the data on csm was still going on, but that, otherwise, Mr Paterson's overall performance was within accepted standards.
- 42 In fact, as regards Mr Paterson's overall performance, the standard that senior managers referred to had been undermined by data as early as 2005. Senior managers had been advised of this by the WMCIU on several occasions from 2007 onwards. Nonetheless, the Trust repeated the assertion, such that the GMC, on the basis of the Trust's assurance, did not impose conditions on Mr Paterson's registration when dealing with complaints against him at an interim stage in 2010. It was several months later that he was suspended by the GMC and excluded by the Trust and then, on the basis of his breach of the agreement of 2008 and failure to obtain consent, rather than on the basis of his surgical practice.
- 43 While being a tragic story, this Review is also a story of the Trust now seeking to put the past behind it; to make a fresh start. It has begun that journey with a determination to be open and to understand and learn from past events. The scale of the challenge, however, cannot be overstated. Some staff feel let down. Many patients, past and present, feel betrayed. Their capacity to trust clinicians has been tested to destruction. The Trust must do all that it can to reach out to them and to the wider community. It must say it is sorry for the past. It must work to rebuild confidence for the future.
- 44 It is not the role of this Review to hold people to account. That is a job for others. What the Review seeks to do is to establish what went on as clearly as is possible, so that others can reach informed judgements. Certainly, there are matters which do need to be addressed:
  - Senior managers did not respond effectively to concerns expressed about Mr Paterson's surgical practice until late December 2007 and then their response was neither sufficiently robust nor rigorous.
  - Other clinicians in the breast team, fellow surgeons, oncologists, radiologists and pathologists, continued to work with Mr Paterson for years. They did not go to the GMC or the regulator, even though they felt that they were getting nowhere in the Trust. The oncologists worked in a separate Trust so could have gone to the senior managers of their Trust.

- The breast care nurses went along with Mr Paterson's assurances that there was no need to be concerned at what they were seeing, even though their training had told them that a mastectomy involved a flat chest wall.
- The process of gaining consent from patients was trivialised and patients as a consequence were sold short.
- Mr Goldman, as Chief Executive, appeared to leave things to others while clearly being closely involved behind the scenes.
- Senior members of the Executive decided to instigate an investigation into Mr Paterson's surgical practice under the disciplinary procedures. In doing so, they ensured that concerns would be investigated in confidence and from the perspective of the clinician rather than the patient.
- Mr Cunliffe, in conjunction with Mr Goldman, clamped down on communication, sought to contain the fallout, chose not to stop Mr Paterson from operating on women with breast cancer, and chose to initiate a very limited recall.
- The Board was excluded from access to information by senior managers and made no formal effort to assert itself and become involved.
- Those responsible for Safety and Governance did not play any formal or prominent role in the Trust's response to concerns about Mr Paterson's surgical practice, despite the nature of their responsibilities.
- The Board and Executive did not meet proper standards of good governance. The Trust's "organisational memory" was impaired through informal ways of working.
- The designated Board member "overseeing" investigations did not formally keep the Board advised.
- The Trust's approach to audit and collecting data was patchy and poorly administered.
- 45 All of these matters are not above comment. I have commented on them. But, they make up only part of the story. The real story is about the leadership and management of the Trust over the years.
- 46 Winning back the confidence of patients, staff and the community will be a very significant challenge for the Board. To begin to meet the challenge, the Board must demand of its senior Executives that they identify what is relevant in determining that the care provided to their patients is safe and of good quality. The Executive must be required to provide routinely all the necessary information to determine whether such care is being delivered. Standards already exist nationally. It is open to the Trust to expand on these so as really to get under the skin of the Trust's performance. Patients and clinicians must be engaged in developing such standards. Information on how it is meeting the standards must be published routinely, not just to let everyone know how the Trust is doing, but also as a way of signalling that the Board accepts that it is accountable.

- 47 Not only will this bode well for the future but it will serve as one of the ways of indicating the Trust's determination to learn from the past.
- 48 This is a Review of the care of patients. It is fitting that the last word should go to one of the many patients whom I spoke to, whose metastatic cancer is now widespread:

"... some of us will always have rotten bad luck and carry on and the disease will develop, that is going to happen, but rotten bad luck is easier to live with than the thought that your surgeon may have damaged you. .... You have this gnawing suspicion that maybe if you had woken up with a nice flat chest wall the day after the operation, maybe you would be feeling well now, but I'm never going to know", Mrs Shena Mason.

# 1 CHAPTER I

## INTRODUCTION

1.1 I was asked by the Board of Heart of England NHS Foundation Trust (HEFT, the Trust) to carry out a review concerning the surgical practice of Mr Ian Paterson. The Board is anxious to learn what lessons emerge, in my view, from what I find. Of course, the Board may also draw its own conclusions.

## **Terms of Reference**

- 1.2 My terms of reference were:
  - 1.2.1 To provide a detailed chronology of events from the time of the Trust's appointment of Mr Paterson within the breast service, to the Trust Board's decision to conduct an independent review, encompassing:
    - The development of the Trust's breast care services, including the appointment of Mr Paterson, and of the organisational arrangements for providing these services to patients;
    - The raising of concerns about Mr Paterson's mastectomy practice, who raised them and to whom, including the senior management of the organisation;
    - The Trust's investigation of these concerns within the various established processes;
    - The action taken by the organisation to safeguard patients and prevent harm.
  - 1.2.2 To examine the nature of the organisation's working environment, culture, systems, particularly regarding the collection, analysis and reporting of information about relevant surgical procedures and their outcomes and the role of audit, and arrangements for decision-making, generally, and particularly in relation to the breast care service.
  - 1.2.3 Once concerns were raised, to establish what action was taken to investigate them, the timeliness of such action, and the measures taken and to ensure that the safety of patients was maintained within the breast care service.
  - 1.2.4 To identify and evaluate the steps taken by the Trust to ensure that relevant external agencies/bodies were alerted and engaged in supporting the organisation in its response to the concerns raised.
  - 1.2.5 To evaluate the effectiveness of the organisation's systems for ensuring the safety of patients, for clinical governance and for responding to whistle-blowing by staff, throughout this period, in relation to the breast care service.

- 1.2.6 To identify lessons that can be learnt from these events: both examples of good practice and areas where improvement is required,
- 1.2.7 To make recommendations which will aim to ensure that lessons are learnt and steps taken to prevent any re-occurrence of the circumstances giving rise to the Review. The recommendations should include measures which can support the NHS in improving its response to concerns raised by clinicians into other clinicians' practices and concerns raised by staff into standards of care. Such recommendations should take account of initiatives across the NHS and professional bodies regarding whistle-blowing.

## My Approach

- 1.3 I approached the assignment by asking the Trust to make available all relevant documents and all those members of staff who might be able to help me. On a preliminary examination of the papers made available, I identified those inside the Trust, as members of staff, and those outside, who had played some role and asked that they be invited to come to see me. I then gave a series of interviews to the local media, television, radio and press, in which I urged anyone who thought that they might be able to help me to contact me through a dedicated e-mail address. A website was also established on which were posted my terms of reference, documents, and, as time went on, updates. I indicated that I was most anxious to talk to former and present patients. An evening meeting was arranged at which I spoke to more than 50 patients and relatives and friends, explaining what I had been asked to do and how I intended to go about it.
- 1.4 The next stage involved conducting interviews. In all, I interviewed 66 witnesses:
  - members and former members of staff of HEFT, Solihull Hospital, Heartlands Hospital, and Good Hope Hospital
  - patients, former patients and relatives and friends of patients
  - others
- 1.5 I also received a number of letters and e-mails from patients and others.
- 1.6 As regards members of staff and others, I held the interviews at either Solihull Hospital or Heartlands Hospital. As regards patients and their relatives and friends, I saw them at a local hotel. I arranged for there to be a waiting room where they could be met by one or more of the support team. Then I interviewed them in a private room, accompanied only by a stenographer.
- 1.7 A stenographer made a transcript of each interview. I gave each person whom I spoke to an assurance that the interview would be in confidence. I draw heavily on these interviews as constituting the voices of those involved. So concerned was I to let these voices inform the Review that I subsequently asked some of those whom I interviewed whether they would permit me to use their words on occasions. Some graciously agreed. Some, for a variety of reasons were not able to agree. In the latter cases, I draw on the sense of what they told me without attributing it to anyone. It is important to note, however, that assertions I make which are not supported directly in the text are in fact drawn from and supported by the evidence that I heard.

- 1.8 The Review was informal insofar as I had no formal legal powers to require witnesses to meet me or give me the benefit of their experience. All who did attend did so voluntarily. I am grateful for the help that they gave me.
- 1.9 In reaching conclusions and making recommendations arising from them, I necessarily had to form judgements as to the strength and reliability of the evidence I saw or which was put to me. Where there was documentary evidence, this, of course, was helpful. But I was anxious to avoid the too-easy assumption that if something was written down it constituted the complete record or account of events and could be relied on unquestioningly. I was equally anxious to avoid the opposite assumption that, if there was nothing written down, there was nothing to rely on. There was, but it existed in the memories of the witnesses. Most of the witnesses whom I saw relied greatly on their memories of events over a period of more than a dozen years. I have had to sift through these, seeking, where possible, some further confirmatory evidence. It its absence, I have had to take a view as to which account I found most plausible. All that follows must be understood on that basis: that the views and conclusions that I reach constitute my best judgement.
- 1.10 I emphasise further that I cannot be sure that I have seen all of the very many papers, e-mails, reports and documents which touch upon my Review. This is not out of any reluctance on the part of the Trust. They have been commendably diligent in giving me access to whatever they had and in unearthing other documents, whether at my request or as part of their attempt to ensure that the whole process was as open as possible. If I have not seen or been referred to something, therefore, it is because it is in the nature of such exercises that some things are missed. My strong sense, however, is that I have been able to paint a fair picture of the events under review<sup>1</sup>
- 1.11 Equally, as regards individuals, with some few exceptions, everyone whom I wanted to talk to accepted my invitation.<sup>2</sup> As I sought to make clear to all of those whom I interviewed and to Executives and the Board of the Trust, my brief was limited. I was not asked by the Trust to deal with disciplinary matters, nor was it my role to examine each and every woman's surgery, or to comment on matters of legal liability or compensation.
- 1.12 Equally, I was not asked to take a view on medical and surgical issues. I am not competent to do so. Instead, I relied on the views expressed by witnesses in their evidence and on the various reports prepared over time, internally and by outside experts. That said, given that my brief was to advise the Board what lessons I thought should be learned, I began with the assumption that lessons for the future can only be drawn from an understanding of the past. To this extent, therefore, I was

<sup>&</sup>lt;sup>1</sup> I asked for and, very belatedly, was given documents (only a very few) relating to the annual appraisal of Mr Paterson. Annual appraisal of Clinical Leads in Cancer was introduced by Mr Wake, as Lead Cancer Clinician, in 2003. I have seen Mr Wake's Note of his appraisal of Mr Paterson in 2003 and in 2006. They are both bland. They give no suggestion of the difficulties which I shall describe shortly. The appraisal of 2006 is noticeable principally for its congratulatory tone regarding Mr Paterson's workload and output.

<sup>&</sup>lt;sup>2</sup> I was disappointed that the past Chairman of the Trust, Mr Wilkinson, and Mr Mark Wake, who led the first investigation into Mr Paterson's surgical practice decided not to meet me. I did not have the opportunity to speak to Mr Paterson. I accept that he may have found it difficult to do so, given the variety of other processes that he is involved in. I do not think that my ability to describe the Trust's response over the years to concerns about his surgical practice was materially affected by not seeing him.

concerned to look closely at Mr Paterson's surgical practice and the involvement of others within and outside the Trust.

- 1.13 My Review is for the Board of the Trust. But there are, of course, two other audiences: the community served by HEFT and the wider NHS. It is for this reason that I made it a condition of my undertaking the Review, a condition that the current Chairman of the Trust<sup>3</sup> was happy to accept, that the Review be published. As regards the wider community, they wish and are entitled to know what I make of things and what lessons I identify. And, insofar as there are matters which are not particular to HEFT but have relevance across the NHS, the NHS may wish to identify any lessons of wider application that it may need to learn.
- 1.14 The Review is presented as a narrative, following events as they unfolded. On occasions, it has been necessary to go forward or backwards in time, for the sake of explaining a particular point or area of concern. But, to a large extent, I have tried to maintain the narrative. The aim is to enable the reader to see things as they were at the time and in their context, and how they developed over time.
- 1.15 The context of my Review is surgery and other treatment for breast cancer. The Review is about how the Trust dealt with a range of concerns over a decade or so. It is not about the details or intricacies of treating breast cancer. But, some understanding of what is involved and of the terms which will appear in the Review is important. I am not medically qualified, nor will most of those who read this Review. Hence, I offer the following explanation drawing wholly on the advice given to me from those I spoke to in preparing the Review.

### **Breast Cancer**

- 1.16 In the words of Dr Stockdale, an oncologist of over 30 years standing, "The purpose of treatment for cancer is to cure it locally, to stop it coming back locally and to, in parallel with that, minimise the risk of it coming back elsewhere and to use adjuvant (something which assists) treatments to reduce the risk of its coming back both locally and elsewhere. It is very clear in all types of cancer that if you cut it out and it is present at the edges (of the cut) there is an increased risk that it will come back at the edge. That is a given and is true of just about any cancer site."
- 1.17 In terms of surgery for breast cancer, there are essentially two responses: a local excision, whereby the diseased tissue is removed, but the remaining breast is left; and mastectomy, whereby the breast tissue is removed leaving behind a flat chest wall (although it is accepted that there may be some small amount of breast tissue which has eluded removal). In the case of local excision, the risk of the cancer returning is between 30-40% over a ten year period, if not accompanied by radiotherapy. In the case of mastectomy, the risk of recurrence depends on the characteristics of the tumour. In some cases, there are clear indications for radiotherapy after surgery because otherwise there is a risk of recurrence in the order of 30-40%. In some cases, the risk of local recurrence is lower, but here also, there is evidence that radiotherapy will reduce the risk. In a third category of cases, where there is a small tumour and no involvement of lymph nodes, the risk of recurrence is 5% or less and radiotherapy is not called for.

<sup>&</sup>lt;sup>3</sup> Lord Hunt of King's Heath who was appointed Chairman on April 1, 2011

- 1.18 If a surgical operation other than a local excision is performed which leaves breast tissue behind, there is a 30-40% risk that over a ten year period cancer will occur in that remaining tissue.
- 1.19 And, if there is a local recurrence after any form of treatment there is a 1 in 4 risk of dying from that local recurrence.
- 1.20 The process of treating a woman with breast cancer, therefore, would first involve a mammogram. This may indicate that the only proper response is the removal of all of the breast tissue. There may be cases when the tumour is fairly discrete, has clear edges and is of modest size. In such a case, the decision may be to remove the tumour with a proper margin and leave a reasonable amount of breast tissue, such that the woman is left with something that looks like a breast. Then, microscopic examination of the tumour may indicate in some cases, that it is spreading. In such a case, a shave may be taken, or more than one shave. The point may be reached when shaves are such that they prevent a good appearance and may not control the cancer locally. In this case, the whole breast tissue should be removed. If there are no lymph nodes involved and the margins are clear and the grade of tumour was reasonable, there would be no indication for radiotherapy. If these conditions are not satisfied, radiotherapy would be considered. If a mastectomy is carried out, subsequent shaves are not called for as the patient should have been left with a flat chest wall.
- 1.21 Margins, and positive margins, figure heavily in what follows. They are really only relevant in the case of local excision, that is in surgery other than a mastectomy. The aim in a local excision is to ensure that there is a clear margin between the diseased tissue and the breast tissue left behind. If there is not, the margin is described as positive; this means that not all of the tumour may have been removed, or the tumour is in a number of locations in the breast (multi-focal disease), or it is what is called carcinoma in situ.

## Themes

- 1.22 In reading this Review, you will see and recognise themes which have figured in a number of reports on the NHS over the years. Indeed, it has been said more than once that, as regards reviews of the NHS, the place may be different, the date may be different, the details may be different, but the underlying issues are only too familiar. They include:
  - challenges in managing difficult and powerful members of staff
  - difficulties in raising concerns
  - inter-professional animosities
  - dysfunctional organisation
  - failures of communication
  - lack of openness
  - a particular style of leadership

- lack of engagement by the Board in the quality and safety of care
- 1.23 In this Review, there are also a separate set of themes which revolve around how to respond to expressions of concern when they are thought sufficiently important to warrant examination. These additional themes are intertwined with the issues just mentioned, yet also have a significance warranting particular attention. One example would be the management of a process of recalling patients. Another is the time taken to do things. As will emerge, the delays in responding to and acting on concerns were significant.

### A busy organisation

- 1.24 Before I begin my Review there is one matter which needs to be addressed. The Trust during the relevant time was always very busy looking after patients. It dealt with all manner of illnesses and needs, including a wide range of cancers. At the same time, the Trust was wrestling with the logistical and other demands of merging hospitals and services, coming to terms with creating a single organisation out of two and then three separate hospitals, geographically separate from each other. Acquiring Foundation Trust status was a further major challenge. The Trust was also learning how to deal with the requirements of the regulatory bodies which emerged, a task made more difficult by the change from the Healthcare Commission to the Care Quality Commission and the sometimes confusing interplay between them and Monitor. And throughout, there were increasing financial pressures.
- 1.25 Some might say that it is a wonder that the Trust was able to deliver any services, let alone do so with some relative success. And, a commentator might then go on to say that, in this context, the breast cancer team was a very small part of a very large enterprise. It would be wrong, therefore, the argument goes, to make too much of the activities of one surgeon in one small corner of the enterprise. Yes, things might have been done differently, or more expeditiously, but, there was a lot going on.
- 1.26 I reject this argument. I accept that there was and is and always will be lots going on. I accept also that the breast cancer team were a small sub-set of the teams looking after patients with cancer and many other illnesses. But, the Trust existed and exists to look after all those in its care. It cannot say that there will always be areas of poor performance (and I have reached the conclusion that there was poor performance in the breast team) and that you have to take the rough with the smooth. Patients are not in a position to choose – given the choice, they would always, of course, choose the smooth. The Trust owes it to them to make sure that there are no pockets of poor performance which go unaddressed because everyone is busy. It is not open to the Trust to say that the big picture is fine even if there is the odd wrinkle here and there. The challenge which every Trust has to face is to ensure that the wrinkles are identified and smoothed out before patients get harmed.

### The voices of patients

1.27 It is possible in responding to the commission which the Trust gave me to become drawn into a range of detailed areas, not least data and statistics, and lose sight of those who must be at the centre of my Review. I refer to patients: women, past and present, who have come into contact with the breast unit. It is their lives which have been affected. It is they who deserve to have an opportunity to understand what went on. The aim of this Review is to give them that opportunity.

- 1.28 In writing the Review, I was most anxious to gain the perspective of patients. They may not know the details of how the Trust was managed. They may not know how the Trust addressed concerns over Mr Paterson's surgical practice. They may not know the statistical details about rates of recurrence. They are, however, experts on how they were dealt with by the Trust and its various employees. They are experts on how they feel in the light of all that has happened. And that expertise is as important to my Review as any other part of the jigsaw. Any lessons to be learned must reflect their experience.
- 1.29 It follows that I am immensely grateful to the many patients who came to see me and who wrote to me. It cannot have been easy to revisit again something which is so painful. But, they did so. And, by doing so, they greatly enriched my understanding. I record my thanks to them.

### **Understanding and Learning**

- 1.30 My responsibility in this Review is to advise the Board on the lessons which should be learned from the events surrounding Mr Paterson's surgical practice. To avoid any possibility of misunderstanding, let me make it clear how I interpret that responsibility. It is to set out the facts as clearly as I can in some ordered fashion and to comment on them as I go along. This will allow those who read the Review to come to informed and considered views and reach their own conclusions.
- 1.31 If lessons are to be learned, those seeking to learn them must get beyond focussing solely on the "name and shame" approach, tempting and appealing as it may be. This is because when things go wrong, (and they did go badly wrong), it is mistaken and naive to imagine that one person or group was solely responsible, with the corollary that blaming and shaming X or Y would make things right again, would solve everything. It would not.
- 1.32 When things go wrong on the scale set out in this Review, it is absolutely crucial to adopt an approach based on systems: to ask what was wrong with the systems of leadership and management in place in the Trust which allowed things to go wrong. That is the question. Once understood and answered, a better system can be put in place which will prevent things being repeated.
- 1.33 The NHS traditionally has not understood the need for this approach. Things have gone wrong, individuals have been blamed, shamed and removed, new individuals have been brought in, and, surprise, surprise, nothing changes. The new individuals are injected into the existing system. If they cannot change it, they are doomed to repeat what went before.
- 1.34 So, in this Review, I am keen to draw attention to features of the system operated by the Trust that led to what happened. I am keen to avoid an approach which focuses solely on blame. This is not to deny that questions of accountability <sup>4</sup> need to be addressed. But, that is not my responsibility. It is a job for others. My responsibility is

<sup>&</sup>lt;sup>4</sup> Accountability is different from blame. Accountability assumes that a system is in place which sets out the rules of behaviour expected, that this system is known to those who are to be held accountable, that compliance with the rules is expected except if there is a good reason to act otherwise, and that non-compliance may attract criticism and sanction. Blame is an after-the-fact, hit-and-miss response, which singles out individuals or groups for criticism without regard to the context or system in which they found themselves.

to offer some understanding of what went on. And, to repeat, more than anything that involves an understanding of the system of leadership and management operating in the Trust over the relevant years and the culture they gave rise to.

## 2 CHAPTER II

## EARLY CONCERNS

## **Mr Paterson's Appointment**

- 2.1 Mr Ian Paterson was appointed by the Trust in 1998 as a surgeon specialising in vascular surgery but also in surgery on women suffering from breast cancer. Previously, he had been a surgeon at the then separate (now part of HEFT) Good Hope Hospital. His appointment was not without incident. He came with something of a reputation as being a difficult person to work with. When he applied for the appointment, Dr Murray, a senior manager at Good Hope Hospital, telephoned one of the Medical Directors at the Trust, Dr Rowland Hopkinson, to alert him to the fact that Mr Paterson had been the subject of an investigation and suspended in 1996 following an incident in which an operation on a patient had exposed the patient to a significant risk of harm. A review had been commissioned by the Royal College of Surgeons. The review had recommended that Mr Paterson should undergo a period of supervised practice before recommencing unsupervised laparoscopic surgery. This was completed and Mr Paterson returned to unsupervised practice.
- 2.2 Clearly, Dr Murray considered this information to be of sufficient importance that he should bring it to the attention of the Trust. Once received, however, it is not clear whether the information was shared more widely, not least with those closely involved in the appointment, Mr Goldman as Medical Director and Mr Gannon as Clinical Director.
- 2.3 Once he had accepted the appointment at the Trust, Mr Paterson's relations with his colleagues at Good Hope, which had been fractious for some time, deteriorated further. Matters came to a head and the Chief Executive of Good Hope Hospital asked Mr Paterson to leave without completing his notice period. In what is a small community of surgeons, it is very unlikely that this would not have been known to those in the Trust. Both Mr Goldman and Mr Gannon were also surgeons and Mr Paterson at one time had been Mr Goldman's Registrar. In addition, even though the decision to appoint had been made prior to Mr Paterson's being asked to leave Good Hope Hospital, the exercise of due diligence would have identified this fact. And, once identified, appropriate action, such as careful monitoring during a probationary period, could have been taken. Solihull was on notice that Mr Paterson's appointment was not without risk.
- 2.4 It is important to understand whether any knowledge of the background to Mr Paterson's appointment was passed on to others, since it is not without significance. Mr Cunliffe, who was the Medical Director during the time of the investigation into Mr Paterson's surgical practice in 2007 and subsequent events and, thus, at the centre of things at a crucial time, was not made aware of the circumstances surrounding Mr Paterson's appointment. There was no record, there was no note, so there was no forewarning of any risk. Mr Gannon was the Clinical Director of general surgery at the time and, as such, involved in Mr Paterson's appointment. So, in theory, he should have been in a position to brief Mr Cunliffe. But he told me, "I recall no communication from any of Good Hope management about Mr Paterson". This must mean that Dr Hopkinson did not tell Mr Gannon, even though Mr Gannon was the relevant Clinical Director and effectively in charge of making the appointment.

- 2.5 What happened would suggest that the corporate memory, so important for a large organisation, was imperfect. Things that should have been known, were not known by those who should have known.
- 2.6 That said, there was a level of informal knowledge. As one of the senior radiologists, told me, "To be honest, when we heard he was coming ... it was, you know, 'What's gone on then?' His reputation was well-known as being difficult and having open rows with a colleague at Good Hope. ... it's always a surprise to us why they took him on when they knew he was trouble".
- 2.7 There was, however, another perspective. The Trust had waiting list problems. There was only one breast surgeon who was finding it increasingly difficult to deal with the increasing numbers of patients. Standards had been introduced requiring that urgent referrals be treated within ten days. The Cancer Network had introduced other Standards. The Trust was failing on all counts. Mr Gannon, the then Clinical Director, was not able to recruit surgeons such that, when the Trust managed to recruit Mr Paterson it was seen as a significant blessing. Another surgeon would help the Trust to deliver the targets.

### The Multi-Disciplinary Team (MDT)

- 2.8 Once appointed, a picture gradually emerges. Mr Paterson is clearly a charismatic person, much liked by his patients and by the nurses who worked with him, extremely hard working, and well-regarded by some as a technically able surgeon. On the other hand, he is not a team-player, was given to being autocratic, and sought to have his own way in the management of patients even though the care of women with breast surgery is quintessentially a collaborative enterprise, calling on the expertise and co-operation of a number of specialists. Mr Paterson was described as high-handed to the point of being dismissive of colleagues. Forewarnings of this pattern of behaviour were already evident when Mr Paterson worked in the vascular unit. This unit was run in a very collaborative way, but Mr Paterson did not participate and rarely attended the MDT. When Mr Paterson moved to breast surgery, he behaved in a similarly challenging way. The hope was, it appears, that the managerial and governance arrangements in place would deal with whatever had to be dealt with. It was a forlorn hope.
- 2.9 Given that care is collaborative, the agency for the necessary collaboration is the multi-disciplinary team (MDT). The MDT was described to me as "the cornerstone" of practice throughout the country. Mr Lee, a distinguished breast surgeon told me that "Multidisciplinary teams in breast surgery are absolutely crucial to delivering good quality practice and one of the things that has been a concern all along with [Mr Paterson] was the poor relationships in the team. Even if you have somebody who is a highly technically competent surgeon [on which, as regards Mr Paterson, Mr Lee expressed reservations, as I shall set out], if they are not working effectively as a member of the team, then their patients will be at risk...".<sup>5</sup> Mr Paterson did not appear to see it that way. He saw himself as the leader, maintaining a high profile,

<sup>&</sup>lt;sup>5</sup> The words "arrogant" and "bully" were used by a number of members of staff. A surgeon who knew and trained and worked with Mr Paterson for some years described Mr Paterson as a "dysfunctional consultant". He had, I was told, "... a very aggressive, bullying sort of personality, which allowed him to get his way ... people would generally go around him, they were afraid of him. ...he didn't want anyone to get in his way. Because of his personality he tended to be isolated and he quite liked that, so people would avoid him, go around him and not deal with him, so he never got questioned or hauled up ...".

doing most of the surgery, and operating on large numbers of patients in a single operating list.

2.10 The result was that the team caring for women with breast cancer did not work successfully as a team and Mr Paterson's behaviour was a central reason why. As a consequence, the care provided to women, given that its success contemplates a well-functioning team, was, on any objective assessment, to some degree compromised. This being so, the appropriate response would have been some sort of remedial intervention by those with managerial responsibility. After all, senior managers at the time were on notice that Mr Paterson, once appointed, would need careful management. And, the concerns of others in the Multi-Disciplinary Team (MDT) were fairly widely known.<sup>6</sup> Moreover, as I shall mention in due course, two surgeons, one of longstanding (Mr Taylor) and one recently recruited (Ms Bello), left the Trust, having found it difficult to work with Mr Paterson. At this relatively early point, however, in the years between 1998 and 2003, no effective action was taken.

### The Oncologists' Concerns

- 2.11 The concerns of others were not confined to the working (or lack of working) of the MDT. From 2002-03, the oncologists, Dr Stockdale and Dr Fernando, in the Breast Team had begun to be concerned about Mr Paterson's surgical practice: how he was carrying out his operations.<sup>7</sup> Both of these oncologists, though part of the team, were employed by a separate Trust, something which may have affected how events developed. As will appear, they felt like outsiders, even though they were members of the MDT; that they were not listened to or that their views did not carry weight. They raised concerns on occasions about Mr Paterson's surgery in the MDT but saw them dismissed.
- 2.12 Speaking of concerns in 2003, Dr Fernando told me that, "what happened was we had had concerns with regard to several individual cases that we had seen clinically and we decided to handle it the proper way ... which is to take it to the Multi-Disciplinary Team meeting and say we were not happy with certain cases because we felt that when we'd seen these patients they hadn't appeared to have the normal standard mastectomy that we were used to seeing. There appeared to us a significant amount of residual breast tissue, so much so that there were some situations where patients were actually able to have a mammogram after a mastectomy".
- 2.13 "We felt that rather than take this immediately to the Trust, we first discussed it directly with the surgeon concerned who was lan Paterson. Ian Paterson, on every occasion, reassured us that he had taken out all the breast tissue and that he was leaving a little bit of skin and cleavage for cosmetic purposes alone. This happened

<sup>&</sup>lt;sup>6</sup> See for example the exchange of letters between Dr Wallis, the Director of Breast Screening at Coventry Hospital and Mr Paterson on September 3 and 19, 2004 respectively.

<sup>&</sup>lt;sup>7</sup> Mr Stewart Nicholson, a Consultant Breast Oncoplastic and Endocrine Surgeon wrote in his report to the GMC which was cited at the hearing on July 6, 2011, "It is clear that [Mr Paterson] deliberately did not carry out the procedure mastectomy [sic] preferring his own version which has no basis in surgical science and in addition not recording at any point in the case notes his deviation from standard practice". Mr Nicholson stressed three other aspects of his conduct which caused him to conclude that Mr Paterson's conduct fell seriously below that expected: performing a form of operation which had not been consented to; failing to acknowledge that by doing so she was exposed to a greater risk of recurrence of the disease; and continuing to carry out the procedure in the private sector when he had been required to discontinue it in the NHS.

in several cases..." . Though the matter was not taken formally to the Trust, it is clear that the Chief Executive and senior managers were aware that there were clinicians who had concerns about Mr Paterson's cancer surgery. But, senior management, for whatever reason, persuaded themselves that the concerns were technical and surgical, rather than deeper concerns about the form of operation that Mr Paterson was carrying out. And, being technical, surgical issues, they were for the MDT and local management, with surgical input, to sort out.

## Dr Stockdale's Audit

- 2.14 So concerned, however, was Dr Stockdale that he decided to carry out an audit of 100 consecutive patients referred to him, beginning on January 1, 2003. To confirm that his concerns were well-founded, Dr Stockdale sent a letter on January 15, 2004, enclosing this audit to Dr Grieve, Consultant Clinical Oncologist specialising in breast cancer and the Lead Clinician for Research in the Cancer Network, "in the hope that this may form the basis of a comparative audit for patients with breast cancer" across the Network. To ensure that his audit was objective, he looked at 100 consecutive cases regardless of who was the operating surgeon. But, given that 90% of the surgery was carried out by Mr Paterson, it was clearly Mr Paterson's surgery that gave rise to the concerns.
- 2.15 I am not privy to any conversations which may have taken place which would have explained the context of the audit, but it does not need a great deal of insight to work out that Dr Stockdale was drawing attention to something of importance. The audit identifies that there were 41 mastectomy operations and 55 wide excisions <sup>8</sup>. The distinction is important, because re-operation and shaves, as I have said, may be a feature of wide excisions but should not be in the case of mastectomies. Dr Stockdale was clear when I spoke to him that what prompted him to carry out the audit was that "what I was seeing was out of the range of what I'd seen in my previous experience with a whole range of other breast surgeons". What concerned him particularly "were patients having multiple operations".
- 2.16 As Dr Fernando explained, the oncologists' concerns were not only about positive margins but also that "all the breast tissue wasn't being removed and ... that he [Mr Paterson] was doing what was being called 'shaves after mastectomy' which is ... a practice which we had never [encountered]". (As I have set out, further operations to remove tissue (shaves) should not be called for if a mastectomy has been carried out).

## The Pathologists' Concerns

2.17 Concerns were also raised by the pathologists at the Trust around 2002/2003. Dr Tanchel, the senior pathologist and, subsequently, one of the authors of a letter about Mr Paterson's surgery sent in December 2007 to the Chief Executive, Mr Goldman, told me that he and a colleague had spoken to senior managers, including Mr Hendrickse, the Clinical Director – Surgery, about a particular case. "We were told that they were aware of these issues", he told me. "It was like 'You're not telling us something we don't know already'", he added. Clearly, "issues" suggests more than one case. Dr Tanchel confirmed this: "It wasn't the only – we felt he [Mr Paterson]

<sup>&</sup>lt;sup>8</sup> The audit is set out in Appendix III

was maybe just working too quickly and margins were getting a bit close and perhaps that's why something got left behind and we did raise that we had some concerns and we were told not to worry about it, so for the next few years we didn't say anything".

2.18 It may be thought that those last few words of Dr Tanchel are of very great significance. He added, "We'd had that one experience and nothing changed; so I guess you're more reluctant to do it again because you think, well, I've raised this in the past. ... We did what we thought we should do and it led nowhere". By way of further explanation, Dr Tanchel threw some light on the prevailing culture by telling me that he and his colleague were, at the time, both young, recently appointed consultants, and "It was quite difficult as a very junior person to comment on somebody". So, concerns went unaddressed.

#### The Breast Care Nurses' Concerns

- 2.19 Similar concerns were also raised at this time by some of the Breast Care Nurses: that Mr Paterson was leaving behind tissue after carrying out a mastectomy. They were reassured by him that any tissue was fatty tissue<sup>9</sup> which was left so that patients could have a more satisfying aesthetic appearance after surgery. Quite whether the nurses should have accepted that assurance is an issue of some importance. After all, the assurance was being given by the person whose operation was being questioned. It might be expected that he would justify it. One breast care nurse, not part of the team at Solihull, told me that she had been trained, as were all such nurses, as to what constitutes a mastectomy. A mastectomy, she said, is the removal of all breast tissue leaving a flat chest. She was of the view that the nurses should have gone to another surgeon to share their concerns and taken advice. That they did not do so can probably be explained by the regard in which they held Mr Paterson initially, and because of his charismatic personality. But, it meant that another avenue of challenge was not opened. An opportunity was missed.
- 2.20 My exchange with two senior breast care nurses about what happened subsequently, around 2007, is instructive. I referred to the fact that they had been seeing patients for some years who had had a "mastectomy" but had tissue remaining and, on occasions, were then having further surgery. I asked them what was going through their minds. One told me, "I think initially for a long time I probably personally ... went along with the Paterson line ... because ... I worked with him, trusted him, believed him when he told me things, but then, when it got to the point where I started to think this isn't right ... everybody else knew about it and I knew that there were things going on which were kept behind closed doors". She told me, "... we didn't know what was going on but we knew something was going on and we were preparing ladies for surgery and he was still operating on them and I ... was worried that we were telling ladies that, 'This is fine, yes, have your operation with him', but knowing that there was something going on but we didn't really know what it was".
- 2.21 They told me that by the time their own concerns were coming to the fore, "everybody was aware of this". One replied, "... it's like stating the bleedin' obvious, they already knew. ... the senior management had been informed by the rest of the

<sup>&</sup>lt;sup>9</sup> See the letter sent to a patient on June 20, 2012 in which the General Manager for Surgery wrote, "... when breast care nurses raised with the surgeon the potential for greater tissue being left post operatively in some patients, they were reassured that any remaining tissue was fatty tissue only, rather than excess residual breast tissue"

team, the consultants, and I can see that us adding our voice to that may have had – well, I don't believe it would have had any effect but I can see that there is an argument that you could say, well, you know, you didn't raise concerns as well but they'd already been raised...". The other nurse added, "We were aware that concerns had been raised in a formal manner by Drs Stockdale and Fernando and they had been quashed, thrown out, investigated".

2.22 She told me that she had asked to see Mr Cunliffe after he had become Medical Director–Surgery and said to him, "I'm worried that I'm, kind of, recommending this guy as a surgeon and because we prepared ladies for surgery, you know, is there something we should know ... and he was very clear that it was not anything that we were to concern ourselves with. They were all HR issues". Clearly, there had been no effective communication between the breast care nurses and senior managers. And, as I shall point out, once the HR procedures were invoked, everything was covered by a blanket of confidentiality. Like others, they were kept in the dark.

### The Procedure

- 2.23 The procedure carried out by Mr Paterson came to be known subsequently as a "cleavage sparing mastectomy" (csm), but at the time was not described as such, save, perhaps, by Mr Paterson himself to some patients as a precursor to their operation. I have seen only one set of notes in which Mr Paterson, in writing to a patient's GP on August 29, 2007, specifically uses the term. He wrote of proposing to carry out "a prophylactic cleavage sparing right mastectomy". In a later letter to the GP on October 16, 2007, Mr Paterson wrote that "I have left her with a little bit of medial cleavage".<sup>10</sup> It would be wrong, therefore, to assert, as do some, that the term was a later creation to lend some kind of validity to Mr Paterson's approach. All that can be said is that, although Mr Paterson may have used it, it was not a term that was used by other members of the breast team, nor the wider surgical community. As a term to describe a surgical procedure in breast cancer surgery, it was unknown.
- 2.24 One patient describes seeing Dr Stockdale on April 22, 2003 after having a mastectomy. She told me that Dr Stockdale, on seeing her in his clinic, said, "You've got far too much breast tissue there". She went on that this "... came as a shock, because we [she and her husband] thought, 'How has that happened?' and he [Dr Stockdale] was annoyed I think, not annoyed with us, but annoyed with the situation." Another patient, having undergone a csm in August 2005, developed secondary cancer in 2007 and began to see Dr Stockdale. She told me that when, in 2009, Dr Stockdale informed her of concerns surrounding the operation, she had said to him, "'If you remember, I did have two small operations in 2007 because I had a recurrence in the scar' and he replied, 'If it had been done properly, that wouldn't have been necessary', which I thought was quite an outspoken thing to say. I was quite shocked. I said to him, 'Right from the word go I distrusted this little mound of tissue' and he said 'Your instincts are absolutely right. I would prefer the chest wall flat, it is much safer'".

<sup>&</sup>lt;sup>10</sup> Subsequently, Mr Paterson (in breach of the procedure which was agreed in 2008) operated on her again in April 2011 to remove residual breast tissue, but she was found on subsequent examination by another specialist in July 2011 still to have in the order of 400g of residual tissue on the right side and "a moderate amount" on the left side.

2.25 By way of interrupting the narrative, it is important here to notice that, while it may have been explained to some patients that the "mastectomy" proposed by Mr Paterson involved, on occasions, leaving behind some tissue, it cannot be deduced from this that women thereby consented to this form of treatment. They were not in a position to determine whether what was, in effect, a "partial mastectomy", or csm, (if it was so described), was an appropriate form of mastectomy, both because they did not possess the relevant expert knowledge, and because the circumstances in which they found themselves, diagnosed with a potentially fatal illness requiring immediate action, meant that they were in no position and had no inclination to question the action of the person into whose hands they were placing their lives. Thus, to be clear, there can be no question that women consented to csm. I will have to return to this issue of the consent of patients in due course.

# 3 CHAPTER III

# MR WAKE'S REPORT

## The Background

- 3.1 The Trust had in place a system whereby clinicians were periodically appraised. In his appraisal by Dr Milligan in November 2003, Dr Stockdale used the opportunity presented by this formal mechanism to raise his concerns. With Dr Fernando, he also went to see Mr Wake who was the 'Lead Cancer Clinician'. What followed was an investigation by Mr Wake. It was commissioned by the then Medical Director Surgery, Mr Gannon, precipitated by "concerns raised by an oncologist".<sup>11</sup> It is clear, however, that the Chief Executive, Mr Goldman, was ultimately responsible for causing Mr Wake to carry it out. Mr Wake produced a Report in January 2004.
- 3.2 Mr Wake's Report is an important milestone in the Trust's dealings with Mr Paterson and the breast team. I must, therefore, spend some time exploring it.
- 3.3 The starting point is the fact that the Report was only unearthed by the Trust in December 2012, as part of the process of identifying documents which would be of interest to my Review and more generally. That there was a Report is clear. That it described concerns and made recommendations is also clear. That some action was taken during 2004 and 2005 seems clear. What is also clear is that, thereafter, it disappeared from view and, thus, disappeared from the collective corporate memory of the Trust. The importance of maintaining and developing a corporate memory, whereby those coming after will be apprised effectively of what went before, and the Trust's weakness in doing so, will be a recurring theme in this Review. What it meant here, in the case of the Wake Report, is that if the Report had any standing, it was not clear, even at the time, what that standing was. And, as time passed, and the words of the Report became replaced by word-of-mouth representations of what it was thought it said, it came to be represented as something much more limited than it appears on its face.
- 3.4 On its face, the commissioning of Mr Wake's Report constitutes the first formal response by the Trust to concerns about Mr Paterson's surgical practice. It followed Dr Stockdale's audit. But, surprisingly perhaps, the audit did not appear to have informed Mr Wake's approach nor his Report. Dr Stockdale told me that he had not given Mr Wake his audit, but, as confirmed by a note of the meeting, had told him that it had been completed. "I explained to him what it [the audit] had been, the numbers of patients I'd seen, the conclusions I'd come to. He [Mr Wake] at no stage asked for the source data; he at no stage collected that to allow himself the opportunity for it to be reviewed. ... That's an extraordinary omission".
- 3.5 When I asked him what he thought should have been done in the light of his audit, Dr Stockdale replied: "They should have said firstly, 'OK, these are extremely serious allegations you are making, show us your data. ... They should [on seeing the data] have said, 'Right, OK. I am not a breast surgeon, let us get someone to look at this

<sup>&</sup>lt;sup>11</sup> Correspondence from Mr Gannon to Mr Wake.

data', and within about half an hour someone would have said, 'Hang on, firstly the margin rate is far too high; and secondly, the patients in here have had more than one mastectomy. What's going on?' End of story".

- 3.6 "You establish you have got a problem, and you take an external review, you confirm you have got a problem and then you put it on record. You say, ... 'there's a problem here ... we will monitor the team for the next six months, look at the results and see where we go'".
- 3.7 That did not happen.

### The Report

- 3.8 Instead, Mr Wake proceeded to produce his Report. It was submitted to the Medical Directors (of whom there were three). It constituted a "... summary statement following my [Mr Wake's] review of personal notes and internal discussions". It is divided into four sections:
  - Performance Review
  - Appraisal of the Breast MDT
  - Leadership
  - Recommendations
- 3.9 As regards the *Performance Review*, Mr Wake refers to the "remarkable performance" of the MDT given the high number of patients referred to it and staffing problems. Mr Wake adds that, "The Lead Clinician's [Mr Paterson] industry is particularly to be commended". This may seem a strange beginning in terms both of what follows and of what gave rise to the investigation in the first place: that there were concerns about Mr Paterson's surgical practice.
- 3.10 As regards the *appraisal of the MDT*, Mr Wake writes that the system of annual appraisals recently introduced had led to "a number of concerns" being raised by members of the Breast MDT. The concerns fell under a number of headings. The first related to the working arrangements of the MDT: too many cases were brought to meetings to allow adequate discussion. There was "particular concern over the infrequency of pre-treatment MDT discussions for new cases of breast cancer .... and insufficient pre-treatment or pre-selection discussion of ladies selected for immediate reconstruction and in particular, there appears to be very little input from oncologists pre-operatively". The difficulties in the arrangements for video conferencing across three sites "sometimes makes the smooth working of the MDT difficult" and "restrict the ability for any inter-specialist reviews and discussions".
- 3.11 The second concern related to pre-surgery discussion. A number of the members of the MDT were, according to Mr Wake, "concerned about the infrequency or irregularity of pre-surgical discussion of cases of newly presenting breast cancer".
- 3.12 A third concern reported to Mr Wake is of very considerable importance. It goes to the heart of the way in which the MDT was working (or not) and captures what other members of the team were concerned about. Mr Wake writes that, "It appears that patients attending for oncology opinions regularly attend with preconceived ideas

regarding the advice and subsequent treatment they will receive. ... the patients' perceptions are ... on occasions confused by the conflicting advice they receive from the surgical and oncological members of the team over the role of chemotherapy in their individual treatment plan". The care of patients cannot have been optimal in the face of such behaviour, whereby Mr Paterson was pre-empting the views of colleagues in advance of the MDT.

- 3.13 The fourth concern referred to by Mr Wake is of crucial significance in the light of what followed. It warrants careful attention such that I need to discuss it at some length here. It is not reflected in the Recommendations that Mr Wake made and is reported somewhat laconically. He writes that "A number of MDT members have observed what they believe to be an unusually high incidence of positive margins <sup>12</sup> in ... patients undergoing surgery for breast cancer at Birmingham Heartlands and Solihull NHS Trust". "Whilst there is insufficient information", he goes on, "at the time of writing this report about the potential significance of the relatively high incidence of positive margins on loco-regional control rates, [the] rates of revision operation[s'] impact on prevalence of metastatic disease, or overall survival, there is a view within the MDT that relatively conservative surgical resections are performed which are aesthetically pleasing but these may compromise the completeness of the excision and that this may have a negative impact on subsequent relapse rates [my emphasis].
- 3.14 Dr Fernando was adamant in his conversation with me that he had specifically told Mr Wake that the presence of residual breast tissue after mastectomy was one of his concerns. He referred to a copy of Mr Wake's handwritten note of the meeting Mr Wake held with him and Dr Stockdale, dated December 18, 2003. At one point, the note records Dr Fernando as saying, "Difficult to tell if they've even had an operation. So much tissue left behind that no need to have a subsequent reconstruction. ... a unique form of mastectomy unique to IP [Mr Paterson]". As a consequence, Dr Fernando was in no doubt that the paragraph I have highlighted above referring to the completeness of the excision was a clear reference to Mr Paterson's practice of leaving tissue behind (what came to be known as csm). As such, he expressed concern that no action was taken, even if there was no recommendation concerning it.
- 3.15 Mr Gannon, however, saw the paragraph as referring to local excisions rather than mastectomies. Since I did not have the opportunity to talk to Mr Wake, I cannot resolve the question. My view is that both of these views are plausible. But, that said, Mr Wake was aware at the same time of Dr Fernando's concerns and Dr Stockdale's audit in which re-operation in the case of operations described as mastectomies was a prominent feature. And, he will have been aware of the concerns expressed by the breast care nurses and the reassurance offered.
- 3.16 On balance, I am drawn to the conclusion that the somewhat elliptical reference to the completeness of the excision should, in the context, have been read as involving a reference to Mr Paterson's failure, on occasions, to carry out a complete mastectomy as well as to the problem of positive margins. This conclusion, which some may not accept, is significant for much of what I say in the remainder of this

<sup>&</sup>lt;sup>12</sup> The margin is the edge of the surgical intervention to remove the tumour and the concerns about positive margins related to whether the tumour is present at the edge, in which case, further intervention is called for, because, as I have explained a positive margin is associated with an enhanced risk of relapse.

Review. I do not reach it lightly. But, in all the circumstances, I think it is justified. I repeat what Dr Stockdale said when I asked him about what should have been deduced from his audit: "'the patients in here [the audit] have had more than one mastectomy. What's going on?' End of story". And, certainly, Mr Jewkes, (a breast surgeon of long experience, then at Good Hope Hospital), told me that he was told by the oncologists that their concerns at the time very much included tissue left behind after mastectomies.

- 3.17 On this view, therefore, Mr Wake was referring to the issue of "partial mastectomies". After all, no concern was being expressed in the MDT about whether the results after a wide local excision were "aesthetically pleasing" or not. Thus, on the basis of what it says, the paragraph could only be significant if it is referring to what would otherwise be a mastectomy. Moreover, even if there was no explicit reference, there was an abundance of other evidence that it was a matter of considerable concern, such that Mr Wake's Report should have been read to refer to it.
- 3.18 I am strengthened in the view that I take by noticing that in a later Report, which I will discuss in due course, Dr Polson, the author of the Report, referred to concerns expressed in 2003 about Mr Paterson's "clinical competence". When I asked Mr Jewkes, who was interviewed by Dr Polson, what Dr Polson was referring to, he replied, "... certainly it was do with margins, it was to do with extra breast tissue left behind, it was to do with in a sense his lack of engagement with the MDT process, that he would not in a sense enter into any collaborative working with them, so they had lost confidence in his ability to deliver up-to-date, modern, safe care ...". Equally, Mr Hennessy, a distinguished breast surgeon who was later brought in by the Trust to undertake a review, was in no doubt that the concerns raised in 2003 included concerns that tissue was being left behind, with the consequence that some patients were have a recurrence of their breast cancer. This duly started to happen in 2007, at which point Dr Stockdale, at this occasion with the support of a surgeon, Mr Ingle, raised his concerns again.
- 3.19 In my view, Mr Wake's Report, and particularly this section, whether read alone or against a background of what the oncologists, pathologists, and others were saying, should have prompted resort to outside advice from an independent specialist breast surgeon. Had such advice been taken, it would have not taken long before the expert would have seen that re-operations after a mastectomy were being carried out and asked what was going on. But, such advice was not taken. An opportunity was missed. Confusion was sown, a confusion which allowed the Trust to downplay the concerns expressed in 2003 and the significance of Mr Wake's Report. What was an important first chapter in the story of Mr Paterson's surgery became re-categorised as mostly to do with the man-management of the MDT.
- 3.20 The fifth concern reported by Mr Wake related to the selection of patients for immediate reconstruction. This was to take on considerable significance later, as women who had undergone a csm followed by immediate reconstruction would not know whether breast tissue had been left behind before the reconstruction was carried out.
- 3.21 In his discussion of *Leadership*, Mr Wake writes that "There are significant interpersonal problems within the working of the Breast MDT". This may be thought to be an understatement. He goes on to talk of the MDT meeting having become a "negative experience" for some members. The atmosphere "is unnecessarily adversarial", there is a "lack of mutual respect shown to non- surgical members of the

team and insufficient regard to other people's opinions, when these are at variance with the Lead Clinician [Mr Paterson]". In his conversation subsequently with Dr Polson, when Dr Polson carried out a later review, Mr Wake described the MDT as "too surgically led" and "too strongly chaired by IP [Mr Paterson]; who was too dogmatic, disregarding others".<sup>13</sup> The reader is left in no doubt as to the disruptive nature of Mr Paterson's behaviour. From the perspective of patients, depending as they did for their care on a well-functioning MDT, this behaviour is deeply concerning. Not only should it not have been allowed to come to pass, it needed to be remedied once known about.

- 3.22 Mr Wake made a number of *Recommendations*. The first three addressed the problems with the MDT. He recommended that the "audiovisual deficiencies causing operational problems ... be addressed by the Trust as a matter of some priority", but it is clear that these remained a source of frustration and concern for years. A fourth recommendation was clearly designed to address the concerns over positive margins. Mr Wake called for an audit to be conducted and the results compared to regional and national norms "if such data is available". Audits supply the raw material, the unanalysed facts, from which understanding and, where necessary, action can emerge. It was natural and proper that Mr Wake would call for one, even though Dr Stockdale had already produced one.
- 3.23 Mr Wake recommended that, as regards patients offered immediate reconstruction, selection criteria should be agreed in line with regional and national guidelines. They were to be agreed by the whole of the MDT.
- 3.24 As I have said, there is no recommendation specifically about ensuring the completeness of the excision rather than being concerned with aesthetic considerations. Given that it was the concern about tissue being left behind that prompted the investigation, the absence of a particular reference to the issue is, perhaps, unfortunate. It seemed to allow the concern that lay at the heart of everything to slip by.
- 3.25 It also contributed to shifting the emphasis to the scientific-technical issue of what constitutes a "proper" margin; a debate which is still going on. The issue for the Trust, and for the breast team and those responsible for managing it, was not one of margins. To a degree, this is one of the several red herrings drawn across the track of Mr Paterson's surgical practice, just as arguments about data became later. The central issues were that tissue was being left behind after a "mastectomy" and that patients were undergoing an operation that they had not consented to.<sup>14</sup> In all that follows it is hard to keep these two issues in centre stage. But, that is where they must be.

### The Aftermath of Mr Wake's Report

<sup>&</sup>lt;sup>13</sup> Mr Hennessy, who also carried out a later review, confirmed that one of the greatest concerns felt at the time was that what was decided at the MDT, which should govern the direction of the patient's care thereafter, was being routinely flouted by Mr Paterson.

<sup>&</sup>lt;sup>14</sup> As Mr Budhoo, put it to me, it "was not just about margins. Margins were actually about lumpectomies rather than a mastectomy".

- 3.26 Mr Wake clearly saw it as important that the audit he called for should be carried out. No such audit was, in fact, carried out. In conversation with Dr Polson, Mr Wake said that he had subsequently asked for the outcome of the pathology audit. He said that he had been met with "What Audit?" The audit was not carried out, Mr Wake told Dr Polson, because "there was a conscious decision not to do it by pathology; even though they had all agreed to do it". The pathologists do not share this view. According to the pathologist, Dr Tanchel, "there was a lot of confusion. ... I think we thought the clinicians were doing the audit and they thought we were doing the audit". What happened was to him an example of "mis-communication" and "poor management". An alternative reason advanced was that Mr Paterson had changed his surgical practice regarding taking shaves, such that the pathologists felt they would not be able to have consistent data from which to draw conclusions. But, whatever the reason, the audit slipped through the net, and no-one told Mr Wake. Another opportunity, this time to be able to point to hard facts, was lost.
- 3.27 The oncologists whose concerns prompted the Report eventually saw Mr Wake's Report, when it was unearthed in 2012. Dr Fernando at least saw Mr Wake's reference to the incompleteness of Mr Paterson's surgery, as a clear, albeit elliptical, way of referring to their concerns that breast tissue was being left behind after an operation which was supposed to be a mastectomy, ie an operation intended to produce a flat chest wall. Unfortunately and surprisingly, the oncologists did not see the Report at the time and so were unable to press this point.<sup>15</sup> This failure to involve them in the outcome of an exercise which was a direct result of their concern is an example of the poor communication between various members of staff and managers, and of a lack of managerial leadership and rigour which runs through the evolving story of the Trust's response to Mr Paterson's surgical practice

#### Response to Mr Wake's Report.

- 3.28 Mr Wake's Report was addressed to the three Medical Directors. One of these was Mr Gannon, the Medical Director responsible for surgery. He responded by instituting a number of activities to remedy the dysfunctional working of the MDT, including four Away Days, between May 2004 and April 2005. He also sought to persuade the other breast surgeon, Mr Balasubramania (known as Mr Bala) to become lead clinician. He finally agreed to do so in 2006 (he was initially reluctant to replace Mr Paterson, given Mr Paterson's standing).
- 3.29 But, what of the Recommendations regarding Mr Paterson's surgery and the concerns expressed which were reflected in one way or another in Mr Wake's Report? An audit, whether limited to the issue of margins or more widely cast, would have been the well-recognised method of addressing at least some of the concerns and exposing the evidence. As I have said, the audit called for was not, in fact, carried out.<sup>16</sup> An opportunity was missed. Nor is there any evidence of an

<sup>&</sup>lt;sup>15</sup> Neither did Dr Fletcher, one of the radiologists who had expressed concern over Mr Paterson's surgery, "... never seen Mr Wake's report; never seen Colm Hennessy's report [which I will discuss later]; we've never seen anything ...". He also did not see Dr Polson's report, which I will refer to in due course: "We were pretty angry about that". Equally, Mr Balasubramania, the other breast surgeon at the time told me that he did not know about nor see Mr Wake's Report. He told me, "Nobody told me exactly what was done but all I heard was that it [the concerns of the oncologists] was looked into and they didn't find any major issues".

<sup>&</sup>lt;sup>16</sup> Mr Gannon claimed that it was in his interview with me, but the paper he referred me to concerned something different, as Mr Bala and others confirmed.

examination of the criteria to be used for immediate reconstruction. Another opportunity was lost.

- 3.30 It is not clear why no action was taken other than with regard to seeking to address (with some limited success<sup>17</sup>) the working relationships of the MDT. There was clearly a lack of leadership by those responsible for the functioning of the Breast Team. There was a failure to address what was happening; a failure to grasp the potential seriousness of the situation if the oncologists were right; and a failure to find out if they were right.<sup>18</sup> There can be no doubt that the Chief Executive saw Mr Wake's Report. It may well be that he would have regarded the implementation of Mr Wake's recommendations as a matter for the local action. In other words, that it was for Mr Gannon to act.
- 3.31 When Mr Cunliffe, the Medical Director Surgery who succeeded Mr Gannon, was appointed in 2007, he had not seen Mr Wake's Report. He was made aware of it after writing to Mr Gannon. It appears that, rather than asking to see a copy of it, he sought Mr Gannon's advice about it. He was told that the necessary actions had been taken and the matter had been brought to a close during 2005. Mr Gannon can only have been referring to the measures taken to improve the MDT. The concerns about Mr Paterson's surgery had not been addressed.
- 3.32 A member of staff with a particular and personal interest in the Trust's actions told me that, in conversation with Mr Goldman, he told her that concerns had been raised in 2003-4 but had not been escalated as far as the Chief Executive. This must mean that he would have known informally but had not been asked formally, as Chief Executive, to act and had not recognised the need to do so, based on what he had been told and knew. The member of staff told me further that Mr Goldman "apologised [to her] and said that, you know, the Trust had made the wrong call".
- 3.33 Thereafter, Mr Wake's Report was filed in the corporate memory, to the extent that there was one, as being only about the MDT and how to improve its functioning. Time and again later, if the Report was known about at all, it was understood in these terms. The very real concerns, backed by Dr Stockdale's audit, and Mr Wake's recognition that the concerns were real and should be addressed, seemed to have fallen on deaf ears. It is not clear why. I was anxious to pursue the question with Mr Wake himself but he declared himself unable to meet me.

#### The Outcome of Mr Wake's Report

3.34 The only real conclusion after Mr Wake's Report is that Mr Paterson continued to carry out surgery on women with breast cancer as before. A number of measures had been taken to seek to address Mr Paterson's behaviour. The MDT performed somewhat better temporarily and, therefore, the care received by women, which is quintessentially a team effort, was to a degree, more considered. But, Mr Paterson's surgery went unappraised and, effectively, unchallenged. He continued to perform

<sup>&</sup>lt;sup>17</sup> Dr Fernando among others spoke of an improvement in Mr Paterson's behaviour: "He was less aggressive and less confrontational".

<sup>&</sup>lt;sup>18</sup> The QA (Quality Assurance) visit on April 21, 2004, which I shall refer to later, also expressed concerns over the MDT, highlighting three areas warranting attention and asking to be informed about action taken. And, Dr Milligan was still writing to Mr Wake on September 4, 2004, asking that Dr Stockdale's concerns be resolved.

mastectomies on occasions in such a way that significant amounts of tissue were left behind. The unacceptable became the norm.

- 3.35 This outcome had a very significant effect on the oncologists and others in the MDT. As has been said, they were not shown Mr Wake's Report nor made aware that it made Recommendations, let alone what they were. This was a serious failure of communication and prompts questions about the style of management and leadership employed by the Trust. The oncologists and the rest of the team saw some improvement in the MDT but their underlying concerns remained. They felt that they had been ignored. They took the view that because they were not surgeons, they were defined out of competence. As Dr Stockdale put it, "I had taken the trouble to go through 100 cases, two thirds of my case-load for a year basically, and anything other than the most rudimentary examination of that would have shown substantial problems and the Trust took not a blind bit of notice of it and, not only that, they swept it ... under the carpet". The level of anger and frustration in Dr Stockdale's comment is plain to see.
- 3.36 And there was more. It was emphasised to me that Mr Wake's responsibility as Lead Clinician was for the quality of cancer services. He was not responsible for matters of throughput and waiting times, important as these might be. Yet, it was pointed out that the first two paragraphs of Mr Wake's Report were concerned precisely with those other matters. The first paragraph refers to meeting the two week waiting target for urgent referrals on 100% of occasions for more than 24 months, and meeting other targets on a 100% of occasions or with "a small number of breaches". The next paragraph states that, "Given the high number of referrals and medical staffing problems with the MDT, this is a remarkable performance. The Lead Clinician's [Mr Paterson] industry is particularly to be commended ...". The breast care team, I was told, on reading the Report years later found those opening paragraphs "very illuminating". "I do not perceive that that report was written independently by Mr Wake", one of them said. Because of the opening reference to the "remarkable performance" and the role of Mr Paterson in that performance, they saw the Chief Executive, while not writing the Report, as having had a hand in ensuring that the initial impression was a favourable one; that any criticism or comment should be seen against that background. This was a perception born, it may be said, of years of frustration and growing suspicion. To a degree, it does not matter whether it is true. It is true that they believed it. And, they believed it because the quality of communication and the unwillingness of senior managers to confront their concerns created the space in which such beliefs, true or otherwise, could fester.
- 3.37 I asked Dr Stockdale what he would have done. He had some experience of senior management as a clinical director in his own Trust. His reply was: "... if, as a Medical Director ... someone said, 'Listen, there's a problem with a colleague', then I would say, 'Document it. If you document it I can look at it and investigate it' I did document it. I presented a large volume of objective data which was ignored. It should have been looked at, it should have gone up to the Medical Director, the Medical Director should have taken an opinion on it, it should have been an informed open opinion ... and probably it should have gone outside. They should have taken a second opinion on it". Any second opinion should have been from a breast surgeon. Dr Stockdale told me that he "was more concerned about the positive margins", but a breast surgeon would have seen the whole picture and identified the central concern. "It would have been abundantly clear that this man [Mr Paterson] was doing 'partial mastectomies' in 2003 and earlier. ... You could see that there were multiple

mastectomies being done ... and anyone from a breast surgical background should have been able to say, 'Well, actually, something is not right here'".

- 3.38 A further point may be of relevance. As I have said, the oncologists were employed by a different Trust. It was put to me that the managers and clinicians from one Trust which relies on services, such as pathology and surgery, from another Trust, can find it difficult to get concerns addressed by the second Trust. There is, of course, a larger point. Organisations can tend to become closed, to exclude others and become disinclined to listen to the voice of "outsiders". This is usually a bad sign in terms of the performance of the organisation. It can make the organisation isolated and defensive. There may have been some element of this in the Trust's response to the oncologists from their base in Coventry. And, of course, it cuts both ways. The "outsider" may see himself in such terms, feel he has done his bit and retreat to familiar territory. As Dr Stockdale put it, "You have to remember that I am not embedded within this organisation [the Trust]. I was a consultant at another Trust visiting Solihull to do outpatient clinics".
- 3.39 Dr Stockdale's comment on his relationship with the Trust is important. He had some experience of management. Many of his colleagues did not. Clinicians of all stripes, caring for patients on the wards and in the clinics, often see the senior management of the Trust, and even more, the Board as some remote and largely irrelevant superstructure. They cultivate and seem to display proudly an ignorance of how the Trust works as an indication of how they are concerned only with the real business of the Trust: caring for patients. But, the Board and managers are equally concerned with the care of patients, albeit in different ways. It behoves clinicians, therefore, to acquire an understanding of how things work, not least so as to be able to know which levers to pull if they have concerns. Equally, it behoves Trusts and senior managers to reach out to clinicians and engage with them. After all, the care of patients was and is posited on the cooperation of clinicians and Trusts working in Networks. Making such Networks work as Networks, rather than as not wholly collegiate factions, was a challenge that the Trust in the case of caring for women with breast cancer had to meet and, it may be thought, did not meet entirely successfully.

### Speaking Out

3.40 In his description to me of the action he took, Dr Stockdale used a particularly telling phrase. He talked of "raising his head above the parapet". This speaks volumes about the perception of the way that the Trust then worked: that raising concerns was to be characterised as putting your head above a parapet, with the implication that the head would be shot at rather than welcomed and invited over the battlements to talk further. Indeed, when I asked him, why, when Mr Wake's report had not produced the result he thought was needed for the benefit of patients, he did not take further action, his reply to me was startling: "What do you want? Blood? You know as well as I do that the NHS does not operate a blame-free culture". And, in fairness, it is important to record the level of Dr Stockdale's commitment and his attempts to attract the attention of those whom he thought able and under a duty to effect change.<sup>19</sup> It is impossible to overstate the emotional burden that he and others

<sup>&</sup>lt;sup>19</sup> And, it is important to bear in mind that Dr Stockdale never saw, nor had any knowledge of Mr Wake's Report until it was "rediscovered" in 2012.

shouldered for years. As Mr Hennessy, who carried out an investigation in 2007, put it to me, while he did not want to emphasise the element of emotion in what he heard as he gathered evidence for his Report, "to see someone virtually in tears was an eye opener".

- 3.41 For the future, and reflecting on the past history of the NHS, Dr Stockdale's dilemma could not be more challenging. He had taken what he, and contemporaries in the NHS, would see as a risk: he had drawn attention to the practice of a senior colleague, outside his specific area of expertise, and criticised it. He had blown a whistle. Whistleblowers do not fare well in the NHS. This is one of the major indictments of management in the NHS: that it is inwards-looking, over-defensive, and prone to destroy, by a variety of means, those who suggest that the Emperor has no clothes. This is not unique to this Review. It is a blight on the NHS and is one of the principal areas where lessons must be learned. This was the context in which Dr Stockdale and his colleagues had to wrestle with what to do.
- 3.42 Dr Polson, who was asked by the Trust to conduct a parallel investigation with Mr Hennessy in 2007, told me that he did not explore the challenge of raising concerns when he spoke to the oncologists. But, he told me, the prevailing culture at the time was that raising the issue "was probably as much as you were able to do, or you looked to move and change job". It would be difficult to imagine a bleaker indictment of the reality of the time. And, he added, the patients were not complaining, because "they did not know that they should be complaining", which made it that much more difficult for one professional to rock the boat by accusing another.
- 3.43 Of course, and this is a point of much wider significance across the NHS, whistleblowers are only needed if the managerial culture of the organisation is already failing. If the culture is sufficiently open and has created a climate in which everyone feels safe to raise concerns, the notion of having to engage in some kind of covert act of resistance falls away. There may still be need for some way of speaking out in a confidential manner, but that is different from having a policy regarding whistle-blowing which effectively entrenches the notion that the culture is not open.

### Conclusions at 2004

- 3.44 The way in which Dr Fernando saw the dilemma which he and colleagues faced is stark and of very considerable significance. In essence, he told me that he carried on working conscious of the fact that he had tried and failed to persuade senior colleagues that there was a problem waiting to happen. He felt that he had not been listened to because he was not a surgeon and perhaps for other reasons. He realised that what he lacked was proof that women were being put at risk. The only way that he would obtain that proof was if women presented with recurrences of their cancer. And given that it might be several years before recurrences occurred, there was nothing he could do in the meantime.
- 3.45 The dilemma reveals what lay behind the concerns about Mr Paterson's surgery. It is a dilemma which is common in the NHS, as is the response. A concern about the practice of a clinician is raised. It is perceived as a criticism of the clinician rather than a concern about patients. The perspective is that of the clinician. The response of managers to the person expressing concerns is to demand evidence: to "put up or shut up". And, the evidence must be of harm to patients. Evidence of actual harm, except in the most obvious cases, is usually hard to come by. It takes careful documentation, proper sampling and statistical analysis. Without all these, the

concerns will be at risk of being dismissed. Dr Stockdale provided evidence but it did not show harm. It showed a deviation from accepted practice and a risk of harm. The risk was dismissed by Mr Paterson. It was not seen, for whatever reason, as significant by Mr Wake. Given the average length of time before a recurrence occurs after surgery for breast cancer, it would take several years, as Dr Fernando appreciated, before it could be proved, one way or the other, that there was a risk of harm, that csm exposed women to a risk of harm. The decision was not taken in 2004 even to look for the evidence. That decision was only taken at the very end of 2007, not least because recurrences had begun to be picked up in mid-2007. So Mr Paterson continued to operate on women for three more years.

- 3.46 The dilemma as I have described it shows how important it is to think things through. The call for proof, in a situation such as the one under review, was based on two flaws. First, it proceeded on the basis that the issues at stake were scientific and technical and could and should only be addressed scientifically and technically. This is the way that clinicians tend to think. It is their comfort zone. And, it allows arguments about data and its interpretation to go on for years. The flaw is that, while there may be technical issues to address, the primary issue is that concerns are being expressed about the care of patients. That being the case, if the concerns meet a certain threshold of importance not just, is there a risk, but what would happen if the risk comes to pass the proper response is to stop and look. This involves an examination of the evidence that exists. It also involves pausing until that evidence has been examined and shows that it is safe to proceed.
- 3.47 The second flaw arose from the first. The perspective to be adopted when concerns of sufficient importance are raised must be that of the patient, and the patient who may, if things go on uncorrected, be exposed to a risk which may in due course harm her. The perspective must not be that of the clinician whose career might be interrupted, or who might be asked to do something else, or change what is currently done. The clinician's perspective was the perspective adopted until late 2007. Then, Mr Paterson was asked to agree to change his practice. Action should have been taken at least three years earlier.
- 3.48 Of course, on this approach, much will turn on whether something is important enough to warrant action. The criteria must be the existence of enough evidence to suggest real grounds for concern that a real risk exists, together with an assessment of how significant the consequences would be if the risk came to pass. It should not be required that whoever is concerned must be able to prove to the satisfaction of the doubters that there is without doubt a risk of harm. This is to demand too much and to fail the patient.
- 3.49 There were two further flaws in the approach adopted which should also be mentioned. First, quite apart from the technical issues, one clinician, Mr Paterson, was so conducting himself as to undermine the team effort which lies at the heart of the successful care of women with breast cancer. Vigorous action was needed to stop this. Some action was taken, but it clearly was not enough as events demonstrated and which could have been predicted at the time. Secondly, the central issue of the lack of proper consent went unrecognised.

## 4 CHAPTER IV

## **QUALITY ASSURANCE VISITS**

## The QA Visit - 2004

- 4.1 One of the mechanisms for evaluating the units carrying out treatment for breast cancer was the QA (Quality Assessment) visit. This was carried out on behalf of the Warwickshire, Solihull and Coventry Breast Screening Service and was led by the Director of the West Midlands Cancer Intelligence Unit (WMCIU), Dr Gill Lawrence. The QA Visit was confined to the care of those patients referred through the screening service, a sub-set of patients. Those not covered were patients who were identified in clinics and elsewhere because of symptoms. The four hospitals in the Warwickshire, Solihull and Coventry Breast Screening Consortium were visited, including the Trust. After the Visit, a Report was prepared which included observations and recommendations.
- The QA Visit carried out on April 21, 2004 called for two audits to be carried out: one 4.2 to examine the high open biopsy rates in the Trust and the second to examine the orientation of specimens being sent for processing to the pathology service. Both of these were issues arising from Mr Paterson's surgical practice and were, therefore, a (perhaps coded) statement that Mr Paterson's surgery warranted attention. The Visit also called for a policy regarding the status of margins (one of the particular concerns of Dr Stockdale) to be developed (by the Arden Cancer Network, of which the Trust was a part), followed by an audit of compliance. It also pointed to the need for all MDTs to have specimen X-rays available. The Visit expressed particular concern about the MDT at Solihull Hospital, identifying a range of concerns. These included the lack of sufficient time in which to discuss the large number of patients, the fact that no records were kept of the patients discussed, and that the video-conferencing link did not always work such that "three-way communication is not possible". (It should be noted that these concerns about the MDT were not limited to the interpersonal relations between members). As a consequence, a recommendation was made that the meetings of the MDT should be reviewed within 3 months.
- 4.3 There was a follow-up QA visit on September 14, 2004. It was noted that some progress had been made in remedying the technical problems relating to the MDT. But, concern was expressed that the list of cases to be considered "appears long and unmanageable for the amount of time allotted, and to the external visitor it seems that some women are not being discussed". Moreover, attempts to split the MDT into two meetings to allow more time had not succeeded. As a consequence, the QA team made seven "Observations and Suggestions for Improvement". Some related to the conduct of the MDT. Some related to technical aspects of the conduct of surgery.
- 4.4 Crucially, all that the QA team can do is to make recommendations. It is for the Trust to respond and take any necessary action. The Trust did, in fact, respond in that the Chief Executive wrote to the Medical Director Surgery, Mr Gannon, on October 18, 2004 asking to be informed as to how it was intended to deal with the points made by the QA team. He was reassured by Mr Gannon that measures were being taken regarding the MDT through the Breast Service Working Group which he had established, and that he had drawn Mr Paterson's attention to the matters relating to surgical practice. It is not clear whether there was any formal follow-up regarding the

latter. The Report of the two QA Visits of 2004 did not feature in the Minutes of the Board, something I will return to.

## The National Cancer Peer Review - 2005

- 4.5 Against the background of the QA Visit of 2004, its three month follow-up and its various recommendations, it is strange to read the Pan Birmingham Cancer Network's "National Cancer Peer Review" Report in November 2005. This Report, as its title indicates, involved an assessment by professional peers and users of services of the performance of units providing care and treatment for a wide range of cancers. There were three elements: a "pre-assessment", a visit, and proposed remedial actions as necessary.
- 4.6 In assessing the breast team, the Report writes that "this team works well together and provides a good service. The MDT meeting was a good discussion with input from all disciplines and included good use of video-conferencing". It is hard to reconcile this picture with the finding by Mr Wake in 2004 that the MDT was dysfunctional, a finding echoed later by Mr Hennessy in 2007. Equally, the repeated frustration of members of the MDT with the video-conferencing facilities and the regular breakdown of communication between the various hospitals, the object of recommendations by the QA Visit in 2004, seems to have gone unheard and unnoticed.
- 4.7 There is no clear explanation for these differences of view. It may be that, in the face of external scrutiny, there was a collective desire to "put on a good show".<sup>20</sup> If so, it meant that the interests of patients (who, it must be said, were not being best served by a dysfunctional team), were subordinated to the interest that the professionals had in passing a test. Alternatively, those engaged in the Review may simply have been less than diligent in their scrutiny. And there may be other explanations. Whatever the case, another opportunity was missed for more robust assessment.
- 4.8 This was not for lack of trying on the part of Dr Lawrence and her team. She recalls having discussions with the Pan-Birmingham Cancer Network in which she referred to "these rumours about oncology; rumours because I hadn't actually seen anything. There were the repeat operation rates, there was the concern about the multidisciplinary teams, there was the fact that we really didn't believe that all his [Mr Paterson's] patients, well, his private patients, were being discussed at his NHS MDT".
- 4.9 One consequence arising from the Peer Review Visit was that the Minutes of the meeting of the Trust's Board on June 28, 2005, recorded a Report from the Cancer Clinicians to the Board which stated that "All key targets continue to be met". It recorded that "A recent peer review was held in eight of the nine cancer teams [including breast cancer]. This was extremely successful with many areas cited as best practice".<sup>21</sup> As I have noted, the decidedly less glowing Reports of the two QA

<sup>&</sup>lt;sup>20</sup> One clinician offered the somewhat cynical interpretation: "Peer Review is not an in-depth analysis of the quality of the service. ... You have a plausible lead like [Mr] Paterson, you've got someone external so you're all on your best behaviour and it's a bit of a waste of time".

<sup>&</sup>lt;sup>21</sup> The "clean bill of health" given to the Trust by the Cancer Peer Review was subsequently cited as a further ground for telling patients who complained about Mr Paterson's surgery that the quality of care provided was endorsed in 2005 and that problems only emerged in 2007, as in the case of the Complaints Resolution Meeting on October 12, 2011.

Visits of 2004 did not find their way onto the Board's agenda or Minutes. This indicates a common phenomenon in organisations where the Board is in the hands of the Executive as to what it is told about the Trust's performance. The Executive prefer to relay good news. Less good news is "work in progress" and can be dealt with by the Executive without engaging the Board. As I say, this is common, but it is extremely damaging to the proper functioning of the Board and the Trust.

Given the preference for good news, there was one particular matter in the Peer 4.10 Review's Report that was not picked up and remarked upon, perhaps unsurprisingly. It is not without significance. In the Appendix dealing with "Compliance with Measures", the relevant Standards were set out and compliance recorded. Opposite the standard referring to "Team attendance at NSSG <sup>22</sup> meetings" it was noted that "The lead clinician [Mr Paterson] has not attended the NSSG". The report later records that "the Lead Clinician of the MDT never attends NSSG meetings". It would be wrong to make too much of one particular point, but the history of things going wrong in organisations is characterised by the relative isolation of senior staff, thereby leading to their failing to learn and develop, and enabling them to avoid scrutiny. If senior managers and the Board had, perhaps, been keen to listen to the whole story rather than just the good news, they might have identified another of the many clues as to Mr Paterson's personality and practice. Mr Hennessy, a distinguished breast surgeon who was later brought in by the Trust to conduct an investigation, made a similar point. He told me that the community involved in breast surgery was relatively small. He said that he had attended every national meeting since 1991 and had never encountered Mr Paterson at a meeting. Given that breast surgery evolves "almost every month", with new ideas and new practices constantly cropping up, this might suggest this same sense of isolation from peers, and reluctance to change and to take account of new ideas.

### The QA Visit - 2007

4.11 There was a further QA visit on April 26, 2007. It was noted that neither the audit concerning localisation of specimens nor the audit of compliance with an agreed policy on margins, both of which were called for in 2004, had been carried out. There was also a reference to the continuing problems with the MDT's video-conferencing arrangements, <sup>23</sup> but the team was reassured that progress was being made. The lack of compliance with the QA team's recommendations was a source of continued frustration to Dr Lawrence and exposes a fundamental problem in the system. As she said, there is this "wonderful QA system ... we make recommendations, but it's very difficult to enforce them if people are not willing to get on and do it. We tried, certainly with the repeat operation rates [a reference to the concern raised by Dr Stockdale in 2003; that women were having more than one operation when having a mastectomy], we raised it with the PCT [the Primary Care Trust] ... the public health people were aware of it, [and with] the Chief Executive" <sup>24</sup>. "My frustration", she observed, "is that there was nowhere you could go to actually say these really important recommendations from a series of experts have not been addressed".

<sup>&</sup>lt;sup>22</sup> Network Site Specific Group.

<sup>&</sup>lt;sup>23</sup> They were still being referred to in the report of the visit on February 11, 2010, as were the incidence of re-operations at Solihull Hospital and the lack of agreement on margins.

<sup>&</sup>lt;sup>24</sup> Mr Goldman, on this account, would have been on notice that "repeat operations" was an area of concern.

- 4.12 Apart from this general frustration with the system, the QA team's report was very positive. It began, "The QA team would like to congratulate the surgical teams on their excellent results and the good service they provide". Across all hospitals, it found that "Overall, the surgical management of the patients is very good and the review of the individual surgeon's data was satisfactory".<sup>25</sup>
- 4.13 This visit was only four months before the Trust embarked on a major investigation of Mr Paterson's surgical practice. <sup>26</sup> It is not immediately clear how the discrepancy between what the QA Visit was saying and what the Trust was dealing with can be explained. After all, the background was one of concerns which had been circulating in the community of specialists for a number of years. Granted that it only concerned a subset of patients (those identified through screening), but the care that they received cannot have been all that different from that received by other patients who were not identified through screening. That said, Mr Ingle, who soon began to raise concerns, had only just been appointed a few months earlier as a third surgeon. He did not yet have an established clinic or job plan and so was not yet aware of what later gave rise to his concerns.
- 4.14 Three possible explanations suggest themselves for the discrepancy, explaining if not justifying what transpired. The meeting itself was not satisfactory as a meeting: fifteen or more people in a small room, with no oncologists who might have taken the discussion in a different direction (the oncologists were routinely not invited). Secondly, the visit was preoccupied with the continuing problems with the video-conferencing and other technical problems faced by the MDT. Thirdly, not one of the surgeons or nurses, drawn from across the area, and therefore familiar with the concerns simmering below the surface, expressed any concerns about Mr Paterson's surgical practice. Perhaps, the most fundamental explanation is to point to how difficult it is for outside institutions to get under the skin of organisations, particularly when they present a particular front to the outsider. Whatever the explanation, there is a strange sense of dislocation between what the QA team saw on the surface and what lay beneath.
- 4.15 What makes this state of affairs even more curious is that Dr Lawrence told me that she and her colleagues "knew from QA Visits that ... this particular surgeon [Mr Paterson] was an outlier in things like repeat operations. ... that was one of the things we picked up when we looked at the records ... that there were these unusual combinations of operations ... people were having breast conserving surgery after having had a mastectomy, or having another mastectomy ... I said 'You can't do this'". It was for this reason that the QA team had recommended that an audit be carried out within 6 months. It does not appear that this audit was, in fact, carried out.
- 4.16 Indeed, Dr Lawrence went on to say that she was aware of concerns expressed by the oncologists even before the QA visit of 2004, but, she went on, "One of the problems with the QA Visits is that there is no oncological involvement". Thus, Dr Lawrence did not know formally, as it were, on the basis of evidence submitted to the

<sup>&</sup>lt;sup>25</sup> The view of senior managers was that the QA Visit in April 2007 was content with the surgical management of the patients and that the review of the surgeon's data was satisfactory. This view sits awkwardly alongside the acceptance that the audit requested three years previously had still not been carried out.

<sup>&</sup>lt;sup>26</sup> Dr Lawrence told me that she was not aware that the Trust had launched an investigation. "This is one of the things that is most worrying about this", she said, "... that the people who have been involved in this have been in parallel lines unaware of what other people are doing".

WMCIU. But, the concerns expressed to her were very significant. "People were being left with positive margins and ... radiotherapy was being used to mop up potential [recurrences] – you know, they [the radiotherapists] were being expected to mop this up". She went on, "I think with the increasing use of immediate reconstruction ... they were being asked to do that. Sometimes, I think, after the immediate reconstruction had been done, which, of course, doesn't work very well". She told me that the clinical oncologists were saying that, "These patients are supposed to have had a mastectomy and yet I'm being asked to give them radiotherapy to clear up ...'. These are horrendously serious [concerns]. ...I know the oncologist who was involved [Dr Stockdale] got very upset and stressed that nobody was listening to what he was saying".

4.17 It is no surprise that Dr Lawrence asked herself whether, at that time, she should have done more about it than she did. "There was nothing I could do officially about it" because she did not have any data. Data was the world in which she operated; data gave what she recommended, for example, through the QA Visits, its validity. That said, in the QA report of 2004 she was keen to make clear the concerns about the failures of the MDT as a way of pointing to the need for "proper multi-disciplinary team discussion". And, as I have said, she drew the attention of the Trust's Chief Executive and the relevant external bodies to her concerns. But, she concluded that "I obviously hadn't rattled enough cages. I was hoping that something had [happened] because of [Dr Stockdale's] report [audit] but I hadn't heard anything [she was not made aware of Mr Wake's report] so we just kept saying 'Somebody needs to look at this' and we tried to get the people who could look at it to look at it". It appears, however, that the Trust was not listening.

#### Conclusions arising from the QA and Peer Review Visits

- 4.18 It is clear that the QA Visits identified a number of areas of concern, some of them relating specifically to Mr Paterson's surgical practice. In particular, the practice of "repeat operations" was commented upon and brought to the attention of the organisation commissioning services (the PCT) and to the Trust, in the form of the Chief Executive. While the Chief Executive did request a report on progress in meeting the recommendations advanced in 2004, it is clear that neither the PCT nor the Chief Executive acted on Dr Lawrence's concerns. An explanation may be that they were not formally expressed and they were not backed by data.
- 4.19 The comments arising from the QA Visits, however, did not exist in a vacuum. They sat alongside the background to Mr Paterson's appointment, the concerns expressed by the oncologists and Mr Wake's Report. In my view a picture was already there to be seen. It does not need hindsight to identify it. There was a pattern of concerns. Senior managers should have seen this pattern. They should have been prompted by the Reports of the QA Visits to take some action, at least to make further enquiries. One option would have been to bring in an outside expert in breast surgery. They did so eventually in late 2007. They should have done so earlier.
- 4.20 For their part, the QA Visits suffer from a fundamental flaw in that they can counsel and recommend, but, if ignored, they are powerless to do more. This is particularly of concern when the reason for their existence is precisely to examine the quality and safety of the care provided to patients. Thought should be given to strengthening the relationship between the QA teams and the Regulators (CQC and Monitor), such that any recommendations made by the QA Visit serves as a criterion to be met in order for the organisation to satisfy the Regulator that performance is satisfactory.

4.21 Peer Review Visits do not have sufficient rigour to be regarded as a reliable guide to performance. They should either acquire the necessary rigour or be regarded as a useful exercise in bringing people together but not a serious examination. Currently, organisations may present the results of a Peer Review Visit in self-congratulatory terms, even though, on occasions, self-congratulation, on a more careful analysis, may be unwarranted. Patients and the public, therefore, should be alert to this when forming a view on the performance of a service or unit.

# 5 CHAPTER V

## THE CULTURE OF THE TRUST

- 5.1 This may be the point at which to reflect on the culture which prevailed in the Trust over the years during which Mr Paterson was working at the Trust. When I talk of the culture of an organisation, I refer to its values and how these values are translated into everyday actions. The culture of a hospital is ordinarily set by the Chief Executive and his (it has usually been 'his' until recently) senior team. Despite its significance in terms of its legal responsibility, the culture historically has rarely been laid down by the Board. This is changing, albeit slowly. It must change, not least because the Board is the only real mechanism for holding the Executive to account. And, the history of things going wrong in the NHS is often a history of an Executive not being held properly and effectively to account.
- 5.2 Clearly, the culture of the Trust while concerns about Mr Paterson's surgical practice were swirling about must provide some understanding of the decisions made and not made. The culture was variously described as oppressive and one in which people felt bullied. Well-regarded members of staff left the Trust as a consequence. The sense was of a culture in which most staff were unaware of what was going on in the Trust in which they worked. There was a lack of engagement and openness between senior member of staff and the rest, a sense of a party line which had to be toed. By contrast, the culture changed with the appointment of the new Chief Executive and Medical Director. It was not only more open, but it was keen to be seen as such.
- 5.3 A manager, with considerable responsibility, told me that he had been in management in the NHS since 1992 and "had never worked in a Trust, in a hospital, that I felt was as dysfunctional as this one was when I came into it [in July 2008]. ... I had largely worked in London teaching hospitals and coming into this Trust it was hard to make sense of the management structure, it was hard to make sense of where decisions were made, it felt like the Executive at that time were not particularly visible to the front line clinical staff in terms of there appeared to be a disconnect between [the fact that] we had got the clinical directorates running the shop floor and the decision-making arm of the Trust working at a different level".
- 5.4 Some, indeed, talked of the building where the senior Executives had their offices as a sort of "West Wing". As Mr Bala put it, "I think very often decisions were made somewhere else ... and I don't know what decisions they have made and what priorities they have. At that time, the Trust was very fiercely trying to become a Foundation Trust and the focus is on that and they were trying to achieve everything. I don't really know at that time whether they didn't want any of this [concerns over Mr Paterson] to negatively impact".
- 5.5 The model of care was very much a medical model with a large number of silos barely interacting. Staff were divided among the various directorates and saw themselves as belonging to that particular part of the organisation. The sense of a coherent and cohesive organisation, with a common vision and set of values, agreed and adopted by all, was seriously lacking
- 5.6 I heard a similar view about the engagement of the senior management, this time with clinicians. I was referred to a meeting of the medical staff, attended by about a hundred consultants on November 3, 2009, in which a number of grievances were

aired, including "We regret the perceived lack of consultation and staff engagement in Trust management, as shown by the dissatisfaction shown in staff surveys and recent staff departures. We look forward to a dramatic improvement in this situation". There was tension, I was told, between the senior management and both clinicians and members of the Board: "It's not an ideal environment to ensure optimum patient care" was how one clinician put it. The importance of these tensions is, of course, that they provide the backdrop against which the events in the breast unit were being addressed.

- 5.7 Dr Anwar, the Medical Director appointed in the Spring of 2011, was asked by a patient in a Complaints Resolution Meeting on October 5, 2011 the question that was on the lips of so many patients: "... how could it [Mr Paterson's surgery] carry on?" The Minutes of the meeting record that he reflected on the impact of culture. The Trust, he said, was "reliant on the honesty, openness, and high levels of professionalism of staff. Traditionally", he went on, "hospitals had been very hierarchical in their nature, some certain people's words carry more weight than others. <sup>27</sup> If you had someone who, for example, appears to offer a legitimate explanation, it can take a while to work out that that explanation is not quite as legitimate as you first thought".
- 5.8 Of course, this cultural challenge of hierarchy and "tribalism" has long been recognised. The central key to addressing it, by common consent, is a style of leadership which asserts the fundamental values and vision of the organisation, ensures that they are understood and embraced by all, that they are reflected in everything that the organisation and its employees do, and that those who depart from them are swiftly brought back into line through appropriate means. This is so self-evident that it needs to be said every day. There is no place, nor was there ever a place for the kind of world which Dr Anwar referred to. But, all too often, it can be found unless effectively challenged. The Trust's response to concerns about Mr Paterson reflects this.
- 5.9 It is clear that the culture of the Trust was dogged by inter-personal tensions and clashes which were not effectively managed. Too often, clinicians in different parts of the Trust behaved inappropriately. Too often, their behaviour went, and to some extent, continues to go unchecked and unchallenged. The failure to confront poor performance and inappropriate behaviour was clearly an abiding feature of the Trust. It may not be easy to confront but failure to do so means that other members of staff, and, crucially, patients suffer. Such a culture develops over time. It is the direct result of a lack of effective leadership. The abnormal is normalised. Once entrenched, it is enormously hard to address without clear, strong and visionary leadership.
- 5.10 Dr Smith, the Acting Medical Director in early 2011 made a similar, albeit, from the perspective of patients, deeply pessimistic observation that, "There has always been a view ... that a consultant is for life and if you have a difficult consultant it's difficult and you have to work around it. ... you managed your consultant body often by working around them rather than with them. So, for want of a better word, [in the

<sup>&</sup>lt;sup>27</sup> A good example of this phenomenon was when a junior pathologist went with her colleague to see the Clinical Director – Surgery, Mr Hendrickse, to tell him that they remained concerned about the margins in specimens sent to them and that Mr Paterson was not listening to their concerns. She told me that they never heard back from Mr Hendrickse. When I asked her why she did not take the initiative and contact him, she replied "I was new. I was not in a position of going and asking". So nothing came of the meeting.

case of] a rogue consultant, the concentration was how to minimise the damage rather than how to fix the problem".

- 5.11 "What we have to do", he went on "is the employer has to make quite explicit that certain behaviour is not acceptable. ... We are particularly weak in allowing some behaviour to continue without stopping it."
- 5.12 During the time when the Trust was seeking to address the concerns about Mr Paterson, it was clear to many that bullying took the place of real, effective leadership. And the Board did nothing.
- 5.13 It is a frequent refrain of members of Boards that a particular feature of the NHS is that, too often, they lack all the levers and mechanisms for managing effectively. They complain that it is as if there were a quite separate governing body within the organisation the clinicians –who protect and control what they see as their territory. The answer to this state of affairs to some is a system of clear lines of engagement, clear lines of responsibility, and a way of working that better reflects good governance. But, if this question effectively "who is in charge" is what concerns Boards, it is their job to put things right, not bemoan the power of others. Indeed, the way in which the Board as whole, and individual members, failed to take action, but just left things to the Executive when concerns about Mr Paterson's surgical practice surfaced, will be a constant thread in what follows.
- 5.14 The Clinical Director Surgery, Mr Hendrickse, saw things very differently. He saw the Board as "remote, it appears remote. ... many of the surgeons won't know who the members of the Board are ... the organisation has become so big that this separation actually seems to have increased". And, he saw the Board as interfering. "... Control is not left completely to the clinicians or the clinical manager. There's always interference". At first blush, this appears to be a comment about power: who is in charge. But, Mr Hendrickse was making a different, much more important point. It is a point which is not specific to the circumstances of Mr Paterson's surgical practice, though it is relevant, nor is it unique to the Trust. It is a point which is relevant across the NHS. In effect, it is a point about the impact of resources and, consequently, the workforce that the Trust has at its disposal.
- 5.15 Clinicians have a view as to what is needed for the quality and safety of patients' care. Partly, this depends on appointing the right people and enough of them. What Mr Hendrickse was concerned with was the extent to which clinicians' views were heeded. As he saw it, the proper care of patients depended on making proper, substantive appointments, and on making a sufficient number of appointments that the care is safe: "... substantive consultants are better than locum consultants .... And I have trouble getting that through a vacancy panel. Now, for me, that is a long-term safety issue". This is a very significant clash of perspective, and of culture, which can exist between clinicians and the Board.
- 5.16 One option, if the view of the clinicians were to prevail, would be to say that it is not safe to treat any more patients and simply to "close the doors". This option is not perceived as being available to the Board since the Trust cannot control the number of patients who present themselves for treatment and feels under a duty to care for them.

- 5.17 The search for consultants <sup>28</sup>, together with the increasing numbers of patients, formed part of the backdrop to the appointment of Mr Paterson. Mr Hendrickse put it succinctly, in the context of this cultural background of tensions, "I think the Board may not be sitting there thinking, 'Mr Paterson's doing a good job', what they probably would have heard is, 'The breast service has been sorted. We've sorted out the problem...'".
- For the Board to be any more deeply engaged than this, of course, they must be 5.18 aware. At the time in question their approach in the area of clinical performance was largely passive; waiting to be told things and taking their cue as to what to explore from what they were told. And, of course, in terms of the Board's becoming engaged, much depends on the granularity of the information which is collected and made available. Data on mortality is an accepted benchmark of performance, though not without its problems. It could be expected to be reported to the Board. But, as was explained to me by Mr Hendrickse, variations in the treatment of women with breast cancer would not be something that might ordinarily be reported to or picked up by the Board, given that the mortality rate from the operation is exceedingly low. "... [T]hey wouldn't have picked up what's happening in the breast service. ... there are some indices that are so coarse that you won't pick [them] up". Far less would they have picked up, through data, the concerns about "partial mastectomies". Obviously, since it was assumed that there was only one form of mastectomy, there was no benchmark about the completeness of mastectomies, so there would not be any data to report and pick up on <sup>29</sup>.
- 5.19 But, there was something that still might have been picked up by the Board. The MDT was the device for monitoring performance at the more granular level. The Board would, or should have seen it as the assurance mechanism that performance was adequate. It could be relied on to ensure that care in that part of the organisation was appropriate. But, the poor performance of the MDT had been part of the culture of the breast unit for years. As an assurance mechanism, it had been failing for years. It was very much on the radar of the Chief Executive, the Medical Director and other senior managers. Its poor performance had been commented on by the QA team, an external agency concerned with the quality of care. It remained a cause for concern, notwithstanding the measures introduced by Mr Gannon after Mr Wake's Report. A key reason for its failure to function properly, the role played by Mr Paterson, had not been effectively addressed.
- 5.20 Despite this, the Board was not formally informed nor engaged. I accept that the Executive must be left to deal with the day-to-day ups and downs of the many units and departments in the Trust. But, at some point, it becomes important to inform the Board so as to allow it to fulfil its obligations to patients. As regards the MDT, that point had been reached, in my view, after the QA Visit of 2004. If the mounting concerns about its poor performance, given its crucial role in the care of patients, had been included in a report to the Board by the Chief Executive, the Board might well have sought some assurance that things would change and, thereafter monitor progress. This would be a proper approach to governance. It did not happen.

<sup>&</sup>lt;sup>28</sup> It will be recalled that Mr Gannon was having difficulty in making an appointment in the period before Mr Paterson was appointed.

<sup>&</sup>lt;sup>29</sup> And, of course, the indices have routinely been of activity rather than outcome, so would not, in any event, identify any questions concerning the quality of the surgery.

## **Conclusions about culture**

- 5.21 The context in which care is delivered by a Trust is extremely important. It affects the Board, the managers, the clinical staff, and, most important of all, patients.
- 5.22 The impression that I gained from those whom I spoke to and from the papers I read was that the culture of the Trust from the period of Mr Paterson's appointment until the change of guard in 2010/11 was one in which it was difficult for clinicians who had concerns to make their voices heard. It was difficult for them to be listened to. The Board and senior Executives were focussed on a series of very challenging structural changes, including the merging of hospitals and the pursuit of Foundation Trust status. This is not to say that the care of patients was neglected. For the most part, care was satisfactory. But, there was a culture which was concerned to see the work done and not to ask too many difficult questions. Senior managers were seen as remote and autocratic. For the most part, they were doctors and injected into the way that they did things the long-standing traditions of hierarchy. Junior staff deferred to their seniors, outsiders (such as the oncologists) were treated as such. The climate created was one in which aberrant behaviour could go unchecked, if the person involved was a senior doctor who was, on the face of it, delivering the goods - doing an impressive number of operations and winning the approval of patients.

## 6 CHAPTER VI

# EVENTS LEADING UP TO 2007: CLINICIANS AND PATIENTS

## The Clinicians' Dilemma

- 6.1 As I have set out, Mr Paterson continued to operate on women with breast cancer, performing on occasions an operation later known as csm, which involved leaving behind tissue. The oncologists saw the effects of this approach in their clinics: women who had discernible volumes of tissue remaining after what had been scheduled as a mastectomy. This state of affairs left them with a challenging ethical dilemma. They were concerned about the safety of Mr Paterson's surgery. They had raised their concerns in the MDT but had been overpowered by Mr Paterson. They had raised their concerns with the Trust but the Trust had looked into them, as they saw it, and nothing had happened. What more could they do? They felt at the time that there was nothing else to do and nowhere else to go.
- 6.2 A number of comments can be offered. First, the sense of powerlessness felt by members of the breast team is a telling comment on the management and leadership of the Trust at the time and the quality of communication between managers and the clinicians concerned. It may be that efforts were made, such as Away Days, but they clearly did not resolve what were deep-seated issues which had ramifications for the care of patients.
- 6.3 Secondly, Mr Paterson continued to carry out breast surgery in the way described. The oncologists found themselves, as it was explained to me, trying to mitigate the consequences of what they saw, on occasions, as Mr Paterson's inappropriate care of patients. In other words, though the patient was described as having had a mastectomy, Dr Stockdale, for example, when confronted with a patient who had not had all her breast tissue removed, provided further care by way of radiation or chemotherapy to seek to ensure that any risk arising from the fact that tissue remained would be minimised. On occasions, as one of the breast care nurses explained. Dr Stockdale would raise his concern in the MDT and ask whether there was any more tissue that could be taken. Mr Paterson, I was told, might say that the only tissue left was fat. "There would be a to-ing and fro-ing, with the patient in the middle, as to what was the best thing to do". The nurse referred me to one patient who Dr Stockdale felt should have more surgery and whom he advised accordingly. Mr Paterson, however, disagreed. After hearing Mr Paterson's advice, the patient decided not to have further surgery. She then developed a recurrence. "That", said the nurse, "was a sort of light bulb moment for me". This example illustrates starkly the disagreements that occurred over the proper course of action as regards whether further treatment was called for. It also illustrates the impossible position that patients found themselves in, not knowing which clinician to trust, which to believe.
- 6.4 Dr Stockdale and his colleagues felt that their first duty was to their patients. They could down tools and say that they would no longer work with Mr Paterson unless something fundamental was done. Or, they could continue to care for patients, mitigating as far as they could any additional risk that, in their view, patients might have been exposed to. For all sorts of reasons, they chose the latter course. As Dr Stockdale put it to me, "Essentially, on a day-to-day basis, the ones that needed

further surgery were sent back and the ones that required radiotherapy got radiotherapy. ... there was no doubt that some of the patients I was looking after hadn't had a mastectomy. We judged that ... we'd done what we could to minimise the effect of that ...". They did what they thought was right by their patients, even though it meant going along with a service in which the leading surgeon was deviating from accepted norms of practice. Let no-one imagine that it was an easy choice or that it left these clinicians unscarred.

- 6.5 There was another course open to them. Perhaps, if they had taken it, things would have developed differently. It would have involved making it crystal clear that they were not prepared to treat patients who had not had appropriate surgery. The argument would have been that the primary treatment of breast cancer is surgery. Treatment thereafter is to prevent recurrence. Any notion of collaborating in the on-going management of a patient who has not had the appropriate primary treatment would, on this argument, be inappropriate and wrong.
- 6.6 This is a powerful counter-argument to the position taken. Ultimately, however, it may be question-begging. The real issue was not whether the oncologists should act in a particular way. It was why they found themselves presented with such an awful dilemma. They did so because no-one was doing anything about Mr Paterson. And those no-ones were senior managers and the Chief Executive. After all, it had been the Chief Executive who had instigated Mr Wake's Report and knew what it said. Moreover, taken on its own terms, the counter-argument assumes a context in which the oncologists would have felt safe to act in this way and would have been supported. Their experience had persuaded them that they were not and would not be. And, then their concern for the patient took over.
- 6.7 There was, of course, a further option available to the clinicians. They had powerful concerns about the care being provided to patients. The organisation responsible for providing the care was not listening, as they saw it. In such circumstances, they could and, in my view, should have approached the GMC as the relevant professional regulatory body.

### The Question of Consent

- 6.8 The third comment is one which dogs this Review. It is that perhaps the most important feature of how to respond to Mr Paterson's surgical practice was overlooked in the early years and thereafter, only finally being appreciated by the Trust's leadership in 2011. I refer to the failure to obtain proper consent from patients for the surgery carried out. I will have more to say on this in due course, but it is important to take a moment here to explain its significance.<sup>30</sup>
- 6.9 From the first emergence of concerns, one of the concerns was that some patients whose care had been discussed at the MDT and who were to receive a mastectomy were not, in fact, receiving a mastectomy. Tissue was being left behind. The patients had given their consent to a mastectomy. The consent form signed by the patient indicated this, as did the medical records. Yet, they did not, on occasions, receive a

<sup>&</sup>lt;sup>30</sup> I should say that it was commented on by Mr Hennessy in his Report, where he stated that he could not find any convincing evidence that patients had consented to a process whereby they were knowingly leaving behind breast tissue. He remarked that, "I would find it very bizarre to think that patients would agree" to such an operation. Equally, Dr Fernando told me that he raised the issue when he wrote to Mr Budhoo in 2007.

mastectomy. Two alternative explanations present themselves. According to the first explanation, instead of receiving the agreed mastectomy, they received Mr Paterson's variation, the co-called csm, a variation carried out intentionally. The other explanation is that Mr Paterson did not carry out the mastectomy properly, such that tissue was left behind in error. This latter alternative calls into question Mr Paterson's surgical technique which I will return to in due course. It does not raise issues of consent. The former alternative, the intentional deviation from the accepted notion of a mastectomy, clearly raises the issue of consent. Mr Paterson might say that at least some of the women on whom he operated gave their consent to this variation.<sup>31</sup> But, it was not an informed consent, since they did not appreciate that Mr Paterson's variation was not a recognised, far less an approved technique. Thus, they may have known what Mr Paterson was proposing to do but would not have known the possible implications. Valid consent in this context required that Mr Paterson explain what his departure from the norm might mean for the patient and some considerable understanding of this by her. There was neither. The consent, under such circumstances, was invalid.

- 6.10 One patient's husband reported that Mr Paterson had said that " 'The way I do the operation, I leave a little bit of flesh there because I think it is nice for ladies to have a bit of cleavage remaining', but it meant nothing to us .... because we thought, 'That's okay, if that's what you do, that's what you do, you're the surgeon', sort of thing". The patient went on that a number of her colleagues at work had been operated on by Mr Paterson and "... as one of the girls said to me, it's his signature operation".
- 6.11 Her husband commented bitterly that when the question arose of her having a second operation, his wife found herself caught between the assurances of Mr Paterson and the doubts of Dr Stockdale. He was incensed to be told by a member of staff dealing with his wife's subsequent complaint, that in deciding whether to have a second operation, "It is usual practice as part of the consent process for a surgeon to discuss various surgical options with their patient .... Ultimately, the decision whether or not to undergo surgery ... has to be the decision of the patient themselves [sic]." His response, quite rightly in my view, was that "his wife should not have been put in the position of having to decide on the correct procedure. ... We were faced with a dilemma we were not qualified to resolve".
- 6.12 Further light is cast on the failure to grasp the importance of consent by the practice, which I still encountered in 2013, of clinicians talking of "consenting" patients. The objections to this awful phrase are not merely linguistic. They go to the heart of a proper understanding of the relationship between patients and clinicians. Consent is a device designed to signal to clinicians that patients are in charge of their own bodies and that clinicians need to ask permission (consent) before doing things to them. If, however, the prevailing culture is one in which the patient is seen as the recipient of whatever is on offer, then consent can come to be seen as some perfunctory exercise to make sure some difficult-to-understand-why hurdle is jumped over. Hence, the patient is "consented" and the clinician can then get on with things, having had to pause as briefly as possible to tick the consent box.

<sup>&</sup>lt;sup>31</sup> It is important to note that on occasions, the process of obtaining consent, which includes confirmation by "a doctor" that the procedure has been explained, was carried out by juniors rather than by Mr Paterson. The ethical principle is clear that consent, including the surrounding explanations, should be obtained by the consultant in charge of the treatment.

- 6.13 As one patient put it to me, "... I wrote to [the Trust] listing my concerns, which were really that I hadn't had the procedure that I consented to, which interestingly they told me Mr Paterson had consented me for and I said, 'Actually, it doesn't work like that. I gave consent to do this. He didn't consent me, I consented him, if you want to use "consent" as a verb. ... but you [the Trust] haven't done what I signed up for".
- 6.14 As regards her surgery, she described how she was given the choice between merely removing a lump and having a mastectomy. "I was very, very clear", she told me, "given that choice, that I would have a mastectomy and my idea was 'That's it, it's out'. Then you have a chat with the breast care nurses afterwards who tell you what the system involves and they actually said to me at one point 'You won't be completely flat. Mr Paterson leaves some fat' and he had said to me, 'You're going to get the Rolls Royce treatment here' and he said he leaves some fat. That didn't alarm me at the time, because I thought presumably that is normal procedure.... I have enough of a scientific background to know that the fat is not going to turn cancerous again".
- 6.15 This same patient went on that when she went to her GP's surgery to have stitches taken out after her operation, the nurse ".... actually said to me, 'Are they calling this a mastectomy?'". She told me that when she went back two weeks later to see Mr Paterson she repeated what the nurse had said to her. Then, she told me, she asked Mr Paterson, " '...You have done a mastectomy, haven't you?' and he said in front of the breast nurse and my partner who was in the room, 'Yes'".
- 6.16 Another patient described how, when she woke up after her operation, "...the first thing I did was to see what had been done .... and there was this little mound here ... which I was surprised about. .... I just assumed I would be flat because I don't know anything about breast surgery. She [the nurse] said, 'Oh, Mr Paterson does it like that because he likes to leave you with a little bit of cleavage'. I am a person who routinely wears a polo neck sweater. I am not worried about cleavage, I just want to get rid of the cancer, you know. It wouldn't have ever occurred to me. I wish I had been asked or given a choice. That has really rankled with me since all this came to light. Why didn't he say, 'I can do it like this or I can do it like that, which would you prefer. ... I am 99.9% sure that if he had said that, I would have said, 'Get rid of the lot, because if you think you are carrying cancer around you want shot of it'".
- 6.17 Right at the heart of the surgical practice there was an ethical (and legal) flaw: on occasions, patients had not consented to the procedure carried out on them. Though, perhaps, appreciated by some members of the breast team, this situation was not formally recognised. Dr Polson was willing to admit to me that when he conducted his investigation in the autumn of 2007, "We missed an opportunity over consent". The implications were very significant. As will be seen, the Trust, when it sought to respond to concerns being expressed in the summer of 2007, chose to do so by seeing them as matters of inter-professional relations between clinical staff, together with the need to examine Mr Paterson's surgical practice. Accordingly, they invoked the disciplinary procedures operated by Human Resources (what I will call the HR process). These procedures are notoriously labrynthine. Indeed, as I write in mid-2013, they are still grinding on.
- 6.18 There was another course open to the Trust had it analysed the situation with greater care. They should not have addressed it as if it was an issue of managing a difficult employee. They should have analysed it from the perspective of the patient rather than that of the employee/colleague. A breach of the ethical obligations owed by a

doctor to a patient was taking place on an unknown number of occasions. But, just one such breach is enough to require action. And, a breach of the legal obligation owed by a doctor to a patient was also taking place. Seen in this light, action would have been of a different order. It could have been prompt and put an immediate end to Mr Paterson's deviation from accepted practice. But, it was a matter calling for proper analysis. Instead, it was under-analysed, or mis-analysed by those responsible for taking action. This is not a judgement of hindsight. The centrality of proper consent to the care of patients is, and was then, a given.

6.19 Put another way, there was an issue of perspective. The Trust would have had to look at matters from the perspective of patients. But, that was not the approach adopted. Indeed, later, as the investigation into Mr Paterson's surgical practice was in its early days, Mr Cunliffe, the then Medical Director – Surgery, responded in a note to concerns once again expressed by Dr Stockdale by saying that a process was in place and while it took its course, it was important to be "fair to all parties". It is not clear from the approach adopted how it was fair to patients. <sup>32</sup>

#### Conclusions regarding matters of ethics and practice

- 6.20 The dilemma which the oncologists found themselves confronting was a direct product of the culture and context in which they were working. A fellow clinician was, in their view, leaving patients at risk and it appeared that they could not get anyone's attention. So, they compromised.
- 6.21 On one interpretation, the compromise they made compounded the problem by leaving it unaddressed. On another, it offered patients protection against the risk of further harm.
- 6.22 In an organisation which invites challenge and discussion and seeks to ensure that all members of staff feel able to speak their minds, it would not have been necessary to contemplate the compromise resorted to for a number of years. The oncologists would have been listened to and appropriate steps would have been taken to address their concerns. The perspective would have been that of the patient: what is in her best interests. The answer would have been clear and senior managers would have ensured that a mastectomy meant a mastectomy.
- 6.23 The Trust during the relevant time was not one in which staff felt comfortable and safe to speak out. One member of staff had taken a stand, but, once rebuffed, felt he had nowhere to go. He should have been listened to and supported.
- 6.24 If concerns are real but are not being listened to and the organisation is not one in which staff feel able to speak out, a clinician should not compromise and collaborate in the inappropriate care of another. In extremis, the clinician should refuse to work with that other and make this refusal known. The patient should not, of course, be abandoned, but should be referred elsewhere. Moreover, if they are persuaded that their concerns are real and that the organisation providing the care is not listening to

<sup>&</sup>lt;sup>32</sup> Two breast care nurses told me that when they went to see Mr Cunliffe, they were still preparing patients for surgery by Mr Paterson and, as one of them put it, "I wanted to say to him [Mr Cunliffe], 'Look, if there's a question over his skill and his ability ... should he be operating' basically". Mr Cunliffe, they told me, "was quite terse. ... we felt we'd been reprimanded. ... We shouldn't have the audacity to ask to see him about this because it's nothing to do with us". The HR process was dealing with things.

them, members of staff ultimately have a duty to report their concerns to the relevant professional regulatory body.

6.25 As regards consent, its central importance was not recognised. This was a major oversight by senior managers and others. Had its importance been recognised, action could have been taken much earlier and in a much more forceful manner. It was not and patients were harmed. Moreover, it is clear that the role of consent, as a means of respecting the rights of patients, was simply not properly understood. Talk of "consenting" patients has no place in the care of patients. By adopting this language and what appears to have been a cavalier approach to consent, patients were let down.

## 7 CHAPTER VII

# THE APPOINTMENT OF MR INGLE AND THE EVENTS OF 2007

## Mr Ingle's Appointment

- 7.1 Mr Paterson continued to operate on patients. For some time, it had been recognised that the case-load that the breast team was dealing with argued for the appointment of a further surgeon to support Mr Paterson. The history of such support is instructive about Mr Paterson's role. There had been another surgeon when Mr Paterson joined the Trust in 1998, Mr Taylor. Relations between the two surgeons appear to have become increasingly difficult, due, it was suggested to me, to the personality of Mr Paterson. Mr Taylor left the Trust. Mr Bala was appointed in mid-2001 as a locum for several months, before leaving for the North East. Another surgeon, Ms Milly Bello had been appointed in 2001, but she resigned within a few months, having, it was put to me, found it difficult to work with Mr Paterson.
- 7.2 Mr Bala was then appointed to a substantive position as a consultant surgeon in October 2003. The appointment of Mr Bala did not, it appears, provoke the same response from Mr Paterson as had previously been the case. This was because, I was told, Mr Bala was someone who would get on with his work and not constitute a challenge to Mr Paterson. As Mr Gannon put it, "I don't think he [Mr Paterson] really wanted strong colleagues and whenever I could get strong colleagues [to apply, in his capacity as Medical Director] he would often be discouraging to them ... so it was quite difficult to recruit ...". As regards Ms Bello's leaving, it is at best surprising that, having secured her appointment, she did not receive sufficient support to persuade her to stay. This was the responsibility of senior managers. They cannot claim to have been unaware of the difficulties created by Mr Paterson and of what Ms Bello was walking into. It was their job, frankly, to protect Ms Bello. This was in the interests of patients as well of Ms Bello. But, they failed to do so.
- 7.3 It was in late 2006 that the Trust decided that the breast team should be supplemented by the appointment of a further surgeon who, in addition to routine surgery for breast cancer, could take forward the increasing need for onco-plastic surgery. The manner of the appointment is instructive. Two candidates were eventually selected for interview. A conscious decision was taken by Mr Budhoo, the Clinical Director Surgery, that Mr Paterson, although the leading breast surgeon, should not be on the interviewing panel.
- 7.4 The reasoning says much about the state of affairs prevailing at the time and the quality and style of management being operated. Mr Paterson had, it was explained, already put off one potential applicant from applying. The danger was that he might do the same as regards other candidates if he was involved in the interviews.<sup>33</sup> So Mr Paterson was excluded from the process. Mr Bala told me, "Mr Paterson was not

<sup>&</sup>lt;sup>33</sup> Indeed, Mr Ingle, who was one of the candidates, told me that his mentor at the hospital where he was working telephoned Ms Bello to find out about the background to the appointment and, according to Mr Ingle, his mentor was told by her "Ask him not to apply unless he wants his career blighted".

happy about that and we all knew that he would not be happy, and, because of his history, he would do his best to block it". When I asked him what it says about an organisation if it can only recruit by keeping a senior figure out of the way, he replied, "It is not good. It is very bad". Here was an example of what already appears to have been a pattern in managing Mr Paterson: a strategy of working around him rather than tackling head on what he was said to be doing and the way in which he was behaving.

### **Cross-Cover**

- 7.5 In the event, Mr Ingle was appointed in January 2007. It was not long before difficulties emerged between Mr Ingle and Mr Paterson. Relations in the MDT deteriorated. Mr Paterson was said to have sought to undermine Mr Ingle, going so far as to cast doubt on Mr Ingle's clinical competence and to telephone referees at Mr Ingle's previous Trust to check on his credentials. Mr Ingle, unusually, was prepared to stand up to Mr Paterson, but the tension clearly had an effect on the functioning of the MDT. It was described later in the year, as I shall point out, as dysfunctional. This is how it had been described by Mr Wake in 2004. More than three years had passed and nothing of any lasting effect had been done, despite the temporary improvement following Mr Wake's Report. And, it must be remembered that the MDT is a crucial element in the care of patients. If it functions well, the care received by patients is optimised. If it functions badly, as the breast team's MDT had for several years, there is a real risk that the care provided to patients is compromised.
- 7.6 One of the consequences of Mr Ingle's appointment was a re-organisation of the clinics in the breast team, so that the most effective use could be made of the surgeons' and others' time. A feature of this re-organisation was what was called "cross-cover", whereby patients were seen by whomever it was who was holding the clinic on that occasion, rather than be only under the care of one particular surgeon. This had very important consequences.
- 7.7 Prior to cross-cover, Mr Bala preferred to keep "his" patients because of the reservations he had about Mr Paterson's surgery. For his part, Mr Paterson saw "his" patients and they were not seen by any other surgeon. Thus, if any concerns were expressed about Mr Paterson's surgery they were necessarily expressed, if at all, by non-surgeons. As I have suggested, this was one of the reasons why, when the oncologists expressed concerns, the view appears to have been taken that they were not surgeons and, therefore, were not competent to comment on surgical practice. Mr Paterson was the surgeon. If he said that the procedure that he was carrying out was appropriate, he was the specialist. He was the one who knew what he was talking about. He was the one to be trusted.
- 7.8 With cross-cover, Mr Ingle began to see some of Mr Paterson's patients. He was struck by the presence of residual breast tissue in women who were supposed to have had a mastectomy. He also encountered patients whose cancer had recurred in their breast after having had what was said to be a mastectomy under Mr Paterson. Mr Ingle made his concerns known at the MDT. Mr Paterson sought to explain them away. He also sought to discredit them by describing them as "tit for tat" for his raising concerns about Mr Ingle's clinical expertise. The atmosphere became increasingly acrimonious.
- 7.9 Mr Budhoo, the Clinical Director Surgery, recalled being called by Mr Bala around the same time to see a patient. Mr Bala said that he was doing a mammogram on

one of Mr Paterson's mastectomy patients. Mr Budhoo told me that he "did a double take. ... A mastectomy is a flat chest and that's it". He remembered that Mr Ingle had mentioned the same thing, so he called a meeting. It was suggested that an audit be carried it, but Mr Budhoo told me that when he found out that Mr Wake had already looked into it, he spoke to him. "The discussion I had with Mark Wake", he told me, "was that they looked into it and they did not think there was a problem <sup>34</sup>. ... [that it was a matter for] the clinician's decision whether [the tissue left] ... is sufficient or not". Mr Budhoo told me that he said to Mr Wake that he did not agree and that it must be looked into.

7.10 As I shall describe, it was looked into. But, Mr Budhoo felt he was sidelined. When the decision was taken to launch an investigation, he said that his role became "fairly diminished". While some had pressed for him to be involved given his position as Clinical Director – Surgery, he said, "I was kept out of it and it was handled by Mr Cunliffe". Thereafter, his involvement consisted of periodic updates by Mr Cunliffe.

## The Investigations – The Background

- 7.11 In May and June 2007, Mr Ingle and then Dr Fernando and Dr Stockdale wrote to Mr Cunliffe expressing concerns about the personal conduct and clinical competence of Mr Paterson. In July, 2007, as a consequence of these concerns and the pressure that they created, the Medical Director Surgery and the Chief Executive decided to establish an investigation. Mr Ingle was advised of this decision in a letter of July 17 from Mr Cunliffe. Mr Paterson was advised that an investigation was to be carried out into concerns raised by his colleagues, in a letter from Mr Cunliffe of July24. Dr Fernando also wrote on July 17 to Mr Budhoo as Clinical Director, expressing the same concerns. It was Mr Cunliffe who replied to him, on September 25, saying that an investigation had been launched. Two months had passed since Dr Fernando had written and, although an investigation had begun, a prominent member of the breast team had not been told. This absence of communication was to become a feature of the Trust's response over the next several years.
- 7.12 In raising his concerns, Mr Ingle had referred to concerns having been raised previously in 2003, something which, as I have suggested, seems to have faded from the corporate memory. Indeed, it had faded to the extent that, while there were rumours that there had been some sort of review and Report, people not involved at the time had no direct knowledge of it. For his part, Mr Ingle had been made aware by colleagues that concerns had been raised by the oncologists, but told me that he had "no idea at all", until I showed it to him, that Mr Wake had investigated the concerns and had submitted a Report containing recommendations.
- 7.13 The Executive followed the Department of Health's procedure, "Trust Disciplinary Procedures for Medical Staff", supported by the National Clinical Assessment Service (NCAS). In other words, they chose to go down the HR route, a decision which I have already commented on. The Board was informed by the Chief Executive on September 25, 2007 that, "The items relating to Mr Paterson's personal misconduct are being investigated internally by a senior physician. The allegation relating to Mr Paterson's clinical performance will be investigated by another breast surgeon external to the Trust. At present Mr Paterson continues to practice without

<sup>&</sup>lt;sup>34</sup> Mr Budhoo had not seen Mr Wake's Report

restriction". This was the first time that the Board was formally made aware of concerns about Mr Paterson's surgical practice.

- 7.14 Dr Polson, a consultant physician in the Trust, specialising in gastroenterology, who had been at Solihull Hospital since 1991 and who had recently acquired a qualification in law, was deemed the appropriate person to conduct the internal investigation. It might be said that, since the Trust had already had one internal investigation, a less than wholly trusting bystander might think that it was time for an external view, a completely independent review carried out by someone from outside the Trust. This is certainly a lesson for the future.
- 7.15 Up until this time, the Board of the Trust, or at least the Non-Executive members, was unaware in any formal sense (that is, through papers going to the Board, or in Minutes) of concerns about Mr Paterson's surgical practice. The Board is, of course, the body ultimately responsible for all that happens in the Trust, including that which affects the care and welfare of patients. And, since the emergence of external regulators in the form of the Healthcare Commission and Monitor, the Board had concerned itself to a degree with the safety and quality of care provided to patients. Given the size of the Trust and the range of services provided, it is a matter of careful judgement what matters are brought to its attention. I have already suggested that the Board should have been engaged concerning the performance of the breast team and the MDT. Moreover, already in 2007 the Board had been made aware of a number of incidents involving the safety and quality of the care provided to patients.
- 7.16 Mr Cunliffe asked two Non-Executive members of the Board, Mr Hensel and Ms East, to attend a meeting in the summer of 2007, along with Dr Keogh and Dr Woolley, the two members of staff with responsibility in the area of safety and governance. The purpose of the meeting was to give those attending an overview of the situation regarding Mr Paterson's surgical practice, although they were not told the identity of the surgeon. Mr Hensel and Ms East were invited as independent Non-Executive Directors rather than as members of the Board, to provide a degree of lay scrutiny. This seems rather a curious status, since the two Non-Executives could not put to one side their responsibilities as members of the Board, including their overriding responsibility for the care of patients. But, that seemed to be the basis on which they were asked to meet Mr Cunliffe. At the meeting, the two Non-Executives were briefed by Mr Cunliffe that a complaint had been made about a surgeon's surgery, in particular whether it was in line with accepted and approved practice. It was not suggested to them that there were any larger concerns about Mr Paterson's clinical competence. It may be thought that, in the light of what was already known at that time, this briefing was somewhat incomplete.
- 7.17 The procedure for establishing the investigation required that the Board be notified and it duly was. Thereafter, the Board was on notice that an investigation relating to Mr Paterson had been launched. <sup>36</sup>

<sup>&</sup>lt;sup>35</sup> Minutes of Board July 31, 2007, para. 6. I was told that there had been a non-accidental injury in paediatrics that was not picked up, a "very serious drug administration error", and a 15 year old who died of appendicitis.

<sup>&</sup>lt;sup>36</sup> Minutes of Board, Sept 27, 2007

- 7.18 One of the themes that must be addressed is the extent to which, once made aware of the issue, (albeit belatedly, as I have suggested), the Board then discharged its responsibilities. The national framework for managing concerns about doctors, "Maintaining High Professional Standards in the Modern NHS" requires that once an internal investigation is launched, a Non-Executive member of the Board must be appointed to "oversee" the investigation. Ms East was appointed <sup>37</sup>. On the face of it, this appears to be a mechanism whereby the Board, and more particularly, the Non-Executive members, have a link with and are kept appraised of developments in the investigation. As such, it looks like a sensible mechanism of assurance for the Board.
- 7.19 I was told, however, that there was no protocol, nor guidance for the designated Non-Executive to follow in carrying out this role. No-one, for example, briefed Ms East when she took on the role that there had been a previous investigation and Report from Mr Wake, which included a number of recommendations about the MDT and Mr Paterson's surgical practice.
- 7.20 The Minutes of the Board, September 27, 2007, at para 5.8 record that, "Ms East stated that the Board should receive progress reports on a regular basis. This was agreed". The Minute invites the clear conclusion that the purpose of appointing Ms East to "oversee" the investigation was to provide assurance to the Board. It was not, however, seen that way, it appears. Rather, it was seen as some form of window-dressing, on the basis that the Executive was there to carry on the investigation and should be left to get on with it.
- 7.21 The view was taken that, while the NHS might have thought it a good idea to establish a procedure involving a Non-Executive, in practice it was a waste of time. The Non-Executive added nothing and was superfluous. Certainly, the appointment of a Non-Executive provided no assurance to the Board about the conduct of an investigation.
- 7.22 Two comments may be in order concerning this view. First, this interpretation of the role assigned to the Non-Executive clearly leaves the Board entirely in the hands of what the Executive chooses to do and to tell the Board. The role of the Board in holding the Executive to account is rendered undoable. Secondly, given that the role exists, the opportunity exists for the Non-Executive to become active, rather than be merely the passive recipient of updates. And, being active might allow a Non-Executive to propose possible actions which, in the Non-Executive's view, might better advance the interests of the Trust. This, after all, is ultimately the responsibility of the Board. It did not happen.
- 7.23 Whatever may have been recorded in the Board's Minutes in September 2007, neither Ms East nor anyone else ever formally reported back to the Board on the progress of the investigation, according to the Minutes of the Board. This was a serious failure. There may have been informal exchanges, but only a couple of months earlier the Minutes record the Chairman of the Board as having "raised the issue of the high number of apologies for the Governance and Risk Committee and highlighted that attendance at this meeting should be a priority", suggesting that it and, perhaps, the area of its responsibility, was not seen as a priority by some at the

<sup>&</sup>lt;sup>37</sup> Ms East is a financial services lawyer who was appointed to the Board in 2005. The Trust had recently gained Foundation Trust status and Ms East's appointment reflected a change whereby the Board sought to adopt a more commercial focus, rather than being focussed primarily on the community and patients. She ceased to be a member in 2013.

time. And, in any event, informal exchanges, important as they are, cannot serve as a substitute for formal reporting. Without such reporting, the organisation, as an organisation, has no knowledge or memory of events.

- 7.24 It is an elementary rule of good governance that matters of such importance that they are judged to warrant both formal internal and external investigations must not be left to the vagaries of recollections of individuals, which, of course, may differ over time. It was undoubtedly wrong and a failure on the part of the senior management that the Board was not kept informed, quite apart from Ms East's duty to do so. When I asked Dr Polson whether he was aware that a Non-Executive member of the Board had to be appointed to "oversee" the investigation and that Ms East was the appointed person, he told me that he was "not aware of any of that. ... I would ask the question why Miss East is not asking where is that Report at future Board meetings". When I asked him whether there was any "overseeing", he replied "No, no, there wasn't. No, no".
- 7.25 A further mechanism, the Governance and Risk Committee, a sub-committee of the Board, was also available to provide assurance for the Board. It had been established by the Trust at least by 2004. At the relevant time, it was chaired by Ms East. Perhaps surprisingly, given its apparent brief, there is no formal record of any engagement with the issues regarding breast surgery until August 10, 2009. The Minutes for that meeting record that the Governance and Risk Committee discussed the "On-going investigation regarding breast surgery" and agreed to convene a sub-committee. There is no further record of this sub-committee's reporting to the main Committee, or of the Governance and Risk Committee's reporting to the Board.
- 7.26 It might be thought that, even if Ms East did not report back to the Board, an alternative route for updates and reports for the Board would have been through the papers of the Governance Committee. Papers may well have gone to the Board, but nothing is recorded in the Board's Minutes about any investigation into Mr Paterson's surgical practice until a brief reference in 2009 and then nothing until late 2010. Nor was there any record in the Minutes of the Governance Committee.
- 7.27 Indeed, the Committee had never discussed concerns about a particular individual clinician, because such matters were regarded as confidential, affecting the clinician's professional life. Rather, the Committee focussed on organisational matters. It might be thought that this approach provides too limited a measure of security for the safe care and welfare of patients, given that the Committee, as its name indicates, was specifically created by the Board to concern itself with the safety of care. In terms of the formal management of the Trust there was a series of gaps in the Board's system (if it can be so described) of assurance. The Board was not kept informed. Its Sub-Committee defined itself out of competence. The Executive were not effectively held to account.
- 7.28 Having been advised that it had been launched, the Board effectively was in the hands of the Executive as to the conduct and outcome of the investigation. It is difficult to see how, in such circumstances, the Board could exercise its overarching responsibility to patients.
- 7.29 Non-Executive members of the Board might claim, of course, that they were not competent to hold the Executive to account Of course, one solution is to have agreed standards and the means of measuring compliance with them. Such an approach can then serve to provide regular objective information for the Board. But, such an

approach was somewhat in its infancy at the time. The extent to which the Board of a Trust is made aware of matters which touch upon its ability to discharge its responsibilities to patients was a major theme in the Bristol Inquiry which reported in 2001. There is no reference, however, in the Board's Minutes that, as a Board, they were made aware of and took steps to respond to the Recommendations of the Bristol Report. Had they done so, it may well be that they would have analysed more carefully the respective roles of the Board and the Executive in addressing what was going on in the breast unit such as to give rise to the two proposed investigations.

## Dr Polson's Report – the Background

- 7.30 Dr Polson was first contacted by an HR consultant on behalf of the Trust on August 9, 2007. He was asked whether he would act as the "Case Investigator" under the relevant HR procedure, reporting to Mr Cunliffe as Medical Director – Surgery. <sup>38</sup> He was advised that there were concerns about the personal conduct and clinical practice of Mr Paterson. As regards Mr Paterson's personal conduct, the concerns related to his care of a private patient and his behaviour towards Mr Ingle. As regards his clinical practice, the concerns were that Mr Paterson:
  - undertook incomplete mastectomies ;and
  - advised patients to undergo breast reconstruction surgery when it was not clinically appropriate.
- 7.31 Dr Polson was advised that he would be supported by an HR consultant <sup>39</sup> and that an external breast surgeon would be appointed to review and report on the clinical matters. He told me that he did not receive any specific guidelines as to how to conduct his investigation. Dr Polson saw his role as addressing matters which could broadly be described as HR matters: the interpersonal issues affecting the MDT and more general working relations. Alongside, his investigation, the Trust, through the Chief Executive and the Medical Director - Surgery, set about obtaining external, independent, expert advice on Mr Paterson's surgical practice. Mr Paterson objected to the first outside expert who was approached, but a second was then agreed upon: Mr Colm Hennessy, a breast surgeon who worked in the North East of England.
- 7.32 While Dr Fernando had been a moving force in bringing about the investigation, Dr Stockdale also played a role. As he told me, "I've stuck my head above the parapet, I was ignored, I'm not sure that I wish to actually do it again at this stage but what I will do is I will observe the cases in my clinic where there is documented evidence of inadequate surgery and that's the string of cases that I submitted ... to the then Medical Director, Mr Cunliffe". Dr Stockdale did so in a letter to Mr Cunliffe on September 14, 2007 in which he made him aware and set out the concerns that he had raised in 2003 through his audit. He then went on: "I have recently kept notes of individual patients about whom I continue to have cause for clinical concern. ... The particular issue is the repeated incomplete resection of breast tissue following an operation described as a mastectomy". These cases were among those looked into by Mr Hennessy.

<sup>&</sup>lt;sup>38</sup> Mr Cunliffe became acting Medical Director in April, 2006 and was appointed Medical Director - Surgery in September, 2007.

<sup>&</sup>lt;sup>39</sup> In fact, over the time, there were three or four different people from HR.

- 7.33 This letter from Dr Stockdale to Mr Cunliffe is clearly of considerable significance in indicating what was known by whom and when; a central feature of my terms of reference. For this reason, I have set it out in an Appendix together with the accompanying copy of the Audit of 2003 itself which was sent at the same time.<sup>40</sup>
- 7.34 Dr Polson and Mr Hennessy prepared separate reports, but Dr Polson drew upon and adopted Mr Hennessy's initial report in reaching his conclusions. Both Dr Polson and Mr Hennessy carried out their work virtually single-handed. Dr Polson continued to meet all his responsibilities as a consultant physician. Mr Hennessy fitted his work into his schedule, to the point that he spent two Saturdays holed up in a room in the Trust going through case notes, and the like, including extracts from the reports of the QA Visits in 2004 and 2007 that he requested. Mr Hennessy was able to complete his work relatively quickly, presenting it in interim form to the Trust in early December, 2007 and as a final report in early February 2008. Dr Polson's Interim Report was sent to Mr Cunliffe on December 18, three months after it was commissioned. His final Report was submitted to Mr Cunliffe on April 14, 2008. Indeed, Dr Polson was moved to apologise in his Interim Report for the "time taken to complete this investigation [Interim at this point]".
- 7.35 The relevance of these factors is the possible light they shine on the urgency and importance attached by the senior managers to addressing and, as necessary, resolving the concerns revolving around Mr Paterson. Three comments can be made. First, the provision of all necessary support to both Dr Polson and Mr Hennessy would have made their tasks easier and allowed them to complete them more guickly. Secondly, not relieving Dr Polson temporarily of his clinical responsibilities inevitably caused matters to take longer. Indeed, Dr Polson added "Additional Comments" to his Interim Report to the effect that "If ever a similar investigation is needed in the future we would suggest the Investigating Officer and HR Assistant take 'time out' (eg one week) to complete their investigation. Their posts should be back-filled". When I spoke to him, Dr Polson put it more strongly: "it would [have been] much better if I could have been released for a month, whatever time it took, or certain days of the week to devote to doing this properly, rather than trying to build it on top of a day job that was already very busy. It stretched over several weeks, which I felt would have been better if it could have been done over a shorter period". 41 This has echoes in the subsequent management of the recall process in 2010-12, which I shall refer to later.
- 7.36 Thirdly, the engagement of Mr Hennessy demonstrated an understanding of the need for the Trust to take external, independent advice as regards the technical aspects of Mr Paterson's surgery. But, that said, recourse to an internal investigation under Dr Polson as regards all the other related matters may be seen, under the circumstances, as reflecting a judgement by the Executive as to how the matter

<sup>&</sup>lt;sup>40</sup> Appendix III

Dr Anwar, the Medical Director appointed in late 2011, made the following observation "when I read the statements that fed the Polson Report you get this impression that something is fundamentally wrong. Ian [Paterson] joins, surgeons leave. I have to be absolutely honest with you, I do not think 2003-4, based on what I had seen, was particularly clear. All I knew was it was not right and the MDT was not necessarily the whole story, but it was not right and I think the most overt rot picked up by the organisation started about 2003-4. It culminated in 2007, but it started then."

<sup>&</sup>lt;sup>41</sup> Interestingly, Dr Polson told me that the HR people advised him that such comments were not properly part of the investigation. They were merely an "aside".

should best be managed: by the Executive, with Dr Polson reporting to them and leaving them thereafter to manage what should be done. This may have been what the HR procedures contemplated, but there were others who thought that getting someone in from outside would have been preferable. And, it would have been even more preferable if such an independent adviser reported to the Board. But that did not happen.

7.37 The approach that the Trust took may have been defensible. It can be said that once it was decided to go down the route of an HR procedure, everything else was ordained, the process had to be followed. But, as I have said, there was another way, drawing on the fact that there were breaches of ethical and legal obligations. There were also concerns about the safety and quality of the care being provided to patients. These issues could have been dealt with quite separately from the issues of interpersonal relations. And, even if the HR route was chosen, there is no reason why an external, independent person rather than Dr Polson could not have been asked to conduct the investigation, and given all necessary support. This is not to criticise Dr Polson's work. It is to suggest that there is a value in any investigation being seen to be, as well as being, rigorously independent of the Trust. In the event, both Dr Polson's Interim and Final Report were very helpful and an important milestone in pointing to how the Trust should deal with Mr Paterson.

## Dr Polson's Approach

- 7.38 Dr Polson interviewed as many as possible of the staff who might help him in understanding his brief: the interpersonal relations within the breast team. He chose not to interview any patients, taking the view that they would not be able to help him in understanding the issues at hand. While, superficially, this may be understandable, it was undoubtedly a missed opportunity. Patients had been exposed to the tensions among and between members of the breast team and had a unique perspective on how their care was delivered which would have been valuable to gain.
- 7.39 Dr Polson's interviews were conducted, as I have said, under the auspices of the HR process. The implications were of immense importance because of one key factor which conditioned how everyone in the Trust behaved over the next several years. I refer to the fact that the HR process, being categorised as dealing with disciplinary matters, was confidential. Confidentiality descended to consign everyone to ignorance for years to come, except for the knowing few. Those involved in the process considered themselves unable to divulge anything to anyone. Those most concerned, members of the breast team, were least informed. Communication, particularly important in times of stress, was non-existent. Rumours and gossip, both potentially corrosive to any organisation, filled the gap. Dr Polson's investigation, his interviews, his Reports, all had a protective cover of confidentiality thrown over them by recourse to the procedures operated by HR. As I have already remarked, the perceived aim was to be "fair to all parties". But, as I have said, it is not clear how such an approach was fair to patients, particularly if they were never involved, nor to members of staff. Staff were interviewed but, remarkably, even those in the breast team most closely involved in the issues only received a one page executive summary of Dr Polson's Report and were never shown Mr Hennessy's Report. If one of the purposes of asking Dr Polson to investigate was to improve the way in which the MDT did its job, and if better communication is an important element in any such improvement, the decision not to share the Reports nor discuss their findings would not appear to advance these aims.

## Dr Polson's Interim Report

- In his Interim Report <sup>42</sup>, Dr Polson set out first what he had learned from the 7.40 conversations he had with members of staff. He began by saying that "it has become clear that there are on-going problems within the Breast Care Team some of which have been raised previously". Several members of staff described the Breast Surgery Department as "dysfunctional", a view which had been expressed by Mr Wake close to four years earlier. Indeed, Dr Polson writes that "This is not a new situation; but it is recognised that this approach [whereby consultants worked "individually rather than as a team"] is becoming increasingly unsustainable and inappropriate with the current trend to team working". Given that he described it as "not a new situation", I assumed that he had seen Mr Wake's Report. Dr Polson said that he had not, nor was he aware of it until I told him of it. All that he knew was that he had been told by those whom he spoke to that there had been an inquiry, but "none of them seemed to know the outcome or the recommendations from that inquiry. ... They felt it had fallen on deaf ears. ... and they were not aware that anything significantly had changed." Had he been aware of Mr Wake's Report, of course, Dr Polson would have been able to ask those whom he questioned about it and about what had happened to the various recommendations. As he put it, perhaps diplomatically, "it would have been very helpful to have been informed of that, without a doubt".
- 7.41 As regards Mr Paterson's behaviour, Dr Polson described him in his Interim Report as having been, historically, "domineering in MDTs, with reports of distress caused" to members of staff. The oncologists described his behaviour as "inappropriate". Dr Polson reported, however, that the oncologists felt that there had been some improvement in Mr Paterson's behaviour, "following the concerns raised in 2003". Dr Polson wrote that "Virtually everyone reported that Mr Paterson is an extremely hard working surgeon", but added that he "is not a good team player". The contrasting attitudes which lie at the heart of everything are reflected in Dr Polson's observations that: Mr Paterson "sees himself as the patient's advocate (in the MDT and out) pushing for a good cosmetic result from surgery as well as an effective treatment"; whereas "Mr Ingle takes a view which is supported by the oncologists that curing the patients' cancer is paramount with the cosmetic outcome although important being secondary". What Dr Polson does not say is that Mr Paterson may, indeed, have seen himself as the patients' advocate but there were clearly occasions when such advocacy did not extend to obtaining patients' properly informed consent before operating on them.
- 7.42 In his Interim Report, Dr Polson describes a state of affairs leading up to his investigation which I have already referred to. It prompts real questions about the strength and quality of the management and leadership in the Trust. To repeat, two breast surgeons, Mr Taylor and Ms Bello had left the Trust, the latter after only a few months, "at least in part due to difficulties working with Mr Paterson". This had left the Department stretched but efforts to recruit additional surgeons had been undermined by Mr Paterson, Dr Polson reports. As Dr Polson put it "Mr Paterson apparently put

<sup>&</sup>lt;sup>42</sup> Of December 18, 2007.

off applicants". In response, Mr Paterson was excluded by the Clinical Director, Mr Budhoo, from the arrangements to appoint a new surgeon, including being excluded from the interview. The result was that Mr Ingle was appointed. Mr Paterson then sought to undermine Mr Ingle's position by casting doubt on his ability. Mr Ingle was "understandably upset" and, when challenged, Mr Paterson apologised.

- 7.43 Dr Polson then reported on the events which triggered the instigation of his investigation. He writes that "opportunistically" some of Mr Paterson's patients were seen by Mr Ingle with a recurrence of their cancer in the cross cover clinics. Mr Paterson's response was telling. As I have described, according to Dr Polson, Mr Paterson saw the appearance of these patients from the perspective of what it meant for him, not them. He saw it as allowing Mr Ingle to make what Mr Paterson saw as a "tit for tat" complaint, given his earlier behaviour.
- 7.44 By contrast, the oncologists, who, Dr Polson records, "had both raised concerns about the clinical competence of Mr Paterson a few years earlier, were pleased to have a breast surgeon who was also now willing to criticise Mr Paterson's technique". Very significantly in terms of what follows, particularly the view that concerns expressed prior to 2007 were about inter-personal relationships and the MDT, Dr Polson records that the oncologists "came up with current and historical examples of these concerns [about clinical competence] as they felt this problem had not been adequately addressed when raised previously". When I spoke to Dr Polson, he told me that what he was reflecting in referring to Mr Paterson's "clinical competence" was the fact that "the people speaking to me had felt disappointed that more action had not been done in 2003 and were concerned that in 2007 still no action would be taken and they were speaking in very strong terms about competence, doing the correct operation". Dr Polson indicated that the mood of the oncologists was one of frustration: they had asked "why are we being asked to be engaged again. ... This has all been gone through before. Last time it resulted in no change. What evidence do you have that this will be different?" While agreeing that Mr Paterson's behaviour in MDTs had somewhat improved, Dr Polson writes that "they did not feel that the improvement necessarily extended to his surgical practice".
- 7.45 In his Interim Report, Dr Polson reached a number of conclusions. They largely address interpersonal relations, the need for the MDT to function effectively, and for clinicians to work together, though he was not sure that this last objective could be realised, given the "great strength of feeling about the concerns that have been raised".
- 7.46 As regards Mr Paterson's surgical practice, Dr Polson "fully support[ed] the recommendations" proposed by Mr Hennessy. In particular, Dr Polson endorsed the view that "the Trust needs to take urgent action to lessen the risk of further problems arising. This is necessary both to protect patients, and will be in the best interests of Mr Paterson and of course the Trust ....."

### Mr Hennessy's Report

#### The reception he and Dr Polson Received

7.47 Mr Hennessy's Report was handed over by him to the Chief Executive and Mr Cunliffe. Once he had given it to them, he left. He was, he told me, rather disappointed with the way his Report was received. There was just a brief chat as to his main findings. To his surprise and regret, he was not thereafter contacted or

consulted, either on his findings, his recommendations, or any other wider issues. "To this day", he told me, "I have had no feedback from the organisation as to what they subsequently did". At the very least, he had thought that, given the level of "frustration and upset" of some of the clinicians and the "apparent dysfunctionality within the organisation", some kind of follow-up meeting and debriefing would have been appropriate.

- 7.48 The reason why Mr Hennessy was treated in this way lay in the perceived demands of confidentiality and the shadow it cast. Once Mr Hennessy's Report was received, it became part of an HR review and thus tagged as confidential. And, being confidential, the senior managers would not feed back to people the actions taken or the outcomes. There can be little doubt that such an approach meant that the Trust lost the benefit of continued discussion with the external expert they had brought in. After all, Mr Hennessy knew all the details, so it is a little difficult to see what confidences were in danger of being breached. To the outsider it looks like a rather over-enthusiastic adherence to a rather narrow view of confidentiality, or simply that the Trust preferred to take things forward on their own. One consequence, of course, was the limitation this imposed on their access to external, independent advice. Another consequence, as will become clear, is that another Report joined the list of those which the team with the most pressing need to be informed and engaged, the breast team, never saw.
- 7.49 Dr Polson received the same response. He sent his Interim Report to Mr Cunliffe on December 18, 2007. There was a meeting on the following day, December 19 to discuss the Report. Dr Polson cannot recall whether he was there, but believes that his clinical commitments kept him away. Subsequently, he presented his final report on April 14 <sup>43</sup> to a group consisting of the Chief Executive, Mr Cunliffe, an HR Consultant, an external adviser and two members of the Trust's Executive responsible for governance and safety. He was not involved in any of the subsequent discussions. His insights, in so far as they were not in the Report, were not sought. He too felt disappointed. As he put it to me, "I was told I didn't need to stay any longer. I wasn't sort of kicked out but 'There is probably no need for you to be staying now, Rex, that's fine'. From memory that's how I I wasn't privy to any 'What shall we do now, folks?' ... to a certain extent I felt disappointed".
- 7.50 The sense was that the investigation had been conducted. Thereafter, things could be managed by the senior management, all within the confines of confidentiality. <sup>44</sup> The Board was not engaged. Neither Dr Polson's nor Mr Hennessy's Reports were put before the Board.
- 7.51 This is the first occasion on which it may be right to mention a view put to me by a number of members of staff whom I spoke to: that the approach taken by the senior managers was one of containment: to contain the problem, control it and prevent any word from getting out, so as not to damage the Trust's reputation. I will have more to say about this later.

<sup>&</sup>lt;sup>43</sup> Various versions of the Final Report appeared dating from April 3 to April 29, with slight differences in wording.

<sup>&</sup>lt;sup>44</sup> Dr Polson received a package with a covering letter from the HR Consultant on April 22, 2008 which he realised was a "later version" of his Report in an envelope marked 'Private and Confidential', "many times", as Dr Polson pointed out.

## Mr Hennessy's Report

- 7.52 Mr Hennessy was asked to address two particular concerns <sup>45</sup>. The first was that "incomplete mastectomies are being undertaken"; the second, that "patients are being recommended for breast reconstructive surgery when this is not clinically appropriate".
- 7.53 Mr Hennessy reviewed the case notes of 63 patients identified by Dr Stockdale, Dr Fernando and Mr Ingle. He reached the view that 54 cases "raise some issues" He noted that there was evidence from the case notes in 32 cases of "clinical evidence of residual tissue after a mastectomy. Fifteen of these had further surgery to excise tissue after a mastectomy. In a number of cases a substantial amount of tissue was excised at the second and occasionally subsequent operations".
- 7.54 Mr Hennessy's Report was emphatic. He made it clear that two procedures carried out by Mr Paterson, that which had acquired the name csm, and that which involved the practice of taking "shaves after mastectomy", were not referred to nor recognised in the relevant literature. Mr Hennessy was moved to comment that the "... practice of taking shaves as part of a mastectomy is difficult to understand. If a mastectomy is carried out correctly ... there should not be any residual breast tissue to be shaved". The two pathologists, he noted, were " ... baffled by the practice of taking shaves at mastectomy". As regards the csm, he stated that there "... is clinical, radiological, photographic and histological evidence of residual tissue left on the chest wall after mastectomy".
- 7.55 He went on, "Mr Paterson suggests that patients are very happy with the outcome of what he calls a 'cleavage sparing mastectomy'. I am sure that this is correct, however if there is residual breast tissue, some of these patients are at risk [presumably meaning increased risk] of recurrence. None of these patients were consented [sic] for a cleavage sparing procedure. I cannot find any description of this procedure in the medical literature". He recommended that the two procedures, "shaves after mastectomy" and csm should cease.
- 7.56 It is worth noting that in what appears to be a rather strange afterthought in their conversation, Mr Paterson suggested to Mr Hennessy that, in the case of reconstruction, Ms Kat, the onco-plastic surgeon with whom he worked closely for years, "... would remove any residual breast tissue". This is an odd comment, suggesting as it does, that Ms Kat would "tidy up" after him. For her part, Ms Kat told Mr Hennessy that "... she simply acts as a technician" and "... does not get involved in any way with the oncological treatment" <sup>46</sup>.
- 7.57 Despite suggestions elsewhere that the conduct of the MDT, so vital to the proper care of patients, had improved, Mr Hennessy was unequivocal. "The majority of the members of the MDT interviewed felt it was not working well and a number felt that the status quo was completely unacceptable. ... It was clear," he added, "that the

<sup>&</sup>lt;sup>45</sup> There was a third, involving a male patient, but it need not be considered here.

<sup>&</sup>lt;sup>46</sup> This is the accepted view of experts in reconstructive surgery. Of course, it assumes a context in which there is no concern about the correctness of the initial surgery.

working relationships had been unsatisfactory for some time". He went on that "Colleagues from surgery and oncology indicated their knowledge of the issues under review, often with great anguish". This, very importantly, tends to counter the view advanced later by some that until Dr Polson and Mr Hennessy reported, there was some general lack of awareness of the issues relating to Mr Paterson's surgery.

- 7.58 Mr Hennessy concluded that there "... are justifiable concerns relating to excision margins and the risk of recurrence. The practice of mastectomy shaves seems to add to the concerns regarding this issue. ... It is obviously impossible to prove whether or not all residual chest wall tissue after mastectomy contains breast glandular tissue. ... Concerns about the risk of recurrence have not been alleviated since the audit [by Dr Stockdale] in 2003. There are clearly faults within the team and within the organisation in not addressing these concerns" [my emphasis].
- 7.59 He saw the MDT as being "at the heart of the problem". "Many of those interviewed", he concluded, "felt that the MDT process was to some extent being circumvented and for some of the cases inappropriate decisions were being taken". These were the complaints that Dr Stockdale and Dr Fernando addressed to Mr Wake four years previously: that Mr Paterson sought to dominate the MDT and made unilateral decisions about the care of patients.
- 7.60 Mr Hennessy made seven Recommendations in his Report. They were:
  - a thorough review of the MDT needs to take place involving all members of the team, looking at data and functioning within the unit.
  - specific attention should be paid to the issue of shaves at mastectomy, the number of mastectomies with margins involved and why. Noting particularly the size and location of cancers and whether or not there is multi-focality.
  - the practice of shaves at mastectomy should cease. The MDT needs to be confident that a mastectomy means as close to 100% as possible of the breast tissue is removed. If all of the breast tissue is removed a flat chest wall should be achieved, therefore cleavage sparing mastectomy will not be carried out.
  - the dysfunctional relationships within the MDT need to be repaired. A successful
    outcome is only likely to be achieved through significant compromises. It is
    possible that some improvement can be achieved through facilitated meetings.
  - the leadership within the MDT needs to have the support and strength to deal with the difficult situations encountered.
  - reconstruction decisions should be taken to the MDT and a detailed review should take place of immediate reconstructions over the past 3 years.
  - the WMCIU [West Midlands Cancer Intelligence Unit] data should be reviewed with regard to margins of excision and shaves. It may require going through the histology reports.
- 7.61 All in all, Mr Hennessy's Report is strongly critical of Mr Paterson's surgical practice and of the Trust's response to the concerns that had been raised. In his reference to the fact that tissue was being left behind, that it was "impossible" to know whether

such tissue was breast tissue, with the consequent increased risk of recurrence, and thus, by implication, that women had been put at greater risk of recurrence, Mr Hennessy left the Trust in little doubt as to how seriously he viewed the concerns.

- 7.62 Mr Hennessy finished his report on December 8, 2007. It was received by Mr Cunliffe on December 14, 2007. Dr Polson's Interim Report, which relied upon Mr Hennessy's review of Mr Paterson's surgical practice, was presented to the small group responsible for responding to it on December 18, 2007. The most significant decision made at that meeting was that Mr Paterson should be required to cease carrying out that operation which had acquired the name csm, and "shaves after mastectomy", with immediate effect. The decision was based on Mr Hennessy's Report. It was conveyed to Mr Paterson by Mr Goldman and he agreed. Mr Goldman, also wrote on December 20 to his counterpart as Chief Executive in a local private hospital, advising that Mr Paterson had been required to cease carrying out these operations and that an investigation was underway.
- 7.63 Mr Budhoo referred me to another stipulation made a few months earlier, in August 2007, which passes almost without notice in the various documents. Mr Paterson was asked to ensure that he obtained consent from his patients. According to Mr Budhoo, there were two or three cases in which Mr Paterson did not obtain consent from his patient. Mr Budhoo regarded this as sufficiently serious to raise it with Mr Goldman, the Chief Executive. As he put it to me, "there was a question of whether or not he should be suspended if he does not pay attention to what he is specifically asked to do". The implication of Mr Budhoo's comment is that this was not the first time. This is another strand of the issues about consent which I have suggested should have been at the heart of the Trust's concerns.

## **Dr Polson's Final Report**

- 7.64 It was over four months later that Dr Polson's Report was finalised by the HR Consultant, and sent to Dr Polson, marked "Strictly Private and Confidential". It runs to 20 pages, supported by another 100 or so pages of appendices. It expands on the views expressed in the Interim Report. Dr Polson notes, for example, Mr Paterson's claim that it was "perfectly possible to remove the cancer, leaving fat not breast tissue", adding that, by doing this, Mr Paterson "feels he can achieve an improved cosmetic effect".
- Dr Polson reiterates the finding that he had previously made and which I regard as of 7.65 very considerable significance in how the history of concerns later came to be understood. He writes that "it has become clear that there have been problems within the Breast Services Unit for several years both regarding Mr Paterson's behaviour and regarding his clinical competence and some of these concerns had been raised previously [my emphasis]", citing interviews with Mr Budhoo, Mr Bala, Dr Fernando, Dr Stockdale, Dr Fletcher, Dr Wallis, Mr Wake, Ms Bate, and Dr Tanchel. While Dr Polson's report was not shared with staff other than those within the small group receiving it, because it was part of the confidential HR process, members of that small group could be in no doubt that, in the view of both Mr Hennessy and Dr Polson, the concerns expressed in 2003/4 related to Mr Paterson's clinical competence. They were not limited to the workings of the MDT and interpersonal difficulties. Yet this latter view became the established story. Had the Reports and their recommendations been shared with others, the record could have been put straight. But they were not. Clinicians in the breast team received a one-page

summary of Dr Polson's Report and nothing else. As a consequence, there remained an atmosphere of uncertainty and deep concern among these clinicians.

- 7.66 Dr Polson's recommendations in full were as follows:
  - A thorough review of the MDT needs to take place involving all members of the team, reviewing data and functioning within the unit. [Dr Polson noted that implementation of this recommendation was already in progress]
  - The practice of shaves at mastectomy should cease. The MDT needs to be confident that a mastectomy means as close to 100% as possible of the breast tissue is removed. Mr Paterson should "cease sub-total mastectomy, cleavage sparing mastectomy and shavings with mastectomy, unless previously agreed with the MDT or if clinically necessary during surgery". Mr Paterson has already agreed this, and he has also agreed to demonstrate his "technical ability to carry out a total mastectomy to a satisfactory standard by allowing an independent Consultant Surgeon to observe him carrying out these procedures on a minimum of five patients".
  - The dysfunctional relationships within the MDT need to be repaired. A successful
    outcome is only likely to be achieved through significant compromises. It is
    possible that some improvement can be achieved through facilitated meetings.
    Processes to address this have already begun and Mr Paterson has agreed "to
    work constructively with the MDT, ensuring all cases go through the MDT and are
    fully discussed and consensus opinion followed".
  - The leadership within the MDT needs to have the support and strength to deal with the difficult situations encountered. This has been addressed with a new independent chair for the MDT having been put in place to try to ensure a consensus view prevails.
  - Reconstruction decisions should be taken to the MDT. As mentioned above Mr Paterson has agreed to ensure all cases go through the MDT and consensus opinion is followed.
  - The WMCIU data should be reviewed with regard to margins of excision and shaves. It may require going through the histology reports. Data relating to those with recurrences and those identified as having a second or subsequent operation after mastectomies should be reviewed. The Breast MDT should be asked to review the management of all patients with breast cancer who have disease recurrence after what was believed to be curative treatment. The size and location of cancers and whether or not there was multi-focality should be considered. Indeed every cancer MDT within the Trust should be encouraged to do this, if they are not doing so already. This should start as soon as reasonably practicable.
  - The notes of all patients of Mr Paterson's who have had sub-total mastectomy, cleavage-sparing mastectomy and shaves with mastectomy, should be reviewed, audited and if necessary [they should be] given further treatment.
  - A detailed review should take place of immediate reconstructions over the past 3 years.

- A database for all patients undergoing breast cancer surgery should be set up or adapted to allow on-going, continuous audit of patient outcomes. All of those treating patients should be encouraged to include patients seen privately on the same database.
- Treatment policies relating to breast cancer, including mastectomy, excision margins, reconstruction and neo-adjuvant therapies should be formally agreed by the MDT. These policies should be presented in an annual audit.
- Ensure that appropriate guidelines are agreed to allow the MDT to make decisions about which patients are suitable for primary and secondary breast reconstruction; and ensure the appropriate distribution of the workload.
- Work is needed to improve the relationships both within the Breast MDT and in the team generally. Everyone involved accepts that things need to change which improves the likelihood of a successful outcome.
- A facilitated mediation session between Mr Paterson and Mr Ingle should be helpful to them both and to the wider Breast Unit.
- Mr Paterson was wrong in making enquiries about Mr Ingle in the way he did and he accepts this. The Trust needs to make it clear to Mr Paterson that such behaviour is not acceptable and will not be tolerated.

## Six Clinicians write to the Chief Executive

- 7.67 At the time that Dr Polson was putting the final touches to his Interim Report, Mr Cunliffe made a note of a telephone conversation that he had with Dr Stockdale on December 4, 2007. According to the note, Dr Stockdale raised several issues: he had six more cases of concern in addition to those referred to Mr Hennessy and expressed the view that Mr Paterson "should not be operating at present till the investigation is sorted, he feels [the note states] it is unacceptable for Mr Paterson to be doing reconstructions and mastectomies". Mr Cunliffe's note went on that Dr Stockdale "feels that professionally he is no longer in a position to work with Mr Paterson and is compromising his own integrity". And, Dr Stockdale warned that he might need to go to the GMC if the Trust did not act. Mr Cunliffe records that he told Dr Stockdale that there was a process that was being pursued. "To be fair to all sides, I said [to Dr Stockdale] that I cannot discuss individual cases with him" and explained "the need to keep confidentiality". This might not be regarded as conspicuously constructive or supportive leadership.
- 7.68 Three days later, six clinicians in the breast team <sup>47</sup> wrote to the Chief Executive expressing their concerns over Mr Paterson's surgical practice and requesting a meeting. Dr Fletcher, the radiologist and one of the signatories of the letter, told me that the letter was triggered by concern over the care of a patient who had been operated on by Mr Paterson for an immediate reconstruction. "The pathologist had no idea which way the margins were [it had been a concern for years that Mr Paterson did not orient his specimens, making the pathologists' task more difficult and the care

<sup>&</sup>lt;sup>47</sup> Dr Stockdale, Mr Balasubramanian, Dr Fernando, Mr Ingle, Mr Jewkes and Dr Tanchel.

of the patient less satisfactory]. ... we said, 'Look', you know, 'at least stop the guy from doing immediate reconstructions because he is not doing them properly'".

- 7.69 A meeting was arranged for 4.30 pm that afternoon. I have not seen a record of the meeting, but it would appear that the clinicians were reassured that action would be taken in the light of the investigations which were going on. All of them had, of course, been interviewed as the Reports were being prepared. What was concerning them was that there was no feedback (everything being deemed confidential). As Mr Bala put it, "We did ask various people. ... what is exactly happening and nobody came back to us, nobody knew. On one side, we had Mr Paterson saying to everybody, including patients and other people, nurses and the GPs as well, that his colleagues have been unfairly victimising him. ... the Trust have looked at it, everything has been fine, he has been exonerated, and on the other hand, we had to do this because there is a concern, it's our duty. Nobody gave us feedback". They did not know what the reports might say. They were, therefore, increasingly concerned that history might repeat itself and nothing would happen.
- 7.70 This state of affairs in the breast team, which prompted the six to write, was of great concern. They were increasingly anxious that something should be done. Their concern was for the welfare of their patients. The outsider can ask with some justification whether senior management really appreciated or were prepared to address with urgency what was going on. After all, from the perspective of patients, the only relevant perspective, a breast team which was consumed by tensions cannot have served patients' interests. As one member of the breast team told me, "We talked as a group because at this stage things were getting pretty intolerable. [Mr]Paterson was still working; he was still in the MDT, being extremely difficult. ... the actual week-by-week atmosphere in the MDT ... was completely intolerable. It was toxic".
- 7.71 "Not only this, but the standard of surgery wasn't improved, even though everyone knew what was going on and Hennessy had been around ... he [Mr Paterson] was still operating the same old way. ... We said 'What are we going to do about this. ... The Trust know and are doing nothing'. So, this letter was basically us fulfilling our responsibility to our patients and making completely certain that there was no possibility that it would be mis-interpreted".
- 7.72 After seeing them, the Chief Executive subsequently wrote to the six clinicians on December 20. He confirmed that their letter would be passed to Mr Hennessy, although he had by that time submitted his draft report. The Chief Executive agreed to ensure that Mr Cunliffe would confirm what interim measures had been put in place. He agreed further to communicate the current state of affairs to Mr Jewkes who would then let them know. What is missing is any commitment that they would see the reports emanating from the investigations.
- 7.73 As I have said, they did not see the Reports. This only added to the prevailing uncertainty and, in the case of some, suspicion about what was being done. It also served to exclude all the members of the breast team, except Mr Paterson, from any meaningful engagement with the issues at hand. They were left in a kind of limbo which merely served to add further to the dysfunctional nature of the team.
- 7.74 It would be difficult to find a more telling illustration of the position in which these clinicians were place than what happened in early and mid-January, 2008. On January 4, Mr Goldman met the six clinicians again to tell them (in outline form only)

about the findings of the investigations and the action taken. On January 5, he followed up this short briefing with a letter. On January 16, he wrote to these same consultants to say that the contents of his letter were confidential, that they were not to discuss it, and that it was "not acceptable to discuss the professional position of a colleague". So, they were left knowing very little and what they did know was a secret.

7.75 What was also missing from the exchange with the Chief Executive in the minds of some of the clinicians was a sense of urgency and a recognition of the level of concern. Dr Tanchel told me that "I felt maybe the Trust wasn't as concerned about the concerns as we were at the time". At this point, Dr Tanchel raised an issue of the greatest importance which will be a recurring theme. Should the Trust have required Mr Paterson to stop surgery, if only temporarily, to allow for a proper examination and to ensure that such an examination could be carried out free of concerns that Mr Paterson was still operating such that more patients might be put at risk? For Dr Tanchel, the Trust "wasn't as concerned as it should be", because "they weren't going to put a stop to anything straightaway. [Mr Paterson had, in fact, by then, been told to cease two forms of operation]. They said, 'We will investigate it and then do something' rather than say 'Well, you've raised a serious concern, let's sort it out this way'. Everyone had to continue working with Ian [Mr Paterson] at that time. It obviously caused a lot of difficulty".

#### **Action and Engagement**

- 7.76 Once Mr Hennessy and Dr Polson had made their recommendations, the Chief Executive and Mr Cunliffe had to decide on a course of action, designed to address the recommendations. I shall set these out later. Crucially, they had to answer the question raised by Dr Tanchel: should Mr Paterson continue to operate on patients with breast cancer? The Trust could have decided to pause, require Mr Paterson to cease operating, and carry out a careful review of what had been going on. After all, Mr Hennessy had not just been critical of the procedures which Mr Paterson had been asked to stop, but of his surgical technique more generally. <sup>48</sup> Mr Hennessy told me when we spoke that he would have advised that Mr Paterson should cease to operate. At the time, however, Mr Hennessy was more equivocal, writing to Mr Cunliffe that more work needed to be done on the relevant data and with the MDT before reaching a decision.
- 7.77 Mr Jewkes, a breast surgeon at Good Hope Hospital, told me that he pressed for Mr Paterson to be stopped from operating; to be suspended until a better understanding of what was going on and its possible implications for patients could be gained. "We were very supportive of this external inquiry [by Mr Hennessy], we felt it was the right thing to do. My only concern at the time, and I did express it to both Ian Cunliffe and particularly to Mark Goldman, was that Ian Paterson was allowed to remain in full employment. ... To get to the bottom of it [the concerns being expressed by Mr Ingle and others], and I'm not alone, without any prejudice he should be suspended from practice so that a full and detailed inquiry could take place, because one of the central issues, as I understood it, was about this extra breast tissue being left behind,

<sup>&</sup>lt;sup>48</sup> As was Mr Lee, a distinguished breast surgeon, who was asked, in accordance with Mr Hennessy's recommendations, to evaluate Mr Paterson's surgical practice, as I will describe later. He advised that Mr Paterson should cease operating until more was known.

how many patients this had affected, how much was left behind and really how long it had gone on for".

- 7.78 Mr Jewkes added that he was of the view that Mr Paterson's behaviour over a long period of time had given more than enough evidence that the Trust needed to take some firm action regarding him. He referred to the decision (which I will describe more fully later) to withdraw trainees from the breast unit as another in a pattern of behaviour that should have warranted action. "There is a significant background to him, a very significant background that most people were well aware of" such that "you would take that [the decision to withdraw trainees] with some concern". There were in his view enough dots to join up so as to make the picture clear.
- 7.79 Mr Budhoo was of a similar view. He told me that "when we had Colm Hennessy's report, my personal view would be actually I have enough here to say this requires a pretty broad review, this requires time to say, 'Ian [Mr Paterson], I think perhaps we ought to take you out of this, move you to an area where you can be of use'. That would have been what I would have suggested".
- 7.80 I have already pointed out that, if the issues at stake had been properly analysed, Mr Paterson's continuing failure to obtain proper consent would have been reason enough to require him to cease operating. But, despite the fact that the oncologists and Mr Hennessy had specifically referred to the problem of consent, the issues were not understood in that way.
- 7.81 In the absence of any clear understanding of what was being done, members of the breast team speculated on why no action was being taken as far as they could see. I was told that they "felt maybe that the Trust were worried about getting their breast surgery done and ... meeting targets ... and that's why they didn't do anything. You didn't know why they did it. You could just speculate really". And one speculation was particularly corrosive to a sense of clear leadership: "Mark Goldman and Ian [Mr Paterson] were vascular surgeons. You didn't know if there was some buddy-buddy connection or not. You didn't know if they actually believed you or agreed with your concerns or not, whether they were taking them seriously". I have not found any evidence to support the notion that Mr Goldman's conduct was shaped by his connection with Mr Paterson. But, this may not be the point. The point is that, in the absence of knowledge and understanding, rumour and speculation, including very damaging speculation, fill the vacuum.
- 7.82 Dr Tanchel, who put his name to the letter to the Chief Executive told me that "I think one of the bugbears about the whole thing is we've not been very fully informed about what's happened or happening the whole way through. ... I felt that as a whistle-blower you feel like you've done something wrong and certainly the information coming back to me was very little, very limited".
- 7.83 For another member of the six who saw Mr Goldman, what he took away from the meeting was that Mr Goldman "was clearly of the view that because he hadn't received the report [he was referring to the meeting on December 4th] there wasn't very much he could do. ... his stance was absolutely that we had a case to prove and that until we had proven the case his responsibility was to support [Mr] Paterson".
- 7.84 One example of exchanges within the Trust at that time may serve to illustrate the difficulties that members of the breast team found themselves in, given their lack of information. A File Note prepared by Mr Cunliffe records a conversation he had with

a breast care nurse, dated January 11, 2008. She reported that Dr Fernando told a patient who was being considered for radiotherapy after a further mastectomy for recurrent cancer, that her initial surgery had been inadequate and that it was this that had necessitated further treatment. He further told the patient that there was an "ongoing enquiry" into the surgery on her and other patients. He did not mention Mr Paterson by name. Mr Cunliffe recorded that he told the nurse that the investigation was confidential and that he would raise the issue with Dr Fernando. He then recorded that he telephoned Dr Fernando, told him that the investigation was confidential, and that it was not appropriate to discuss it with patients. Simultaneously, he noted that he told Dr Fernando that he was "entirely within his rights to give his honest clinical opinion to the patient on their surgery". This may not have been an easy set of messages to interpret. He then spoke to the Cancer Manager, stressing the need for confidentiality. The hatches were closed again.

- 7.85 It was clear that only a tight circle of senior staff were aware of what Dr Polson and Mr Hennessy had recommended regarding the concerns about Mr Paterson's surgical practice. This put other senior staff who were outside the circle in an impossible position. Though they were responsible for the leadership of their staff, many of whom were aware of the various rumours doing the rounds, they could not meet those responsibilities as leaders effectively while in a state of ignorance. Nor could they carry out their responsibilities to the Board as senior staff. Things were happening under their noses which they were unaware of.
- 7.86 Another exchange, relating to the recognised need to do something about the MDT, was between Mr Cunliffe and the Chief Executive. Mr Cunliffe wrote to a number of senior managers, including Mr Goldman and Mr Bala (on December 19, 2008) that in the light of the two reports he would be "putting in place a neutral chairman of the MDT". The language of "neutrality" reveals not only what the situation was like before but how the Trust proposed to deal with it. Collaborative team work was not being advocated, as possibly being unattainable. Instead, a "neutral" would hold the ring. It is important to bear in mind again what that might mean from the perspective of patients. The MDT was the critically important environment in which the care of patients should be discussed and agreed upon. To accept that clinicians were at loggerheads and needed a referee may be thought to be a less than appropriate response. Something rather more robust was perhaps called for, requiring, in turn, robust leadership. In the event, Mr Cunliffe decided to be the "neutral" chair. And, in the view of colleagues, the MDT's overall performance improved. After six months, he was replaced by a clinician whose brief was to create better working relations. That is to say, he concentrated on the dysfunctional nature of the MDT. Then he left during 2009 from which point Mr Bala took over the chair and, in the view of some, it reverted to type, made worse when decisions about recalling patients fell to be made.

#### Conclusions about the Events of 2007

7.87 The process for appointing Mr Ingle demonstrated clearly the failure of senior managers to get to grips with what they saw as the disruptive behaviour of Mr Paterson. They preferred to work around him rather than tackle his behaviour and, thereby, deal with the continuing difficulties in the way that the MDT operated and show to other members of the breast team that no-one was more important than the team. This was another missed opportunity which sent a message both to Mr

Paterson, provoking his resentment, and to the other members of the team, suggesting weakness.

- 7.88 When Mr Ingle raised his concerns, the Trust, through its senior managers, acted properly in deciding to launch an investigation. They were also right to bring in an independent, external expert to evaluate Mr Paterson's surgical practice.
- 7.89 While Dr Polson carried out his part of the investigation commendably well, it would probably have been better to put the whole of the investigation in the hands of an independent, external adviser. There had already been an internal investigation almost four years previously, with little or nothing to show for it. More robust and confident management would have recognised that an investigation by an external adviser was what was needed.
- 7.90 Both Dr Polson and Mr Hennessy received very little administrative and other support in carrying out their investigations. This meant that the process took too long. The reason is not clear. It may have been simply a misjudgement as to what was needed. It may have been a failure to grasp the seriousness of the issues under investigation, although, given the evidence already in existence, this is difficult to imagine.
- 7.91 The decision was taken that the investigations should be carried out in accordance with the established disciplinary procedures. These procedures are well-known to be prone to last for years. The decision was to affect the Trust's response to concerns and dealings between the Trust and Mr Paterson for the next six years, up to the present.
- 7.92 The Board, while informed that the investigations were being carried out, played no effective role in them thereafter, nor was it informed formally of the findings of either Dr Polson or Mr Hennessy. The consequence was that the Board was not able to assess how its responsibility for the welfare of patients might be affected by the investigations. There was a failure on the part of senior managers to engage the Board and a failure on the part of the Board to exercise any sort of superintendence. No assurance for the Board could be gained through the appointment of a Non-Executive to "oversee" the investigation. The role was not understood and the opportunity to use it to inject the wider interests of the Trust into the investigations was not taken. If the Trust seeks a mechanism for reassuring itself about the conduct of such investigations, and it should, a better approach is needed.
- 7.93 Dr Polson and Mr Hennessy refer back to the events of 2003 and to the fact that the concerns they were investigating in 2007 were known at least in 2003 and were unresolved. Moreover, they both make the point that these concerns were about more than the conduct of the MDT; they related to Mr Paterson's surgical practice and clinical competence. Thus, it cannot be said, though it was repeatedly said, that concerns about Mr Paterson's surgery first surfaced in 2007. This was not the case and those who read the Reports were aware of this, in particular Mr Goldman and Mr Cunliffe. It was Mr Cunliffe who managed the response to the Reports and briefed his successor (in 2010) when he handed over responsibility.
- 7.94 The Trust invoked the disciplinary procedures through HR. Concerns over the safety and quality of care should not be investigated through these procedures. The disciplinary procedures should be concerned with personal misconduct. They may run parallel to investigations about the safety and quality of care but the disciplinary procedures' recourse to confidentiality must not prevent these investigations from

being open. The organisation will only learn the necessary lessons if investigations into the safety and quality of care are conducted in an open manner with the engagement of all.

- 7.95 The resort to the disciplinary procedures led to a complete clamp-down on communication between the senior managers who received the Reports and the rest of the staff, in particular, those in the breast team. This, in turn, led to festering ill-will, suspicion, rumour and speculation. The leadership and management of the team were parlous, though defended by reference to the fact that there was a disciplinary process in progress and so confidentiality ruled. It is frankly extraordinary that those most intimately involved in the care of women with breast cancer should not be made aware of what was happening in relation to the leading surgeon in the unit.
- 7.96 I am drawn to the conclusion that the decision to resort to the disciplinary procedures was a product of the perspective adopted and the culture of the time. The perspective was that of the professional whose career might be harmed. It would be harmed, the thinking goes, even if he were exonerated (which, on closer analysis, was not going to be the case, given what I have said about consent). The harm would be the inevitable damage to Mr Paterson's reputation and, perhaps, the loss of skills if not operating. There is, of course, another perspective: the patient's perspective. From her perspective, being fair to Mr Paterson would be important, but so would protecting her from possible or real harm.
- 7.97 I am also drawn to the conclusion that resort to the disciplinary process, whatever was or was not intended, had the effect that it allowed the senior management to control and contain what they saw as a problem to be managed.
- 7.98 There were two other options available by way of approach, rather than resort to the disciplinary procedures. The first would have depended on a proper analysis of the role of consent. It had been flagged up by the oncologists in 2003 and by Mr Hennessy in his report. Senior managers had the opportunity to stop Mr Paterson from further surgery on the basis of a failure to obtain proper consent. Once stopped, an investigation into what was going on could have been conducted with all due speed. No further patients would have been exposed to an increased risk of a recurrence of their cancer.
- 7.99 Alternatively, senior management could have decided that the effect of the Reports of Dr Polson and Mr Hennessy should be that there should be a pause in Mr Paterson's surgery on women with breast cancer, while the various strands of the Reports were explored. Mr Paterson could have been redeployed, for example to vascular surgery, and supported in the interim. This would have allowed the Trust to be fair to him. It would also have allowed the Trust to be fair to patients and other members of staff.
- 7.100 Neither of these options was taken. But, the Chief Executive and senior managers did act promptly in requiring Mr Paterson to cease carrying out csm and "shaves after mastectomy" once they received Mr Hennessy's Report and Dr Polson's Interim Report. In doing so, they acted correctly.

## 8 CHAPTER VIII

# THE RESPONSE TO THE REPORTS OF 2007

### **Initial Actions**

- 8.1 At a meeting on April 14, 2008, Mr Goldman brought together Dr Cunliffe, an HR Consultant, an External Consultant Facilitator, the Director of Governance and the Director of Safety. The purpose was to discuss Dr Polson's Final Report and Mr Hennessey's Report and decide on action <sup>49</sup>. It was noted that:
  - "The MDT process needs to be reengineered
  - IP [Mr Paterson] needs to accept his practice is unacceptable
  - The Trust needs to recognise that colleagues who raised concerns were right to do so and MG's [Mark Goldman, the Chief Executive] role was critical".
- 8.2 So far so good, but, of course, actions were required rather than a restatement of what was known. And, Mr Budhoo, who had several years' experience in dealing with Mr Paterson, told me that he had sought to persuade Mr Goldman and his colleagues that "You're not going to win". When I asked him what he meant, he replied, "I said that Ian's [Mr Paterson's] personality is such that he lacks insight into what his problem is and, therefore, if you have not got any insight into what you do that is not right, you can't correct it and Ian has very little insight into his behaviour in particular and his practice and if he does lack insight, I am afraid you are not going to be able to succeed, because the very first thing to change somebody is they have to understand that there is a problem. I do not know if Ian has actually accepted he has a problem anyway". Here was another argument to cause Mr Paterson to cease operating.
- 8.3 Once the general direction to be taken was agreed, the discussion turned to identifying patients who might need further care. The thinking was that Mr Paterson had been required to cease the two unacceptable procedures. It was then a question of dealing with whatever fallout there might be from when he was carrying out these procedures. Mr Goldman is recorded as saying that he was, "concerned about the 63 cases [identified by Dr Stockdale and considered by Mr Hennessy] and that if any had been undertreated then something needed to be done". Mr Goldman went on that "IP [Mr Paterson] had continued to undertake an unacceptable procedure. ... the Trust had contained the risk by containing IP's practice but had not yet dealt with IP's poor practice". Presumably, this means that the Trust had not dealt with the consequences of Mr Paterson's poor practice: they were still to be assessed. The note then goes on to record that Mr Cunliffe concluded by asserting that Mr Paterson's "colleagues [who were at the meeting] would wish IP to stay". None of these "colleagues" were, of course members of the breast team. They might well have taken a different view.

<sup>&</sup>lt;sup>49</sup> Mr Goldman wrote to the Chief Executive of the Primary Care Trust on April 26, 2008 advising that the Trust was dealing with the matters which had been raised, and to two other local private hospitals on May 21, 2008 advising them of the actions taken regarding Mr Paterson.

- 8.4 Mr Cunliffe took over as chair of the MDT for about six months to address the interpersonal problems which bedevilled it. Mr Ingle moved to Good Hope Hospital to join the breast team there. Then, the chair of the MDT was passed on to one of its members, Dr Dylan Jenkins, for another six or so months, before it was assumed more permanently by Mr Bala. During Mr Cunliffe's tenure, there was a view that the MDT had settled down somewhat and was functioning better.
- 8.5 After an initial approach in July, 2007 by Mr Cunliffe to NCAS (the National Clinical Assessment Service, the agency established by the Department of Health to advise Trusts on how to manage issues of personal conduct by consultants), Mr Cunliffe advised NCAS in March 2008 that he had received the reports from Dr Polson and Mr Hennessy. Dr Boyle, from NCAS noted that the Trust was proposing "...to address any clinical concerns through local action".<sup>50</sup> Mr Paterson was advised by Mr Cunliffe on May 21, 2008 that, if he were to agree, his "case" would be referred to NCAS for assessment. An Action Plan would follow the assessment, which would require his agreement. After some delay, Mr Paterson signed up to the Plan in September 2008, a year after Dr Polson began his investigation.
- 8.6 A comprehensive and detailed Action Plan was drawn up by the Trust in conjunction with NCAS. There were a number of components to this Plan. As I have said, before the Plan was put together, the Trust had already, immediately on receiving Dr Polson's Report, required Mr Paterson to cease with immediate effect carrying out the procedure described as csm and he had agreed to do so. The first objective of the Plan was for Mr Paterson to be observed by a fellow breast surgeon while operating, to satisfy the Trust that he was able properly to carry out surgery for breast cancer, particularly a mastectomy. In addition, he was required to undertake some further cpd (continuing professional development), which was to include a visit to London, to Mr (now Lord) Kakkar's clinic.

## Mr Lee's observation

- 8.7 It fell to the Medical Director Surgery, Mr Cunliffe, as the responsible Director, to monitor and record Mr Paterson's compliance with the various elements of the Action Plan. A detailed set of papers was compiled recording progress and reporting to NCAS. The first objective, the observation of Mr Paterson's surgery, was carried out by Mr Martin Lee, a distinguished surgeon and consultant at University Hospital Coventry and Warwickshire who had been the President of the Association of Breast Surgery. He undertook the task without having been shown either Dr Polson's or Mr Hennessy's Reports. Equally, he was not made aware of Mr Wake's Report and the reference to tissue being left behind. To that extent, he was free of any influence that those Reports might have on him. But, on the other hand, without seeing the Reports, his observation was context-free, not least that concerns were not just about technique but about the consequences of Mr Paterson's surgery. This may be thought to be another lost opportunity to draw on the undoubted expertise of a leading national figure.
- 8.8 As Mr Lee put it, his conversation with Mr Cunliffe "was along the lines of, 'His practice has been looked at ... we don't think it is good practice and we want to check that he is now operating properly". Mr Lee told me that he was "surprised to have

<sup>&</sup>lt;sup>50</sup> Correspondence dated March 6, 2008.

heard about all these other reports. I did this as a bespoke bit of responding to a request. Maybe it would have been better if I had said 'It sounds like you've got a real problem here, I'm not going to touch it' or 'You should get a College review [by the Royal College of Surgeons] done immediately', but I did tell them subsequently when this data started appearing, that I thought there was a massive problem that needed to be looked back into. I think there was a bit of resistance." Mr Lee added that he regretted that "this has gone on for so long and we [breast surgeons] have been asked as individuals to look at the practice without there being a coordinated approach".

- 8.9 The lack of coordination, for which there may have been a number of reasons, is a central factor in understanding how the Trust responded over the years. It may have been due to the fact that there was only a gradual awareness of the scale of the concerns. It may have been due to managerial inexperience or reticence. It may have been due to a desire to retain control over the matter and deal with it effectively behind closed doors. The fact remains that actions were piecemeal and the insights of one investigation or examination did not always inform the next step in the process. The complete picture, if there was one, was known to only a very few.
- 8.10 Mr Lee reported to the Trust on November 28, 2008, nearly a year after Mr Hennessy had given the Trust his views.<sup>51</sup> His findings were not exactly reassuring. Indeed, they were contested, but eventually accepted by Mr Paterson. As it happens, Mr Lee was not made aware of Mr Paterson's criticisms, not least so as to allow him to offer his view, and only became aware of them when I showed them to him. This is another of the many examples of information existing and being kept in silos, thereby preventing comment and the ability to paint as broad and rich a picture as possible of what was happening.
- 8.11 Mr Lee observed 5 operations. He wrote a Report for Mr Cunliffe. Of the four particular comments in his Report, one expressed concern about Mr Paterson's maintenance of a sterile environment. Another refers to the sense that Mr Paterson's surgery should be "less rushed". This is a serious concern. Mr Lee remarked in his report that "there is wide variation in the time different surgeons take to do the same procedure". "However", he went on, "a point can be reached when excessive operating speed compromises outcome. ... Operating too rapidly may jeopardise the oncological aim of complete breast tissue removal, increase the risk of post-operative bleeding, and compromise healing."
- 8.12 When I spoke to him, Mr Lee described Mr Paterson's surgery as "slipshod". This concern was not new. It had been expressed on a number of occasions previously. Mr Paterson had gained a reputation for being a fast operator. He could do several operations for breast cancer in a morning while others would do two or three. To some, this was because he was a very dextrous and quick operator. To others, it was because he was not sufficiently careful. The word "slapdash" was put to me. Indeed, the speed at which he operated was suggested as a reason why breast tissue of varying amounts was sometimes left behind. That is to say that the reason was not, or was not exclusively, because of csm but also because, on occasions, he operated in too hurried a manner. As one clinician put it, this notion of a hastily carried out

<sup>&</sup>lt;sup>51</sup> As with other Reports, it was not shown to members of the breast team, even though it might be thought that they would be interested in and need to know what was being said about a senior colleague's surgical technique and what recommendations were made.

operation "is the only explanation [why tissue was left behind] because if he was doing it ... as a planned procedure it would be the same procedure on every patient". Clearly it was not, given that some had a complete or near-complete mastectomy, while others had significant residual tissue left behind.

- 8.13 Mr Lee put it as follows: "Watching him operate was like a whirlwind really. He would breeze into the theatre, a sort of constant impatience with things and just try and get on as quickly as possible and that is something I have not seen very often. ... there are some surgeons who operate slowly and some who operate more quickly, but the point is that you should do it without rush, with care and attention".
- 8.14 In the conclusions to his report, Mr Lee focussed on three areas: basic technique; oncological technique; and training environment.
- 8.15 As regards basic technique, Mr Lee reported that he "found some technical deficits in Mr Paterson's operating that require attention". He pointed to the need for:
  - "fastidious attention to haemostasis
  - meticulous gentle and precise dissection and handling of tissue
  - a less rushed approach to operating
  - consistent adherence to sterile technique"
- 8.16 As regards oncological technique, Mr Lee wrote that "To be assured that as complete a mastectomy as possible is achieved on every occasion, there is a need for Mr Paterson to ensure that he pays meticulous attention to the goal of removal of all breast tissue".
- 8.17 As regards the training environment, Mr Lee wrote, somewhat cryptically, that "Mr Paterson provides training for specialist registrars. The breast training of those under his supervision needs to be addressed".
- 8.18 Mr Lee made four specific recommendations:
  - "That Mr Paterson is advised of the specific concerns about his surgical technique and given the opportunity for targeted intervention to include proctoring, monitoring and validation
  - That he attends and completes an agreed programme of relevant breast surgery cpd [continuing professional development]
  - That the Director of the Regional Training Programme in General Surgery is advised of the breast training issue
  - That he is provided with mentoring to support him through a difficult professional experience".
- 8.19 It is not clear how much was done in the light of Mr Lee's observations. It could be said that, taken together with the comments made about Mr Paterson's surgery by Mr Hennessy several months earlier, some significant action was called for; at the very least a period of closer monitoring of Mr Paterson. Some reassurance was

forthcoming. Members of the MDT were reporting that the surgery they were seeing was satisfactory: Mr Paterson was producing a flat chest wall. But, while Mr Paterson did receive some mentoring, the recommended sessions of continuing professional development were more problematic, as no specific programme for breast surgeons existed. In the event, Mr Paterson produced for Mr Cunliffe, according to a note, "the various reports and meetings and papers that he had been to and done, which seemed to fulfil the CPD-type requirements". He did not visit Mr (now Lord) Kakkar's clinic in London, though it was part of the package of agreed measures. <sup>52</sup>

- 8.20 One issue which I find significant is Mr Lee's reference to the fact that Mr Paterson "provides training for specialist registrars. The breast training of those under his supervision needs to be addressed". Mr Lee was clearly right. It would be a matter of great concern if a new generation of surgeons were exposed to csm and other practices as being an appropriate way to operate.<sup>53</sup> Mr Lee told me that he regarded it as "a matter for serious concern and that the Regional Training Director should be advised". Mr Jewkes, who was the Programme Director for Surgical Training for the West Midlands told me that such was the concern over Mr Paterson's conduct as a trainer that the decision was taken to remove the person currently being trained in 2008, and, thereafter, to stop sending trainees to the breast unit. This was done independently by the Training Committee of the Postgraduate Deanery. It was not instigated at the request of the Trust, as a response to Mr Lee's Report <sup>54</sup>. In fact, despite Mr Lee's expression of concern, Mr Jewkes, who was responsible for the training programme, was not shown nor made aware of Mr Lee's Report. This might be thought to be extraordinary given its clear importance for the future welfare of women needing surgery for breast cancer. Again, it might be thought that the claims of respect for the confidentiality of the HR process were given undue priority as against the interests of patients and the wider public interest.
- 8.21 I read to Mr Lee what Mr Hennessy had concluded and asked him whether, if he had been shown Mr Hennessy's Report, he would have formed a view that something else was called for beyond just observing Mr Paterson's operating technique and making recommendations. He replied, "Yes. Hearing that now, I would have taken the view that a systematic review of what had happened to all of those patients was required. It seemed pretty clear from that [Mr Hennessy's Report] that there were problems with the technical approach to operating, but the proof is in the outcomes and that would need to take account of the whole cancer treatment for those individuals".
- 8.22 A systematic review is what the Trust ultimately decided on.
- 8.23 But, would Mr Lee have gone further and called a halt to Mr Paterson's surgery till there had been an opportunity to take stock? I have already raised this point. I return to it here as I was keen to get Mr Lee's view since, besides being a distinguished breast surgeon, he also has considerable experience as a senior manager. Mr Lee

<sup>&</sup>lt;sup>52</sup> He was due to visit twice a month for four months.

<sup>&</sup>lt;sup>53</sup> I was assured by Dr Anwar that the Trust had subsequently looked into the issue and found that trainees had been exposed to and, indeed, had undertaken csm under Mr Paterson's supervision. He advised me that, although not all trainees had yet been contacted, those contacted did not appear to have continued the practice.

<sup>&</sup>lt;sup>54</sup> Although Mr Cunliffe did at some point write to the Director of the Regional Training programme.

told me that "I feel that if there was information available at the time which showed increased recurrence rates as well as concerns by colleagues in the team as well as concerns about operative technique then that adds up to the need to actually say that actually we put patients' safety first and stop him operating on breast cancer". The first of Mr Lee's conditions was difficult to satisfy, given the potential for arguments about data which later bedevilled the response to concerns, as I describe later, though there was the experience of Mr Ingle and others that they were seeing patients with recurrences. The two other conditions were more than satisfied. Mr Lee went on to point out that the Trust could have asked the Royal College of Surgeons to carry out a "rapid review of practice". If there had been such a review, Mr Lee thought it "highly likely" that it would have proposed that Mr Paterson should stop operating.

#### **Taking Things Forward**

- 8.24 In addition to being observed by Mr Lee, another objective of the Action Plan was that Mr Paterson was required to develop the necessary skills for working in a team. A number of measures were put in place to achieve this. One, however, involving Mr Paterson's involvement in 360 degree evaluation was not completed. A further objective was that Mr Paterson co-operate in the development of changes to the way in which the MDT was managed, in audit programmes and reviews of patients.
- 8.25 Mr Paterson's compliance with the various elements of the Plan as originally formulated was monitored. Progress was reported on most fronts. Mr Paterson submitted himself to coaching, though to what effect is not clear. Significantly, slow progress was recorded on the development of tools for auditing performance (something that had dogged the scrutiny of Mr Paterson's surgery for years) and in reviewing and identifying patients who might have a recurrence of cancer after what was believed to be curative surgery. Also, as I have said, the proposed visit to London to Mr (now Lord) Kakkar's clinic never took place because of difficulties in arranging it.
- 8.26 Mr Paterson then carried on.<sup>55</sup> He did so in an environment in which other members of the Breast team were unaware and not made aware of the overall Plan and how it was proceeding. They did see, they said, a change in the surgery carried out by Mr Paterson and in the discussions in the MDT. They were aware that Mr Lee had visited and that Mr Paterson had been observed, but only in general terms. So, that said, the bush telegraph had to serve as the default means of disseminating information as regards the senior breast surgeon. Undoubtedly, this was because of the cloak of confidentiality which was part of taking the HR route. If so, it made for the opposite of good HR. And the unawareness extended to middle managers. Mr Hendrickse had been Clinical Director Surgery from 2003 2005 but told me that during that time and later he was not made aware of the concerns regarding breast surgery. It was only when he was asked to conduct a review in late 2008 that he became aware.

<sup>&</sup>lt;sup>55</sup> On July 23, 2008 Dr Milligan wrote to Mr Cunliffe after an appraisal meeting with Dr Fernando to report that Dr Fernando remained "very concerned about what he sees [as] the continued inadequate surgery in the Breast MDT". Dr Milligan made it clear that he was referring to Mr Paterson. He wrote "I find it worrying that a senior Clinical Oncologist still feels that the quality of surgery being delivered is not safe". It should be said that Dr Stockdale, Dr Fernando's colleague, took a different view. He told me that once Mr Paterson's practice was challenged, it changed. "It became abundantly clear that [Mr] Paterson was more than capable of doing the operation properly". Perhaps, Dr Stockdale's comments should be seen against the background of the views of Mr Lee about aspects of Mr Paterson's technique which Dr Stockdale might be unaware of.

### The Trust's view of the world

8.27 This may be a good point to reflect briefly on what the Trust might say of its actions. Leaving aside, for the sake of argument, the history of concerns from 2003 to 2007, the Trust could say that concerns had been raised in 2007; prompt action by way of an internal and external investigation had been launched; Mr Paterson had been required to cease certain unorthodox and unrecognised forms of operation; an investigation was in train to determine whether that form of operation posed any risks to patients and if so what should be done; and, Mr Paterson had undertaken some retraining and would continue to be part of the surgical team on certain conditions. On this view, a picture is painted of the Trust as having behaved at every step in a reasonable and responsible way. The question for the observer, when assessing what has gone before and what comes after, is whether this view of the world as seen by the Trust is valid.

## The Trust's Approach and its Implications for Patients

- 8.28 Dr Polson and Mr Hennessy had reported that Mr Paterson was not, on occasions, carrying out a mastectomy as properly understood, but was leaving behind tissue. In doing so, they confirmed the concerns expressed by Mr Ingle in mid-2007 and those expressed earlier by Drs Stockdale and Fernando. Moreover, Mr Ingle had reported seeing recurrences of cancer in breast tissue in women who were supposed to have had a mastectomy. Quite apart from the issue of how to manage Mr Paterson, the Trust was then faced with another question. What should it do about the many women patients on whom Mr Paterson had carried out what had been recorded as a mastectomy but may not, in fact, have been one?
- 8.29 It is important to understand how this question was approached. Put shortly, it was defined by the senior management as a question of risk. Mr Paterson's surgical practice was approached as if it was a variation to the normal way of performing a mastectomy. Implicit in this approach was an assumption, therefore, that, though there was a departure from the norm, it did not follow that any harm was done to patients. The position adopted was one of neutrality: it may be no more than a different and innovative procedure. Alternatively, there may be a risk of harm.
- 8.30 The notion of its just being an innovative procedure could not hold water. For him to carry out some innovation, Mr Paterson should have been following the protocol which set out what should be done before innovations were actually incorporated into practice. The days of surgeons just deciding that they would "have a go" and introduce their own variation to existing procedures were over. This had been one of the consequences of the Bristol Inquiry. Mr Paterson had not followed any protocol. He had not provided the evidence to justify his particular deviation from standard practice. His surgery, therefore, could not be justified and defended on the basis of innovation, though some did and do.
- 8.31 This left senior managers with the second option. Mr Paterson's surgery was a departure from accepted practice. It should, therefore, cease and it had. But, the question still remaining on this view was: had women been put at greater risk of harm. This was the option adopted by senior management over the next several years. It led to what could be described as a bifurcated response. On the one hand, Mr Paterson should continue to operate subject to his ceasing to do csm. On the other hand, the Trust would seek to determine whether csm posed a risk of harm to women.

- 8.32 The approach is well illustrated by reference to a meeting that I have already referred to, attended by Mr Cunliffe, the Director of Safety and Governance, and Ms East and Mr Hensel, as Members of the Board, though their precise status and role at the meeting are unclear. At the meeting, it was reported that a surgeon (Mr Paterson was not named) had been carrying out csm and the issue of recalling patients was being considered. The question put to the group was how to deal with a case where women may or may not be adversely affected by the surgeon's procedures, because, they were advised, it was not absolutely clear whether he had actually done them harm.<sup>56</sup>
- 8.33 A number of comments can be made. First, as I have said a number of times, there was another option: to take the opportunity in the light of the Hennessy/Polson recommendations to require Mr Paterson to stop operating on women with breast cancer, draw breath and evaluate what was in the best interests of patients past and future. After all, Mr Hennessy did not pull his punches. His Report was strongly worded.
- 8.34 Secondly, as part of what I have described as its bifurcated response, the Trust adopted as a central premise of Mr Paterson's continuing to operate on women with breast cancer that he would comply with the Trust's requirements, including that he cease to carry out csm. At least one person present at the meeting on April 14, 2008 to finalise arrangements for the future, warned that Mr Paterson's personality was such that he might not, in fact, do what he was being asked to agree to. This is an important point. It again raises the question of perspective. From the perspective of fellow-clinicians in the Executive of the Trust, it was enough to get Mr Paterson to agree. This is how professionals dealt with each other. No more was called for. From the perspective of the patient and the notion of good governance, however, if he was going to operate at all, some system of ensuring that he complied with the conditions was essential, rather than waiting to react if a breach came to light. But, no such system was put in place. And, Mr Paterson did breach the conditions that had been laid down.
- 8.35 Thirdly, the neutral position adopted by senior managers on the issue of risk was hard to justify. Clinicians had been saying since at least 2003 that Mr Paterson was leaving behind tissue after performing a "mastectomy". Mr Hennessy confirmed this. It was, therefore, at the very least, strongly arguable that women were being exposed to a greater risk of recurrence. Although it is accepted that it cannot be guaranteed that all tissue will be removed during a mastectomy, volumes of tissue of the order that had been discussed and documented were considerably in excess of the recognised norm and meant that an increased risk of recurrence was well-nigh inevitable.
- 8.36 It was accepted by all to whom I spoke that intentionally leaving tissue behind in the process of carrying out a mastectomy not only was not a mastectomy, but inevitably created a greater risk of recurrence. This being so, the Trust asked itself the wrong question. It was not whether there was an increased risk. On any reasoned analysis, there was. The Trust should have asked itself two different questions: first, given that there must be an increased risk, what was the extent of the risk, and, even more important where a potentially fatal disease is being considered, what are the

<sup>&</sup>lt;sup>56</sup> Of course, many women had been harmed already, whatever might be the case as regards csm, because of the failure to obtain consent and, on occasions, the exposure to additional surgery and anaesthesia in the case of "shaves after mastectomy", but this seems not to have been appreciated.

consequences if the risk were to become a reality. But, as I have said, the Trust asked itself the question whether there was an increased risk associated with csm. This set the Trust off on a course of action which over the following several years slowly and spectacularly unravelled.

- 8.37 Taking all these points together, they argue strongly that when the senior management of the Trust were deciding what to do about women operated on by Mr Paterson over the previous nine or so years, it should have been clear to them that some of the women ran an increased risk of the recurrence of their cancer. A position of neutral inquiry as to whether they did or not was untenable. It should then have been clear that treating the issue as one of scientifically attempting to define the risk that women were exposed to was the wrong approach. Women were at risk. A decision to recall patients was called for. And, given the arguments set out, it was difficult to see how it could be other than a recall of **all** the patients on whom Mr Paterson had operated in the relevant time. And, it is important to add, this is not a judgement based on hindsight. The relevant facts were known at the time.
- 8.38 There was no plausible alternative: every woman on whom Mr Paterson had performed a csm needed to be checked. Clearly, such an approach would involve identifying those women who had had a csm. But, no-one (except Mr Paterson) knew which patient had had a mastectomy and which a csm. The consent form in each case recorded that a mastectomy had been carried out. The patient's notes recorded a mastectomy in all cases. Therefore, the consent form would not tell anyone who had had a csm, nor would the medical records. Photographs of the patient after surgery would not necessarily indicate whether a csm had been performed, particularly when the patient had had an immediate reconstruction. The treatment record would not indicate this either, because, except when the radiologists or oncologists "compensated" for the fact that a mastectomy had not been performed, the treatment regime would have been that appropriate for a mastectomy, whether one had been performed or not. Thus, in the circumstances, it was next to impossible to assess which patients were at an increased risk without examining each woman.

#### The Decision – A Limited Recall

- 8.39 Although there was no plausible alternative, a different decision was taken. It was decided to recall only a limited number of patients. The reasons behind this decision are complex. In my view, they include the following. First, a recall process involving hundreds of patients is logistically a massive exercise. It may have appeared simply too daunting, or have been excluded as an option as being unthinkable. Second, the mindset of some of the senior managers was as I have described it: that what was involved was a variant of the normal procedure, carried out by someone deemed an able surgeon (despite the mounting evidence). They appear, therefore, not to have come to terms with how serious the issue was.
- 8.40 Third, a limited recall meant that most of the women who had undergone breast surgery for cancer would not be alarmed by being recalled. Only, those who might be thought (albeit on grounds which are hard to understand) to be most likely to be at some increased risk would be recalled. Advice on the question of the balance between alarming past patients and safeguarding those at increased risk was sought from an academic specialising in medical ethics who is also medically qualified. Her advice in a letter of January 9, 2010, was as might be expected. She set out the arguments for and against and then handed the issue back to the senior managers.

- 8.41 Fourth, the reputation of the Trust was at stake and would be more likely to be safeguarded if any recall was limited. Anything that could control the fallout from Mr Paterson's surgical practice was to be preferred. As I have suggested already, the overall approach appears to have been one of containment (or as one patient put it to me, "The Trust didn't seem terribly engaged with the people out there in the community who were worrying about this really. It was kind of, 'Let's damp it all down' sort of thing, you know, damage limitation").
- Mr Jewkes told me that he resigned as Lead Clinician for breast services in 2008 8.42 because he had no confidence in the process being adopted. As he put it, "... serious concerns had been expressed about ... this breast tissue being left behind. ... There are reasons to be concerned about that as a practice, that patients are being undertreated and under followed up because of that and are at much higher risk of recurrence and subsequent death. It wasn't clear how extensive the problem was. Nobody knew. ... We felt that the only way really, particularly for such a potentially big issue, was what subsequently happened, to have a full recall of all his patients ...". By opting for a limited recall, he went on, "they set up a situation ... where patients who are on routine follow-up ... and these are all Mr Paterson's patients, so they were normally seen in his clinic, so either himself ... a Trust grade doctor or the breast care nurses would have to identify that patient as potentially having a cleavage sparing mastectomy, that information would be passed to Charlie Hendrickse who would then ask, at the time it was Bala, to conduct a further review, a formal review of that patient. Certainly myself and my colleagues at Good Hope felt this was guite a mess in terms of being transparent. It could be viewed externally as a cover up. ... I did feel", he added, "that there was an enormous reluctance by senior management at Heartlands to take this on, to escalate it further. This was as far as they were going to go". Mr Jewkes told me that he proposed to Mr Goldman that there "should be a total recall and it should be external and impartial to have external validity. ... we were very uncomfortable with this and didn't see it as the right route". His argument and proposal did not prevail.
- 8.43 A senior nurse put it to me that there was a real sense of concern over what was going on. "I suppose", she said, "I felt that ... it [the concerns over Mr Paterson's surgical practice] hadn't been addressed because they didn't understand the implications of it or maybe they didn't want to understand the implications. ...What bothered me is the fact that, if members of the Solihull MDT raised it in 2003/2004 and it was never acted upon, where did their concerns disappear to? Did they suddenly decide as a team ... these concerns weren't ... important in the first place. ... maybe we don't need to worry about it?" This member of staff offered the view that "If I'm totally honest ... I felt .... It was all protecting one another and trying hard to brush it under the table and hope it went away". This, of course, is a perception, but it is important in reflecting the mood and level of understanding of what was in fact going on in the Trust. And, it is a perception allowed to gain weight, through the lack of any alternative explanations as a consequence of the HR process and the commitment to confidentiality <sup>57</sup>.

<sup>&</sup>lt;sup>57</sup> By contrast, Dr Smith rejected the notion of a "cover up" as I describe later.

#### Conclusions about the response to the Reports of 2007

- 8.44 The Trust's approach to NCAS was of symbolic as well as practical significance. It involved the working up of an Action Plan regarding Mr Paterson which, on its face, would appear to be a positive step. But, it also reflected a mind set in which the relevant perspective was that of the professional. NCAS's role was to facilitate the reintegration of professionals back into the Health Service. While this may have been a laudable objective, it may not have been the most important objective in the case of Mr Paterson. The welfare of past, present and future patients with breast cancer should have been the overriding concern of the Trust. The decision to invoke the disciplinary procedures led them to NCAS and thus, inevitably, to the perspective of the professional. As I have said, there were other choices in which the perspective of the patient would have been paramount.
- 8.45 Mr Paterson did not signify his agreement to the Action Plan until September, 2008, almost ten months after the Reports of 2007 appeared. This suggests at least a lack of a sense of urgency on the part of the senior managers. It also suggests a lack of determined and robust leadership.
- 8.46 Mr Lee's observation of Mr Paterson's surgery led to another critical assessment. And, it is important to notice that the critical comment was not limited to the csm and "shaves after mastectomy". It related to Mr Paterson's clinical competence generally. Nevertheless, Mr Paterson continued to operate on women with breast cancer for nearly four more years after the Reports of 2007 were submitted (albeit subject to Mr Paterson's agreement not to carry out the two identified procedures and the acknowledgement that there was an improvement in his surgery).
- 8.47 The cloak of confidentiality continued to cover everything that was going on from the perspective of the breast team. Those with most claim to know what was going on, not least so that they could do their best for their patients, remained in the dark. They managed on rumour and speculation, feeling abandoned by the Trust.
- 8.48 The Trust was right to take the view that, having stopped Mr Paterson from carrying out the proscribed procedures, they must turn their attention to the patients whom he had operated on in the previous years. The approach they adopted proceeded from two premises. First, Mr Paterson's operation (csm) was not conventional but that did not mean it was harmful. Second, it was necessary, therefore, to proceed on two fronts: to identify who had undergone csm and, at the same time, to establish whether it was harmful. This second premise took them into territory that was scientific/technical, a territory where clinicians feel more comfortable. There was a puzzle to solve, which could be solved by resort to a careful, scientific approach.
- 8.49 These premises were wrong. The approach was misguided. Women had clearly been exposed to a risk. The question was its scale. And its scale was important because of the consequences if the increased risk turned into reality.
- 8.50 It was urged by many of the clinicians most closely involved that it would be impossible to determine how many and which women were at increased risk, because there was no way to identify who had undergone a csm by looking at records and other documents. The only sure way was to recall all patients. This view was rejected by the Chief Executive and Mr Cunliffe in favour of a limited recall. The reasons are not clear but, in my view, include a concern at the sheer magnitude of organising such an large, open-ended recall, a failure to realise how serious the

problem was, a reluctance to alarm women who might be recalled only to discover that they were not at any increased risk, and a desire to safeguard the reputation of the Trust.

## 9 CHAPTER IX

# THE RECALL

#### Mr Paterson's Involvement

- 9.1 The decision was taken in the early summer of 2009 to recall only a limited number of patients: those who were thought to be most at risk. I have already suggested that this was both theoretically and factually flawed as a basis for proceeding. The absence of data on rates of recurrence of cancer in Mr Paterson's patients was used as a reason for adopting this limited approach: that it was not clear whether there was an increased risk of recurrence. But, according to the view of most others, the risks were clear and real. The process of recall should be concerned to demonstrate the extent of the increased risk. And, the extent of the increased risk would only emerge if **all** patients were checked. As I have explained, however, the converse position, that, until the risks were understood, the process of recall should be focussed and not provoke anxiety, prevailed. It is hard to justify.
- 9.2 After the initial arrangements were agreed between Mr Goldman and Mr Cunliffe, they were shared with the breast team. It then fell to Mr Cunliffe to organise the recall. As the first step was to try to establish who had received a csm, Mr Paterson was consulted. Given his stated position that any tissue left behind was only fat and posed no risk, he was a less than eager participant in the process. Dr Fernando was clear that "The appropriate strategy would have been that we can't tell who's had this operation or not, every patient needs to be recalled and they need to see somebody who's independent of Mr Paterson because Mr Paterson, in all fairness to him, cannot be relied upon to make an objective judgement on this matter. So to say that we need to discuss it with Mr Paterson and get Mr Paterson to review the patient, which of course when you bring it back to the MDT is what happens, is totally inappropriate".
- 9.3 If, however, the prevailing perspective was, as I have suggested, that Mr Paterson's surgery, while a deviation from accepted practice, may be experimental or innovative, and that it was not clear whether it posed any increased risk of recurrence, it was understandable to involve Mr Paterson in the exercise. Members of the MDT, however, found that Mr Paterson's involvement increased the level of tension, both in the day-to-day management of patients, since all of the clinicians involved continued to care for new patients as they presented, and as regards the process of trying to identify those to be recalled. As regards the latter, one of the pathologists who attended the MDT during this time told me that "until the last day there were discussions when that person [Mr Paterson] was defending himself that, no, he had been doing the right procedure and he was [told] by Mr Bala that 'enough is enough, don't you know what sort of mess the whole thing is in, we are in, now you have to stop saying that'. That was the last discussion and after that [Mr Paterson] disappeared and now the MDTs are like any other MDT should be".
- 9.4 Mr Paterson's involvement also to an extent weakened the efforts which were being made in the light of the several previous Reports, to improve the performance of the MDT. The breast team felt that the process whereby the MDT should identify patients who had undergone a csm and might be at increased risk of recurrence, and who might, therefore, need to be recalled, seriously undermined the MDT. Unsurprisingly,

Mr Paterson was critical of the whole process as being unwarranted, claiming that his procedure did not put patients at greater risk.<sup>58</sup> In the words of Dr Tanchel, "it was difficult because Ian [Mr Paterson] was very defensive and would contest everything and anything and never conceded he'd ever done anything wrong and there were a lot of tensions". The corrosive atmosphere which had been a feature of the MDT for years continued to prevail.<sup>59</sup> The problem was that, once it had been decide to institute a limited recall, the MDT needed to be involved in the process and so did Mr Paterson, since only he might know which patients had undergone a csm.

- 9.5 The dilemma was spelt out as late as April 29, 2011 in an e-mail sent by Clare Bate, the leading breast care nurse to the recently-appointed Medical Director, Dr Anwar. She refers to "a difficult and unpleasant Breast MDT" on April 26, 2011. Patients were being discussed who had asked to be reviewed because of what they had read in the press. Ms Bate writes that, "Mr Paterson has expressed the opinion that 'we' are raising anxiety unnecessarily and should be more reassuring with these ladies. ... My concern is", she goes on, "that Mr Bala has put these patients down for discussion", but "we are not able to have a valuable, unbiased and open discussion about these ladies in Mr Paterson's presence, partly because he cannot be unbiased in his opinions and partly because his being there inhibits discussion. ... Mr Bala needs a safe and unbiased environment in the MDT to help him advise these ladies and I am concerned that this is not happening". And, this was just weeks before the decision was taken to exclude Mr Paterson from the Trust.
- 9.6 And, it needs to be added, throughout the whole period, Mr Paterson continued, on occasions, to re-operate on patients who needed further surgery, despite the fact that this need had been created by the previous surgery he had performed. This led to even further tensions and, to a degree, incredulity in the team.

#### Managing the Limited Recall

- 9.7 Given that the first question to be answered was which women had undergone csm, the recall team, effectively Mr Hendrickse, the Clinical Director Surgery and Ms Marnock, as General Manager, with input from members of the breast team, set about examining records, databases, treatment plans, and photographs as a way of identifying who had had csm.
- 9.8 I have already referred to the disquiet among members of staff at the inappropriateness of this approach. Members of staff described how they had been to see Mr Cunliffe in March 2009. Concerned that the approach of identifying patients from records was inherently flawed, they urged that" if women were going to be recalled ... it should be all women, not just a few". But, they said the Trust "just carried on anyway". They said that they had the feeling of " 'did the organisation truly not realise the potential scale of the problems, did they not want to, did they think it would go away', because it always felt a little bit as though things happened or slightly moved forwards every time there was a press release because obviously

<sup>&</sup>lt;sup>58</sup> In a note to Dr Ann Keogh on November 2, 2010, Mr Paterson talks of its being "in bala's [Mr Bala] interests to potentiate a problem to deflect growing criticism that he is frightening ladies into further surgery to remove residual tissue".

<sup>&</sup>lt;sup>59</sup> It is worth noting that Mr Ingle was moved from Solihull Hospital to Good Hope Hospital during 2008 with the explicit aim of reducing the level of tension at Solihull and in the MDT. This was a further example of the response of senior managers – to see Mr Ingle rather than Mr Paterson as the problem and move him out. A replacement breast cancer surgeon came (reluctantly, I was told) from Good Hope Hospital to Solihull, Mr Ganesh, but he left within eighteen months.

once this first ... recall clinic ... happened, then obviously patients were alerted and obviously started to talk about it and that was ... a point that we made as well, that if you recall twelve women, women talk. That's what we do. ... You are sending shock waves through a community ... but with what message? What are we saying here and what are we doing about it?"

- 9.9 Dr Smith, who became the Acting Medical Director in September, 2010 told me that he was briefed as to the process and found it "really quite muddy and confusing. ... It was hardly a recall, in that how you can determine from a set of notes whether a mastectomy is complete or not is debatable. ...They identified some patients by a methodology which is still not clear to me...".
- 9.10 The flaw in the approach was not the only concern. There was also the question of how long the approach would take, involving as it did, the scrutiny of notes and records. Dr Stockdale drew my attention to a letter that he received from Mr Cunliffe in September, 2009, after going to see him. Mr Cunliffe wrote: "Dr Stockdale told me that he was increasingly concerned about the delay in the process of recall." In Dr Stockdale's words, he had said to Mr Cunliffe, "Listen, I've handed you all these cases. What have you done about it? ... this was September 2009 and the letter [from Dr Stockdale to Mr Cunliffe] was in January 2008. ... so we'd gone 21 months".
- 9.11 The Trust commissioned three external experts to assist in the process. These experts submitted a note to Mr Cunliffe and the Chief Executive on July 10, 2008. It might be thought to justify the view that members of staff took at the time and that I have taken: that a limited recall was not plausible. The experts advised that they had reviewed case records on two occasions. They make it clear that "we have conducted a notes review and that all we are able to assess is the information contained in the notes. ... It is clear", they go on, "that many patients are likely to have had incomplete mastectomies but we are unable to assist in determining if this is the case in the majority of cases reviewed because the operation notes seldom describe the technique in sufficient detail and there is no other evidence on which to reach a conclusion".
- 9.12 The experts pointed out, echoing the views of Mr Hennessy, that "We are concerned that many patients have consented to mastectomy and treatment protocols have been applied on the understanding that all macroscopic breast tissue had been removed. Our experience from these notes indicates that this is frequently not the case. There are examples where patients who have been described as undergoing mastectomy were subsequently referred by the hospital's oncologists for surveillance mammograms on the operated side".
- 9.13 In what might be thought to be a crucial observation when considering recalling patients, the experts comment, "We are unable in most cases to determine how much residual breast tissue remains but there is a major concern that [there are] other patients [who are ] not [being] considered for review. It is possible that these women have undergone incomplete mastectomies and are at increased risk of recurrence of the original disease or at risk of development of new pathology in residual breast tissue".
- 9.14 In their subsequent Note of July 29, 2008, the three experts repeated their concerns. Having again endorsed the view of Mr Hennessy, they draw specific attention to Mr Paterson's practice of "shaves" which they describe as "most unusual". In such cases, they refer to the fact that most of these patients will have received

radiotherapy, but go on that "Radiotherapy however does not compensate for involved margins in terms of risk of recurrence and we agree ... that it is impossible to identify from case notes alone which of these patients have residual breast tissue left. ... For any individual patient it is impossible to determine from case notes and photographs how much breast tissue, if any, this residual tissue contains".

- 9.15 It is hard to see how the Trust, in the face of these comments could justify to themselves the limited recall they decided on.<sup>60</sup> It is even harder to see how they were able to claim that their decision was based, in part, on the opinions of external experts. But that is what happened.
- 9.16 In the event, 12 patients were identified as being sufficiently at risk of recurrence that they should be recalled.<sup>61</sup> Mr Cunliffe, Mr Paterson, Mr Bala, HR, the Trust's Solicitor and others attended an initial meeting to discuss the process to be followed regarding these patients. Mr Paterson argued, I was told, that the recall would lead to a great deal of anxiety for patients and "unnecessary" litigation for the Trust. He proposed, therefore, that the patients involved should be sent a letter of appointment, as if it were a routine appointment. He would then see the patients and decide what, if anything, was called for. The patients, on this approach, would not be told that they were part of a recall process. Others at the meeting objected to the approach and it was rejected in favour of a more open approach. A letter was sent, the woman came to the clinic, and she was examined.
- 9.17 Meanwhile, the other arm of the approach adopted was being pursued. As I have said, it involved determining whether csm gave rise to an increased risk of recurrence when compared to a mastectomy properly so called. This would be a second attack on the question of who should be recalled. It involved identifying the rate of recurrence of cancer in those patients who had csm. This would reveal if there was an increased risk of recurrence. The Trust was seeking to develop data which would help to answer this question. Although it is an entirely understandable exercise in the abstract, it was never going to produce results which could be a definitive guide as to whom to recall, attractive as the idea might be. This is because, to establish a rate of recurrence, as a first step the Trust had to know the baseline, what statisticians call the denominator: how many operations Mr Paterson had performed. This was very difficult to ascertain. Mr Paterson worked extensively in the private sector as well as in the NHS (and, moreover, in the NHS, it was not clear how many operations assigned to Mr Paterson, were, in fact carried out by his Registrar).<sup>62</sup> And, in the private sector, the reporting of cases of cancer to the local (and thereby national) registers was not mandatory. So, there may not have been a full record of operations carried out and hence, the baseline could not be confidently identified.
- 9.18 And, of course, even if the base line were known, such that the Trust knew how many operations Mr Paterson had performed, there was no way of knowing which of the operations were csm because the records did not show this. The operation was

<sup>&</sup>lt;sup>60</sup> Dr Smith, the Acting Medical Director from September 2010 to February 2011, told me that, when he looked at the issues on taking office, he thought it would have been sensible to recall all of the patients. He found the case "irresistible".

<sup>&</sup>lt;sup>61</sup> See the letter from Mr Cunliffe to Mr Paterson of December 11, 2008, identifying the patients by case number.

<sup>&</sup>lt;sup>62</sup> One patient reported that Mr Paterson did not, in fact, carry out her surgery, as disclosed in the report commissioned by her solicitor from Professor Nigel Bundred, Professor of Surgical Oncology in Manchester.

uniformly described in the records as a mastectomy. Thus, the pursuit of a rate of recurrence associated with csm was a non-starter. It was a misbegotten exercise. Of course, if the women who had had a csm could be identified from the records, things would be different. But, they could not. Nevertheless, the initial recall team took the view that by examining photographs of patients, looking at their treatment plans, and at databases, a view could be reached.

#### The Limited Recall Unravels

- 9.19 Whatever the motives were for settling on a limited recall, whether to avoid provoking anxiety unnecessarily, or uncertainty, or containment, or all of these, the process soon began to unravel. Patients began to present in clinics who had not been part of the limited recall process, but were found to have undergone what, on physical examination, proved to have been csm. So, while the pursuit of data to evaluate the risk continued, and would continue for a long time, another form of data, in the shape of patients coming through the doors, was emerging.
- 9.20 Meanwhile, members of staff described the limited recall process as increasingly "fragmented" and "piecemeal". A protocol was agreed that if staff identified a patient in a clinic, in radiology, or any other context and suspected that she had had tissue left behind after a mastectomy, the patient's name and hospital number would be sent to the senior breast care nurse, or to Mr Bala. They would then get in touch with Mr Cunliffe to discover whether the patient had been included in the review of notes and records and the initial recall. If she had not been part of that recall, Mr Bala had to see her. The nurses said, straightaway, that patients should be seen in a special separate clinic, with just Mr Bala and a nurse. But, given Mr Bala's already busy schedule, "it proved increasingly difficult to set up those clinics with what felt like very little administrative support". I was told by a senior nurse that, in meetings with Mr Cunliffe and the head nurse, she kept saying "you either call everybody or you call nobody. This just doing a bit here and a bit there is just causing a whole load of distress for patients and a whole load of distress for staff". Moreover, the process was dragging out into "more than months".
- 9.21 It was recognised that the pace of the initial recall was too slow; that it went on for a lot longer than it should have done. One reason which was offered for this was how busy the department was, with staff occupied in so many other ways, as well as with the recall. After all, it was said that, at least initially, senior managers did not know the numbers of patients who would ultimately get caught up in the recall. Of course, on another view, the limited or focussed recall was never going to work. It could have been foreseen that the numbers would grow and the small team involved would increasingly struggle.<sup>63</sup> Delay was almost built into the system.

#### The Decision to Recall All Patients

9.22 The unravelling of the attempt to control and manage the recall of patients occupied the period between 2009 and early 2011. Finally, in the Spring of 2011, the decision was taken to recall all patients treated by Mr Paterson while at the Trust who had had

<sup>&</sup>lt;sup>63</sup> One member of staff told me that she thought that too much was having to be done by one surgeon, Mr Bala, and that "we could have been running more sessions, we could have been seeing more people far more quickly because having this hanging over these ladies was just awful to watch". She also echoed the views of several nurses that counselling and psychological support, which were not made available, should have been available for patients and staff involved in the recall.

a "simple mastectomy". The first letters went out to patients on June 21st, and the first clinic was held on July 4th 2011. In January 2012 the recall was extended to include all patients who had had a mastectomy with immediate reconstruction, and, in the February and March, it was further extended to include all of Mr Paterson's patients who had had a mastectomy while he was employed at Good Hope Hospital prior to coming to the Trust in 1998. (The extension of the recall to include patients who were operated on by Mr Paterson in the private sector is still under way.)

- 9.23 One consequence of the fact that it was two years before a general recall was launched was, of course, that some who might have benefitted from an earlier recall did not have that opportunity. In Mr Hendrickse's words, "The lesson I would take is that as soon as the problem is raised, we've got to be open about it, open and upfront and say 'This what we are going to do.' What seemed to happen was a bit of an investigation was started and it is still rolling and it's still going and it should have been full on from the very beginning. ... People may not have wanted to do that, but that's the right thing to do". He added, however, that Mr Paterson "wasn't a particularly easy person to deal with and the breast service at the time was thought to be a very highly efficient service ...".
- 9.24 The recall, as it developed, was clearly a major exercise. It also needed to be carried out as quickly as possible. That women might be at risk of a recurrence of their cancer created the need to act with some urgency. This urgency was made greater by the fact that former patients were suddenly made deeply anxious by being plunged into the uncertainty of whether they might have cancer. This was particularly hard to bear for those who had successfully completed years of treatment and had begun to allow themselves to believe that they were cured.

#### An Internal or External Recall Team

- 9.25 In addition to the scale and urgency of the recall, there was another factor that the Trust needed to consider. Women had been treated by Mr Paterson and the breast care team at the Trust. They were being recalled because of doubts about the surgery carried out by Mr Paterson. It should have been clear, therefore, to those in charge of the process that women's ability to trust the breast team might be undermined. For example, they might find it difficult to establish the relationship of confidence and trust with the Breast Care nurses which are an essential feature of the care provided by these nurses, given that, in the eyes of many of the women, they were the same nurses who, as they saw it, had stood by while Mr Paterson carried out csm. Equally, the confidence of the nurses might itself be affected by the knowledge that they had to face and look after women who may harbour suspicion or resentment. This would not be an ideal working environment for either party.
- 9.26 A patient told me, "My concern always with the recall clinic was that it should never have been done by members of the Solihull team ever. ... I just found it very strange that you're asking a team, who I felt was also involved with it [csm], to see these patients, not only because I think it was uncomfortable for patients but actually it probably wasn't very healthy for the team either. How can a patient go and be completely honest about ... how they felt about their care when you're talking to people that actually were involved in it ... there's no doubt there's a trust issue there. But from the team's point of view I thought they shouldn't be subjected to patients' kind of anger ... 'Well you must all have known what was going on'!"

- 9.27 A member of staff brought in to assist with the process of recall told me that she "didn't think it was the best place". When I asked why, she said, "I didn't come to this opinion until I'd met some ladies ... who had been living their lives quite happily for the last ten years, had breast cancer treatment, they were fine and they would tell me, describe to me how they were now back in Solihull and it was like they had just been transported back in time ... and this was worse. The whole feeling was worse than when they first had been told they had cancer...". While it was accepted by senior managers that the breast care nurses were placed in a difficult position, their view was that with support and advice they could do the task and were also a valuable resource in identifying patients in the initial stages of the process of recall.
- 9.28 Taking these factors together, the Trust could well have decided that the recall process should be conducted by nurses and doctors who were not part of the Trust. Indeed, this was urged on the Trust by a number of people, including a nurse who was also an ex-patient of Mr Paterson, and by Mr Bala. Bringing in an external dedicated team would mean that the recall could proceed at all due speed and be independent of and be seen to be independent of the Trust. Efforts were, in fact, made, particularly by Mr Bala, to bring in external clinicians. They foundered not for want of trying, but for one reason or another: surgeons were too busy or were not tempted to put their heads into what looked like a hornets' nest; breast care nurses were equally too busy. So, apart from the employment for a short time of a retired breast surgeon from Cardiff, and of a breast care nurse from another hospital in Birmingham for a short time to assist in the process, the recall was carried out entirely by the staff within the Trust.
- 9.29 Leaving aside patients' perceptions of the independence of the process, against the background of a growing collapse of confidence, the decision to do it themselves, meant that the recall had to be managed alongside all the normal range of clinical responsibilities borne by the breast team. Moreover, there was in place a protocol whereby Mr Paterson was required to refer to one of the other surgeons any patient recalled or presenting herself in a clinic who needed further assessment. In effect, this largely meant Mr Bala. He it was who bore the brunt of the workload of the recall while he continued with all of his clinical duties. Two consequences flowed, both of which could have been predicted and should have been avoided. First, the process of recall inevitably took much longer than if there had been a dedicated team. One patient recalled taking six weeks to get a date for one meeting and three months for a letter to arrive. When she put the issue of delay to staff, she told me that "... all they said basically was they were very sorry there had been all these delays and obviously they need to improve on that. ... I couldn't work out what was happening, whether they were hoping I would go away or whether it was just inefficiency". This clearly was not in the best interests of patients.
- 9.30 Second, Mr Bala was put under quite unreasonable pressure, putting at risk his own health and well-being, willing as he undoubtedly was to do what was called for. One patient told me that her impression was that "Mr Bala was pretty much dealing with all this on his own. I had the distinct impression that there were no extra staff in there. ... My first impression was that this man was being run off his feet trying to deal with all these people, some of whom were probably far more emotional about it than I was.... The first appointment they offered me was eight o'clock one evening and I remember thinking then that that's a funny sort of time to be still sitting there."
- 9.31 Meanwhile, Mr Paterson continued to carry out surgery on women with breast cancer in the Trust. As part of the agreement reached in 2007/08, he had agreed not to

perform csm and to abide by a protocol whereby patients who were recalled or presented needing further examination were not to be assessed by him but referred to a colleague in the breast team. Mr Paterson failed to keep to this agreement. He performed a csm on at least one patient in the Trust and on patients in the private sector. He saw patients whom he should have referred on. So, a further investigation was launched leading in relatively short time to his being excluded. I will return to this strand of the account shortly.

#### Conclusions about the recall

- 9.32 The idea that it would be possible to identify those women who had csm through records and notes meant that Mr Paterson should be involved in the process of identifying those who should be recalled. But, his involvement was demonstrably problematic. It was clearly disruptive as regards the rest of the breast team and the functioning of the MDT. This should have been appreciated by those managing the process. The approach again reflects the perspective of the HR process, concerned to be even-handed with Mr Paterson, whatever the cost to others, including patients dependent on an optimally functioning MDT. It also reflects, in my view, a lack of strong, clear and robust management.
- 9.33 It was right for senior managers to call in external experts once they decided to embark on the limited recall. It is difficult to understand why they then decided to ignore the advice they were given: that, in effect, the process as conceived was bound to fail.
- 9.34 The simultaneous pursuit of a rate of recurrence as regards women who had undergone csm was equally flawed. There was no way, through the examination of records and notes, to determine who had csm, Thus, there was no way to arrive at a denominator from which to calculate a rate. This is not a judgement of hindsight. It was clear, and was being said by others, at the time.
- 9.35 The flawed nature of the limited recall process is perhaps illustrated best by the fact that only 12 patients were identified, which, even at the time, must have appeared to be an extraordinarily low number. Mr Paterson, by 2007, had been operating at the Trust for 9 years. It is past incredible to imagine that the level of concerns generated over the years related to only about one or two patients a year.
- 9.36 Even though the recall was initially limited, it was clearly labour-intensive. This led to its being slow and appearing fragmented. Patients were made anxious. Mr Bala was reduced to carrying the process virtually single-handed, on top of his usual heavy work-load. It is hard to avoid the conclusion that the Trust, once again, did not allocate enough resources and support to expedite the process. There is a very real sense that, as time went by, the Trust lost control of the process and was reacting to the next thing that happened rather than managing a carefully worked-out project. The reason for this is not clear. It may have been simply a failure to realise or accept the gravity of the problem that the Trust was facing.
- 9.37 The subsequent decision to recall all patients was clearly right and long overdue. Women not recalled initially had been exposed to further risk through the delay. The time then taken to manage the recall added to women's anxiety. The delay was caused by having to rely on the efforts of one surgeon who acted with commendable dedication.

9.38 It would have been preferable in principle to bring in an external team who would manage the whole process while the breast team got on with their regular clinical duties This would have been more efficient in terms of time, would have been more sympathetic to the feelings of patients, and would have avoided the problems encountered by the breast care nurses who some patients considered complicit in what had gone on. But, in the event, despite efforts to bring in assistance from outside the Trust, apart from assistance briefly from two clinicians, it proved not possible to do so.

## **10 CHAPTER X**

## COMMUNICATION

### **Members of Staff**

- 10.1 It is important at this point to ask how the Trust managed the decision about recall and the process thereafter in terms of communication with members of staff, patients and the wider community which the Trust served and from where came their patients. As I have said, members of staff in the breast team did not feel that they were wellbriefed on what was going on regarding Mr Paterson. The cloak of confidentiality associated with the HR procedure served to keep them in the dark. Once the recall process grew, of course, it became common knowledge that there was a recall going on. But, that was about it. There remained the sense that things had happened, were happening and would continue to happen without members of staff knowing what it was all about?
- 10.2 Neil Rogers told me that when he was appointed as the General Manager for Surgery in November, 2009, his predecessor told him that there was an audit taking place. This presumably refers to that part of the recall process concerned with collecting and analysing cases and data. She (his predecessor) said that she did not know what the outcome was. According to Mr Rogers, she said that it was, "being dealt with separately". Nonetheless, Mr Rogers spoke to Mr Hendrickse, his manager, who he understood had been involved in the review of case notes. Mr Hendrickse told him that he did not know the outcome of the review or what measures had been taken; he understood that matters were being dealt with at an Executive level, meaning Mr Cunliffe. Mr Rogers also asked Mr Budhoo who had been Clinical Director - Surgery. According to Mr Rogers, Mr Budhoo told him that "he knew next to nothing ... had been kept out of it" and had "nothing to tell me by way of background, so that is essentially where it was for the first few months in post". He saw Mr Budhoo as saying, "This is being dealt with somewhere else, it is nothing to do with me' and almost 'Don't worry yourself, this is being dealt with by the Senior Executive team'. ... That is about all I knew", he went on. "It was not coming up, no one was having conversations about it, certainly not that I was aware of. It was not coming up in directorate meetings. It did not seem to be being talked about". So, the General Manager of Surgery, the administrative head of that part of the Trust's service which, of course, included the breast team, was completely in the dark as to what, by early 2010 was already of considerable significance.
- 10.3 This state of affairs is all the more surprising since one of Mr Rogers' responsibilities, from November, 2009 onwards, was to deal with complaints made by patients about the care received from the surgical units. In the absence of any information or briefing, Mr Rogers found himself having, in his words, to do some "digging". He was left to find his way through the history of the Trust's dealings with Mr Paterson, with, of course, the concomitant risk that he might get things wrong or identify only part of the story. It would be hard to imagine a less appropriate preparation for someone dealing with patients' complaints than to expect him to respond in an informed and sensitive manner when, apart from the inevitable gossip, he did not know what was going on or what lay behind the particular complaint. As Mr Rogers put it, "I suppose you don't know what you don't know and I had got no idea at that point of the scale of what appeared".

- 10.4 More senior members of staff experienced similar frustration over the period from late 2008 to 2010 in seeking to find out what was going on, both as regards the investigation into breast surgery and the recall. They were unaware that there had been a Report by Mr Wake or an investigation by Dr Polson. They had no idea that questions had been raised concerning Mr Paterson's clinical competence. Their position was made that much more difficult because they were in positions of trust, guardians of patients' safety, and yet were kept in the dark. Their teams looked to them for answers to their concerns and queries and they had none. They felt compromised. They felt unable to provide the leadership that the Trust expected of them.
- 10.5 Efforts to gain some understanding involved working their way up the hierarchy within the Trust until they reached what appeared to be a very small group consisting of Mr Goldman, Mr Cunliffe and the Director of Governance and Safety. At that point, they, as others, were given the same assurance that things were being looked into, that Mr Cunliffe "was dealing with it", but nothing more. Recourse to the HR process caused or enabled a cloak of secrecy to be thrown over what was happening. The sense grew among some staff that something was amiss, that, in one memorable phrase, there was something cloak and dagger going on.
- 10.6 One of the senior breast care nurses who had worked at the Trust for some considerable time used exactly the same words. She told me that, although she was a pivotal member of the team, providing a link between patients and clinicians, she did not know what had been said and recommended by Mr Wake, Dr Polson, Mr Hennessy or Mr Lee. "There was no sort of, 'Let's all get together and tell you what's happening'", she told me. "There was nothing like that. It was all cloak and dagger. ... and if you heard anything it was bits of snippets, somebody might have mentioned something, but you didn't really know the context of it. ... it was secretive; it was behind closed doors".
- 10.7 Hitting this brick wall was particularly problematic for those who had a role to play in the Trust's agenda concerning the safety and quality of care. A crucial feature of this agenda was the maintenance of a Risk Register. Clearly, once it was known that an unknown and unauthorised operation, in the form of csm, was being performed, this would ordinarily have been registered as a "serious untoward incident". As such, it would have appeared on the Trust's Risk Register and attracted a significant response.
- 10.8 Remarkably, nothing ever appeared on the Trust's Risk Register concerning Mr Paterson's surgery. This was a very significant failure. It blocked off another route of scrutiny. It was another lost opportunity. And, more, it gave further life to the allegation that senior managers were keeping other staff out of the loop in a bid to control the fallout and protect the Trust's reputation.

#### Patients and the Community

10.9 Patients who were recalled were dealt with considerately and well, as were those who came into the clinic and were found to warrant follow-up. But, some patients, at least at the start, were not recalled because of the limited nature of the initial recall and when, later, they presented or were recalled as the process grew, they felt let down that they had not been contacted earlier. Some even felt that valuable time had been lost which could have significant implications for their health.

- 10.10 As regards the wider community, the Trust made no public statement as to what was going on, whether about Mr Paterson or the recall, even as it grew in scale.<sup>64</sup> Given that openness is desirable and that the Trust is part of the local community and owes it a duty to look to its welfare, the failure effectively to engage with the community may be thought to have been ill-judged. It is a commonplace that stories such as one combining breast cancer, a recall of patients, and a surgeon under a cloud (or at least a microscope) are likely to be seized on by commentators. The Trust could choose to ensure that the story was told accurately and with proper sensitivity towards the patients involved and future patients in the community, as well as respecting the interests of staff. Or, by saying nothing, and citing confidentiality to all comers, it could guarantee that rumours would fly and fill the vacuum of information.<sup>65</sup>
- 10.11 A File Note written by Mr Cunliffe on January 28, 2008 (in the thick of the consideration of what Dr Polson and Mr Hennessy were advising), recorded a conversation he had with a breast care nurse who worked with Mr Paterson in the private sector. She related various things she had heard and had been told. She described how Mr Paterson had advised her that, at a meeting she was due to attend of Breast Friends (a support group), she could inform those women attending that "an audit and external review was underway and was 'all OK' and Mr Goldman has been in touch with everyone and the investigation was coming to a close". Mr Cunliffe noted that "I told her that I could not discuss the investigation with her. ... I hoped that it would be brought to a conclusion shortly".<sup>66</sup> By not commenting on Mr Paterson's alleged comment, and reciting the mantra of confidentiality, it may be thought that Mr Cunliffe gave greater priority to Mr Paterson's interests than to the women who may have been harmed and who had a right to know what in fact was going on.

#### The Board

- 10.12 The Trust, in the shape of the senior Executives, said nothing. These Executives even said nothing formally to the Board (of which they were, of course, members), notwithstanding the Board's responsibility for the health and welfare of every patient. There was a brief report to the Board by Mr Goldman on June 3, 2009 accompanied by an assurance that the Board "... would be kept advised as to developments", but no evidence of their being advised appeared subsequently. And, the Non-Executive member of the Board "overseeing" the investigation into Mr Paterson had not, as I have said, reported back formally to the Board since taking on the responsibility in 2007.
- 10.13 This failure to engage with the Board on the part of the Executive (and the failure, similarly, of the Board to engage with the Executive) is all the more worthy of remark when it is seen in the context of the Board's increased interest in and concern for the safety and quality of the care of patients, at least in a formal sense, through

<sup>&</sup>lt;sup>64</sup> The Trust contacted the private sector hospitals at which Mr Paterson practiced in December 2007 and May 2008 to advise them of the measures it was taking, including the review and recall of patients and, thereafter, advised them of developments.

<sup>&</sup>lt;sup>65</sup> As was clear from the many different versions of events that I heard from patients.

<sup>&</sup>lt;sup>66</sup> He also told her that he had written to the relevant private hospital advising it of the investigations and would write again when matters were concluded.

exchanges at Board meetings.<sup>67</sup> Indeed, the Minutes of meetings of the Board in March 2010 record members of the Board pressing the Chief Executive "whether there were other services [apart from those relating to the relocation of Maternity Services, which was under discussion] that had safety issues". The Minutes record that the Chief Executive advised that "the Trust was proactive in seeking out the safety issues. The Trust was continuing to work on becoming an open and transparent organisation with regard to these issues".<sup>68</sup> It may be thought that there was much work remaining to be done on this front. And, there was no mention of breast cancer surgery.

- 10.14 It was put to me that the Board simply did not have the capacity to give the attention needed to what was happening in the breast team, indeed was not aware that attention was needed, given everything else that was going on. The Trust was going through a merger with Good Hope Hospital, which was less than plain sailing, it was struggling to meet the 4 hour waiting target for Accident and Emergency, and was under considerable financial pressure. But, these pressures on Trusts' Boards are a familiar feature of the NHS over the past decade or so. They will not get any easier. Boards, therefore, need to respond and plan appropriately. It is not open to them to look back on times when things have gone wrong and say "we were too busy." Even less is it open to senior managers to decide not to engage with the Board when confronted with serious issues to do with the safety of patients' care because the Board is busy, and instead choose to get on with things themselves.
- 10.15 The Minutes of the Board show that, as a Non-Executive member of the Board, Mr Hensel, had pressed for reassurance about the safety of care on a regular basis, to the point of succeeding in having it become a standing item on the Board's agenda. But, after attending the initial meeting with Mr Cunliffe in the summer of 2007, he had heard nothing. He had not seen Dr Polson's Report, nor Mr Hennessy's. To that extent, he was disabled in carrying out his responsibilities, except through asking general questions.
- 10.16 Clearly, once mentioned, concerns about Mr Paterson's surgical practice had disappeared under the radar. Two Non-Executives had received an initial briefing, and one had been appointed to "oversee" the investigations. But, thereafter, as far as communication from the Executive, there was silence. Of course, it was open to those Non-Executives to press the Chief Executive, through the Chairman of the Board, for further information. They appear not to have done so. The concerns did not acquire the high profile which they would have had if they had featured in the reports going to the Board on governance and risk. In part, the responsibility for this lay with members of the Board itself.

#### Hand-over to New Leadership

10.17 In mid-2010, with the recall process becoming increasingly more extensive, the Chief Executive of the Trust and Mr Cunliffe both decided to step down from their respective positions. An acting Medical Director, Dr Smith was appointed who served from September 2010 to February 2011. A new Chief Executive, Dr Mark Newbold,

<sup>&</sup>lt;sup>67</sup> See the Minutes of the Board, earlier in May and November, 2008, and September 1, 2009, when it was recorded that the Board did look at "patient safety [sic]" at every meeting, and Minutes of the Board, February 2, and September 7, 2010

<sup>&</sup>lt;sup>68</sup> And see the further reassurance from the Chief Executive to the Board, Minutes of May 4, 2010

took over from the summer of 2010. A senior member of staff described how the appointment of Dr Newbold was, to her, a "turning point". She told me that on an early visit to the Good Hope Hospital in the autumn of 2010, she "sat and spoke to him [Dr Newbold] for nearly the best part of an hour about all my concerns and he said, 'I will do something about this". She went on that "OK I mean it has taken time but I felt from that point on .... I felt listened to, action would be taken". The sense is that there was a cultural shift. Not everything would go smoothly, but the approach would be different.

- 10.18 Amongst his many other responsibilities, Dr Smith inherited responsibility for the HR process relating to Mr Paterson which was still rumbling on. He was also in charge of the recall. As regards Mr Paterson, Mr Cunliffe left a hand-over note for Dr Smith, entitled "Executive summary Breast surgery review", by which was meant the investigations of 2007 and the subsequent Action Plan. This may well have been the same Executive Summary prepared by Mr Goldman which he attached to a letter that he wrote to the Chief Executive of the Care Quality Commission in 2009. In the letter, Mr Goldman advised that the "breast surgery review" had been concluded (even though the Summary indicates that Mr Paterson still had not met all the stipulated conditions).
- 10.19 The Summary set out the background from the point at which Mr Hennessy conducted his investigation. It referred to the Action Plan agreed with Mr Paterson and indicated, among other things, that most of the measures agreed in 2008 had been completed, though some were still "being organised". Curiously, the NCAS which helped to draw up and monitor the Plan had the view that Mr Paterson had, in fact, met all the condition to the Trust's satisfaction. Their letter of November 24, 2010 to Dr Smith stated, "The NCAS case was closed following acceptance and initiation of the plan by all parties at a Trust meeting. The local action plan was completed to the satisfaction of the Trust in 2009". Mr Cunliffe's note, however, documented what he had said at a hand-over meeting with the new Chief Executive, Dr Newbold, Dr Smith, Mr Bala and the two senior staff members charged with responsibility for governance and safety. And, what he had said was that, in October 2010, there were a number of conditions which Mr Paterson still had yet to meet.<sup>69</sup> In his note he wrote that "Some of the NCAS' timescales have been exceeded but most have been completed". The Plan had been agreed, finally, in September 2008. It is open to question whether the subsequent action and time scales reflect a sense of urgency or robust management.
- 10.20 A paragraph in the hand-over note was to take on considerable significance later, as I shall describe. Mr Cunliffe wrote that "An audit performed by the WMCIU (West Midlands Cancer Intelligence Unit) did not show Mr Paterson to have an overall local recurrence rate that was higher than the Association of Breast Surgery guidelines. He noted, however, that "a subgroup of patients undergoing primary reconstruction ... had a higher recurrence rate than conventional mastectomy at 5 years follow up". (This was in addition to a higher rate in those undergoing 'shaves at mastectomy', the data on which was disputed because it could refer to shaves after a wide excision, which was accepted practice, or "shaves after mastectomy", which was not, and most of the cases fell into the former category).

<sup>&</sup>lt;sup>69</sup> Some confusion arises from the fact that Mr Cunliffe wrote to NCAS Adviser, Dr Boyle, on March 25, 2008 advising that "NCAS can close the case now and it can be reopened for advice and support if required at a later date".

## The Media and Outside Agencies

- 10.21 In early November 2010 Mr Paterson's surgery and the response of the Trust in sending out letters recalling patients finally became public knowledge. Stories appeared in the local press. The issue could no longer be contained and dealt with inside the Trust. The Trust's Board was advised that the newspaper stories would be appearing on the following day.<sup>70</sup> This is the first formal record of the Trust's being exposed to the issues surrounding Mr Paterson's surgery and the response of the Executive to them since the report of the investigation in September 2007, (save for one update on June 3, 2009).
- 10.22 What the Board was told in November 2010, however, again raises questions. According to the Minutes, Dr Newbold, the new Chief Executive, "alerted the Board to a story that would come out in the next day's press. It dated back", the Minutes record him saying, "to 2007". As I have made clear, this is not the case. Things had been known and had been done several years earlier. But, Dr Newbold was new to the job and could only know what he was told. And, of course, as I have emphasised, there was little or no formal record for him to refer to or rely on. The Minutes go on to record that "The Chairman confirmed that he was completely satisfied with how the Trust responded at the time and how it was being handled moving forward". The Minutes do not record the ground(s) on which the Chairman relied.
- 10.23 Outside the Trust, the Chief Executive had written to the Chief Executive of the Care Quality Commission (CQC) on July 1, 2009 advising her of the proposed recall of 12 patients and the possibility that this may attract the attention of the media. A subsequent letter from the new Medical Director, Dr Anwar on May 19, 2011 provided CQC with an update, with copies sent to Monitor, the Strategic Health Authority and the NHS Litigation Authority. I have not seen any evidence of a response from any of these bodies.
- 10.24 Apart from Regulators, there were others affected by what was going on in the Trust. It is salutary to notice the remarks of Dr Lawrence about the Trust's communication with an important external agency critically affected by the concerns about Mr Paterson - the West Midlands Screening Service. The Service referred to the Trust patients whose cancer had been detected through screening. In the case of Mr Paterson, there was very little communication between the Screening Service and the Trust. Dr Lawrence, the Director of WMCIU, told me that "It was only late in the day after ... concerns had been expressed in the press regarding Mr Paterson [in late 2010], that the Screening Service became so concerned about Mr Paterson's practice that it informed the Director of the Breast Screening Service at the University Hospital Coventry and Warwickshire that patients with screen-detected breast cancer [a sub-set of patients treated by the Trust] must be treated by a surgeon other than Mr Paterson. At no point had the Screening Service been kept up to date on the ongoing saga relating to the investigations into Mr Paterson's surgical practice [or at the very least there had been very little communication], even though screening patients were being referred for treatment to HEFT.... It is my belief", she went on, "that if services are provided by one Trust to another in a consortium such as the ... breast screening service, there has to be a formal agreement in place between the

<sup>&</sup>lt;sup>70</sup> Minutes of the Board, November 2, 2010

Chief Executives of the two organisations to ensure that any service issues can be speedily and satisfactorily resolved".

#### Conclusions about communication

- 10.25 Communication within the Trust is important at all times. It is particularly important when external experts are brought in and investigations set up. If there is no communication about what is going on, rumour and gossip will fill the gap. Moreover, morale and trust in the organisation will be damaged. These are obvious truisms yet they do not appear to have weighed heavily in the minds of senior managers in dealing with the recall of Mr Paterson's patients.
- 10.26 The recourse to disciplinary procedures stifled all communication. Once they were resorted to, it was if the senior management switched on a sort of auto-pilot. Confidentiality was the order of the day. It was applied with a kind of unthinking inevitability. It excluded everybody but a small number in the know. The rationale advanced was the need to be fair to Mr Paterson. But, the balance was struck too much in his favour. Fairness to others, especially colleagues working in the breast unit, demanded that they be kept better informed. In turn, they could then better serve their patients. Careful judgement was needed but not evident. In my view, senior managers not only were in thrall to the notion of confidentiality but also found refuge in it as a way of managing an increasingly difficult problem, keeping control of it and containing it.
- 10.27 As an example of the lack of communication, Mr Rogers was put in an impossible position when he was asked to manage the recall process (and subsequently, the complaints process) while being kept in the dark as to much of what had taken place. He could not do his job to the best of his ability and, given that his job involved dealing with patients in very fraught circumstances, patients were also failed.
- 10.28 It was equally ill-considered, again under cover of confidentiality, to disempower managers whom the Trust expected to lead. Their position was made untenable. They were keen to support and offer leadership but they were flying blind because they were not in the know. This meant that, in turn, staff were ill-served. And, when staff are ill-served, there is always a danger that patients may receive less than optimal care.
- 10.29 The hand-over note from Mr Cunliffe is a standard and appropriate mechanism of good governance. The confusion over whether Mr Paterson had complied fully with the required Action Plan and the time taken illustrated, perhaps, a lack of robustness in confronting Mr Paterson which was a constant thread running through engagements with him.
- 10.30 Present, past and future patients were unaware that there was a problem in relation to the treatment of breast cancer. Again, rumour took up the slack. Patients were constantly appearing who might have wished to know more before deciding what to do about their care. They did not have this opportunity. A policy of openness would have been fair to patients. But, the Trust adopted the perspective of the professional rather than that of the patient.
- 10.31 The exclusion of the Board from doing its job by not reporting in any formal sense was a serious failure on the part of the senior managers, who were also part of the Board. Informal briefings and contacts are all very well, but are not recorded and

depend on who speaks to whom and who remembers what. In a large organisation, when the issue at stake was of such importance, informal exchanges are not enough. Good governance and the need for a corporate memory require more. Board members also have a responsibility to challenge and enquire. If a member of the Board is made aware or becomes aware of matters of concern regarding the care of patients it is not enough to sit and hope that the Executive will advise them. They have a duty to be active and not merely reactive, particularly if the Executive does not supply them with anything to react to.

- 10.32 The Screening Service and other external agencies involved in the process of sending patients to be cared for at the Trust were entitled to be aware of what the Trust was doing in relation to Mr Paterson. Not to inform them adequately meant that patients were at risk of being exposed to care which was the cause of continuing concern.
- 10.33 In short, the Trust chose to manage things itself and tell as few others as possible. Such a strategy can never work in a modern world where information will always become known. It would have been far better to have been fully open from the outset. It need not have involved being unfair to Mr Paterson if properly managed. It would have involved being fair to others.

## 11 CHAPTER XI

# A NEW APPROACH

### **A New Investigation**

- 11.1 Events were gathering pace. Early in 2011, Dr Smith, the Acting Medical Director, launched a second investigation into Mr Paterson's conduct. Again, it was brought within the ambit of the HR procedure. The NCAS was again involved.<sup>71</sup> There were three grounds put to Mr Paterson, two of which I have noted: that he carried out a csm having agreed not to do so, and that he failed to observe the agreed protocol for dealing with patients who presented at clinics.<sup>72</sup>
- 11.2 The third ground was one which appeared formally for the first time. As I have made clear repeatedly, it had existed from the moment concerns were expressed about Mr Paterson's surgery. It was that Mr Paterson had failed to obtain consent to the operation he in fact carried out whenever he performed a csm instead of a mastectomy. Mr Hennessy had, of course, referred to it and so had others, but it had not formed part of the thinking behind the previous investigations. As Dr Smith put it to me, "There was another element which, I have to say, was one of the things that really surprised me right from the start, is that the previous investigation through 2007 onwards had not considered the issue of consent ... at all [Mr Hennessy had, as I have mentioned]. That was the most striking thing from my point of view, apart from the recall and everything else, that consent for this procedure was non-existent".
- 11.3 The fact of the investigation was reported, as was required under the procedure, to the Board. As was required, the Board was asked again to provide a Non-Executive to "oversee" the investigation. Ms East volunteered and was duly appointed. I was assured by the Director of Workforce, that whatever had been the case previously, in the case of this further investigation, there were regular discussions between Ms East and Dr Anwar, the Medical Director, to brief her on progress. Although there was still no report from her, as a Non-Executive member to the Board, the Board was routinely briefed by Dr Anwar. He incorporated into his briefing, I was told, matters raised between him and Ms East.

## **A Total Recall**

11.4 As regards recalling patients, the decision was made, as I have said, that it was no longer tenable to seek to limit the numbers of women to be recalled. Two particular factors made a total recall impossible to resist. The first was the fact that the story was out. The second was that it was finally accepted that the only way in which the breast team could determine whether one of Mr Paterson's patients might be at

<sup>&</sup>lt;sup>71</sup> See the Revised Terms of Reference regarding the investigation into concerns raised regarding Mr Paterson's surgery, June 6, 2011.

<sup>&</sup>lt;sup>72</sup> See, for example, memos from Mr Bala to Dr Smith of November 11 and 12, 2010, identifying a patient who had csm in 2000. Mr Paterson was proposing to carry out a further csm. The patient had not been entered into the csm protocol so as to be seen by a surgeon other than Mr Paterson. This was one of a number of memos sent to Mr Cunliffe and Dr Smith about csm after Mr Paterson had agreed to cease carrying out the procedure.

increased risk was to recall every one and offer them a physical examination and anything else that might be appropriate.

- 11.5 The approach adopted by Dr Smith in taking forward the recall is worth noticing. Hitherto, the Trust had written to patients' GPs asking the GP to contact the particular patient and arrange for her recall. Dr Smith decided to write directly to the patients: "I wrote the letter which went out to the patients to recall them with careful thought about the language that we should use so that we wouldn't alarm, but we certainly didn't want to deceive and my general approach to this sort of thing is to be truthful and direct". The telephone number of a dedicated helpline was included in the letter. It was also arranged that the letter would be received on a weekday when the telephone line would be manned. This signalled a different cultural approach, with the emphasis on openness and concern for patients which the senior managers intended to pursue.
- 11.6 From Dr Smith's perspective, during the brief time that he was Acting Medical Director, the aim was to get to grips with things once and for all and for the Trust to put behind it what had gone before. He told me that, "the enormity of the problem wasn't appreciated, even by me at the start of my involvement in it". His sense "through this [was] that things have been handled less than perfectly through ' incompetence' is a strong word but lack of attention, lack of focus and lack of time, rather than any malevolent or dishonest or untoward intent to hide the truth. That's been my impression overall. ... I don't think it has been well handled but I am trying to be completely open and clear. I don't think it was a cover up. I think opportunities were missed that could have been handled earlier on. I don't think personal relationships with individuals or anything of that sort had anything to do with it".
- 11.7 The process of total recall began in the Spring of 2011 and ended with the final clinic in March 2012. By that time over 500 patients had been seen. As Dr Keogh, the Director of Medical Safety, described the process in a letter to the Parliamentary and Health Ombudsman on October 5, 2012, patients were contacted by letter, a dedicated helpline was set up, bespoke clinics were established and patients were offered the opportunity to see a member of the PALS (Patient Advice and Liaison Service), a breast care nurse and a breast surgeon. The support of a counsellor or psychologist was also offered.
- 11.8 The person who was managing the process saw the process as being less clear cut. According to Mr Rogers, the General Manager – Surgery, while he was not involved in the decision-making process to recall everyone, he was "involved in putting it together and making it work operationally ... it was just a matter of, 'You need to get on with it, work out who the patients are and get them seen as soon as possible'. ... one of the things I find quite odd again in this Trust", he went on, "is the lack of formality and documentation around these sorts of things. ... Someone will appear at your door and it will be a conversation, 'This thing needs doing like vesterday' as opposed to having a project board, say, set up to work out how best it will be undertaken". He told me that he was not given any additional resources (apart from a retired colleague, hired for a month when complaints were at their peak), he was not excused from his other day-to-day responsibilities, he was not given any advice as to how to undertake recalls, nor was there anyone senior who knew about the breast unit whom he could seek advice from: "there appeared to be no-one in the Trust with knowledge of how to carry out a recall on this scale and, as such, I found myself having to navigate my way through on top of my day job".

- 11.9 So, the Trust was about to embark on recalling a significant number of patients in highly fraught circumstances by, effectively, flying by the seat of its pants. The body of experience within the NHS of other hospitals dealing with recalls was not tapped. It is only surprising, therefore, that the delays and other problems were as few as they were. Moreover, when Mr Rogers raised the point, made a couple of years earlier, that the patients who were recalled should be seen by clinicians who had no connection with Solihull Hospital, he was told that the process had to be carried out as quickly as possible, such that there was no time to put together an external, independent team.
- 11.10 Meanwhile, the process of recall has continued to grow beyond the Trust. Organisations in the private sector have begun their own inquiries. Women will, therefore, continue to live with the shadow of risk hanging over them for some time to come.

# A Number of Fronts

- 11.11 Alongside the action of the Trust in early 2011 onwards, Mr Paterson's surgery began to give rise to a number of complaints to the GMC and to a number of legal claims against the Trust. Complaints to the Trust from patients and relatives also mounted up. In short, the Trust was dealing with the fallout from Mr Paterson's surgery on a number of fronts, each demanding effort and time. And, for a long time, the sense was that the Trust's response had been reactive, with no clear strategy to deal with what was by then a major challenge to the reputation of the Trust and, more important, a cause for very great anxiety and uncertainty on the part of patients and their families. But, the approach was beginning to change. A clear commitment to confront what was needed to be done, and then seeking to do it, was embraced by the new leadership of the Trust. This was reflected in the decision to embark on a total recall. It was reflected in the engagement with the GMC. It was reflected in the decision to meet patients who had lodged complaints through the medium of a Complaints Resolution Process.
- 11.12 But, even as these important steps were being made, they were dogged by the uncertainty, rumour, claim and counterclaim which was the history of the Trust's dealing with Mr Paterson from the outset. The questions of who had said what and when and what, if anything, had been done as a consequence, resurfaced. The references to confidentiality which had shrouded what was happening, such that many intimately concerned did not know what the Trust, their employer, was doing, still swirled about. Supporters and detractors lined up such that hyperbole became the currency of exchanges. And, meanwhile, patients, past and present were fearful, anxious, angry and searching for answers.
- 11.13 The strategy of the new leadership was to draw a line. The uncertainties of the history and the lack of a sustained and collective corporate memory made this an elusive goal. Indeed, until the decision was taken by the Board to invite me to carry out an entirely independent review, the Trust was struggling to draw the desired line. I can illustrate this by referring to two exercises that the Trust embarked on. The first is the Complaints Resolution Process. The second is the issue of data, generally and particularly as regards the engagement with the General Medical Council.

# **The Complaints Resolution Process**

- 11.14 The Trust had a formal procedure which promised on its website a prompt response to patients who made a complaint. It was clear, however, that on occasions, the Trust's response to women's complaints about the care provided by Mr Paterson was anything but prompt. Whether this was due to the Trust's giving a low priority to complaints, or lack of administrative support (which amounts to the same thing), or whether it was just simple inefficiency is not clear. What is clear is that some of the patients whom I saw spoke of delays of weeks and months (in one case, for example, a response to a letter sent on Jan 20th 2009 was received on June 29th 2009, a delay of six months).<sup>73</sup>
- 11.15 Patients who made a formal complaint to the Trust about the care that they received from Mr Paterson were offered the opportunity to attend a complaints resolution meeting intended to resolve the complaint. The meetings were chaired initially by Dr Smith as Acting Medical Director and subsequently by his successor as Medical Director, Dr Anwar, and ordinarily attended by Mr Bala, Mr Rogers, the General Manager Surgery, and a breast care nurse. The patient could, if she wished, attend with a friend or relative and some did. The complaint made by the patient, and, as was usually the case, the questions to which the patient and others wanted answers, served as the basis for the meeting. A note was taken and then a written statement was drafted by Mr Rogers. This draft, once agreed, was given to the patient. What shines through this process is the self-evident desire of the staff, led first by Dr Smith and then by Dr Anwar, to apologise for what had been done, to answer openly any questions put to them, and to demonstrate their concern for the welfare of the patient in front of them.
- 11.16 But, that said, the commitment of the Trust's staff to openness was undermined by their understanding of the past. It was unsurprising that the most common question asked by patients was when the Trust first became aware of concerns about Mr Paterson's surgery. Obviously, the next question was what action had been taken. Patients had, by that time, heard the very many rumours and stories that played the role of history in the absence of any communication from the Trust or true understanding of all that had gone on. The answer that patients received in the meetings was always the same: that concerns had been raised in 2007 and action had been taken. When pressed, as they often were, that concerns had been expressed before 2007, Mr Rogers, Mr Bala, Dr Smith, or Dr Anwar would agree that concerns had indeed been raised earlier. But they told those complaining that the earlier concerns related to the functioning, or lack of it, of the MDT. Very occasionally they said that concerns had also been raised about the margins left after surgery. But, as Dr Anwar put it to one patient, the "main concerns" related to the MDT and decision-making. "... the issues were not whether the mastectomies were compliant with what was nationally agreed practice". On the rare occasion when Mr Bala or Dr

<sup>&</sup>lt;sup>73</sup> Mrs Stone, and for further examples see also the cases of patients whose case numbers I use rather than their names: 08.5856 (from September 2011 to March 2012), 11.10125 (from February to July 2012), 11.9929 (from January to May, 2012), and 11.9910 (from January to July, 2012).

Anwar suggested that the concerns did, in fact, go wider, they were promptly corrected by Mr Rogers.<sup>74</sup>

- 11.17 Of course, as I have described, it was not the case that the concerns prior to 2007 had been confined to the working of the MDT and the question of margins. Certainly, the dysfunctional nature of the MDT had figured prominently in Mr Wake's Report in January 2004 and in the Medical Director Surgery's response to it. But, equally certainly, Mr Wake's Report went further, as did Dr Stockdale's audit. The concerns held by Dr Lawrence of the WMCIU, particularly regarding repeat operations, had been made clear to anyone who would listen, at around the same time. Concerns had been raised, in short, about Mr Paterson's clinical competence. But Mr Rogers, who was the most prominent purveyor of what might be seen as a mantra (that everything started in 2007), did not resort to the mantra out a desire to cover up the past or mislead patients. He did it, as did the others, because they thought it was true: that any investigation or concerns prior to Dr Polson's investigation in 2007 was entirely, or almost entirely, concerned with the MDT.<sup>75</sup>
- 11.18 When I asked Mr Rogers whether he was aware that there was a Report in 2004 by Mr Wake, he immediately responded that it was about "the dynamics of the MDT". When I pointed out that the concerns raised in 2003 were also about Mr Paterson's clinical competence, as echoed by Dr Polson in his Report, he replied, "I don't even think I am aware of that even now, to be honest. My understanding was that the issues from that era were put down to a dysfunctional MDT, because the key players didn't get on with each other, of which Mr Paterson was one. I have never seen the report. I have got in my head at some point that there was not a hard copy of the report still in existence and it appeared to have gone mysteriously missing. I understood that the outcome of all that was that they did some sort of team building, Away Day type exercise".
- 11.19 Those involved in the complaints resolution meetings took the approach that I have described notwithstanding Dr Polson's clear reference to concerns raised earlier which touched on Mr Paterson's clinical competence. Dr Anwar told me that they felt "uncomfortable" with the view that 2003–4 was about the MDT. He said they had asked themselves, "Surely, there was more to it than just that". But, they persisted with the received view. As I have said, the answer to Dr Anwar's question was painfully clear: there **was** more to it than that. It had been pointed out by Dr Polson, whose report he and colleagues had read. But, that said, Dr Anwar told me, "I think certainly the message around 2003–4 very firmly in the institution was 2003–4 MDT issue, 2007 surgery". They thought this because that is what they were told (only Mr Rogers was working in the Trust at the time, but he was in an entirely separate area of the Trust) and they were never shown Mr Wake's Report, nor, presumably, were

<sup>&</sup>lt;sup>74</sup> The Minutes of a Complaints Resolution Meeting on May 25, 2011, record Mr Bala as telling the patient that "in 2003, there were concerns raised by the oncologists within the multi-disciplinary team (MDT) that patients were presenting with breast tissue and inadequate margins, where it was understood that patients had consented for and undergone a full mastectomy performed by Mr Paterson". But, The Minute goes on, "Mr Rogers, however, clarified that the issues in 2003 related to MDT working and possible margin issues only".

<sup>&</sup>lt;sup>75</sup> A typical example of the 'mantra' can be seen in a letter of May 9, 2012 to a complainant, "I understand that clinicians working in breast care raised the possibility of patients having residual breast tissue following mastectomy with the then Medical Director in 2007". In the Minute of a meeting with another patient on March28, 2011, Dr Smith, the Acting Medical Director, was recorded as saying, "... this situation came to the Trust's attention in 2007, when concern was raised that this particular surgical procedure was causing a problem". Yet, in the same Minute, he admitted, "that there was some discussion in 2003 when reviews and audits [sic] were carried out, but advised that he was not sure why it didn't go further at that time".

they aware of the concerns of the oncologists beyond concerns about the MDT. Moreover, while some, may have seen Dr Polson's Report, it must clearly have been filtered through an existing strongly reinforced set of received understandings.

- 11.20 Mr Bala was routinely involved in the complaints resolution meetings. He had been appointed as a locum in 2001 and had been a consultant surgeon in the breast unit at the Trust since October 2003. It could be thought, therefore, that Mr Bala knew or should have known more than what was repeated as the mantra. But, as I have said, until the surgeons began to see other surgeons' patients in cross-cover clinics in 2007, he had no direct knowledge other than what he had been told was the concern examined in 2003-4 the dysfunctional MDT. On the other hand, he was aware of Dr Polson's Report. The position he took in the meetings, therefore, is not entirely easy to understand.
- 11.21 There was one exception to this view that I have called the mantra which was allowed in the complaints resolution meetings. It was that, prior to 2007, concerns had been raised but that they were only (if "only" is an appropriate word) been about the MDT, except for the occasional reference to the fact that breast care nurses had raised questions about tissue being left behind. But, complainants were told, they had been reassured, on being told that what was left behind was only fatty tissue. In other words, the mantra remained intact.
- 11.22 When I spoke to Dr Smith, he recalled that he had found himself in meetings with patients who were understandably seeking answers, but he, himself, felt underinformed. He was anxious to be as open as possible with patients but did not feel that he was properly prepared. "It would have been helpful to me", he said "to have had a more complete and comprehensive appraisal of the whole situation at the start. I wouldn't go as far as saying things were deliberately hidden from me, it didn't feel like that, but I sensed it was an episode that perhaps people felt hadn't been properly handled after the event, and I think it was felt that things had not been properly handled the second time around, which was 2007. I have to say at that point I was not completely sure in my own mind that things had been properly handled in 2007 either. I had some reservations, significant reservations about several aspects of the way it had been handled ...".
- 11.23 The complaints resolution meetings were, therefore, conducted on a false premise: that concerns surfaced in 2007 and that action had been taken. It does not appear that there was any intention to mislead. But, there was an alternative narrative which had been circulating for a long time, in which concerns had surfaced much earlier. The meetings did not, therefore, achieve the stated aim of resolution. Many patients remained dissatisfied. For many, the meetings had the opposite effect from that intended. So far from feeling that at last they had got to the bottom of things, they felt that not everything had been disclosed. It is a small step, and one that it is easy to take in the context, for some patients to believe that they had been deceived once again.
- 11.24 The fundamental reasons for this state of affairs, in which, for some, anger and loss of trust were exacerbated rather than dissipated, were the lack of a corporate memory and the fact that communication among managers and between managers and staff and patients was, at best, limited. It might seem inconceivable that the person who is charged with managing the complaints resolution meetings was unaware and was not made aware of important parts of the history of the Trust's dealings with Mr Paterson, but that was what happened. Mr Rogers innocently misled

patients in a process aimed at being brutally honest and in which those representing the Trust were exemplary in their concern to express regret, to apologise and to offer help.

- 11.25 The situation in which Mr Rogers found himself is well illustrated by his letter of December 6, 2011 to a patient. She had written to the Trust complaining of how she had been treated and asking for answers to a series of guestions. She asked "Did Mr Paterson conceal in the notes the kind of surgery he performed?" As I have explained, Mr Paterson recorded the operation as a mastectomy even in those cases in which he carried out csm. Mr Rogers replied, "... the records document that a mastectomy was performed, and that you were consented [sic] for a mastectomy. It is this which has triggered your inclusion in the recall process, to ensure we have reviewed your current clinical condition, and to better understand whether you underwent a variation of a full mastectomy". Put more simply, Mr Rogers is saying that the Trust does not know what operation she had. He simply cannot answer the direct question asked: were the notes accurate. He then went on "There is a separate on-going investigation into how the csms were documented and consented [sic]. which due to the confidential nature of the investigation I am unable to explore further here". Well, the csms were not documented; that was the problem. And, secondly, in a process designed to be open and supportive, the patient had the door shut in her face because of the deemed demands of confidentiality.
- 11.26 A couple of other points are worth making before leaving my consideration of the complaints resolution meetings. First, it might appear curious to the outsider that the letters of invitation and the subsequent Minute of the meetings were written by a manager rather than a clinician and were written only after extensive access to the medical records of the complainant. The first point is a minor one but not unimportant in terms of the confidence that the patients might have in the process. Technical medical terms were often used, drawn from the notes, without being followed by an explanation or expressed in plain English. It is, of course, very unlikely that most patients would know what the terms meant. The consequence was that in the very act of seeking to be open, the patient was excluded from understanding what was being said. The other point is more important. The complainant's medical records are, of course, confidential. Access to them should be limited to those whom the patient has agreed, expressly or impliedly, should be entitled to see them. A general manager would not ordinarily be regarded as such a person. I was concerned to discover whether some form of consent was obtained from the patient entitling the manager to have access. The point had not been considered. It should be.
- 11.27 Secondly, the Minutes of complaints resolution meetings frequently went through a number of drafts. One immediate effect was that if the best form of resolution is that it be prompt, it was not. The delay was often measured in months. This is just another example of the Trust's failing to dedicate sufficient resources to the task. From the perspective of patients, it was really important that they had, in tangible form, the Trust's answers, explanations and apology. Having to wait not only added to their unhappiness, but again raised fears that some sort of under-the-counter activity was going on, so strong were their suspicions.
- 11.28 In addition to lack of resources, a further reason for delay is important. Drafts were scrutinised by the Trust's lawyers. They were approached from the perspective of lawyers seeing it as their role to protect the interests of their client (the Trust). Anything that looked like an admission of something not previously admitted, or perhaps too broadly defined, was picked up and argued about. While accepting that

this is what lawyers ordinarily do, and should do, this was no ordinary situation. It is impossible to read the papers to-ing and fro-ing without getting a sense of tension between the Trust wanting to turn over a new leaf and the lawyers over-cautiously holding them back.

- 11.29 After all, the Trust was not contesting claims being brought against it by women operated on improperly by Mr Paterson. And, the complaints resolution meetings were posited on a commitment to total openness and to saying sorry. In such a context, legal nitpicking was not only unnecessary but demonstrated a misjudgement of what was in the best interests of the client, given that the client (the Trust) had itself defined its interests in terms of openness.<sup>76</sup> An example can be found in the draft dated November 28, 2011 of a letter to a patient. A paragraph began: "The breast care nurses and other members of the team raised concerns when residual tissue was apparent in a number of patients". The next sentence originally continued: "They were told by Mr Paterson that it was fatty tissue". This sentence was crossed out even though it is what happened, appears in other letters, and is an important step in understanding how things came about.
- 11.30 Mr Rogers, charged with the responsibility of drafting the Minutes of the complaints resolution meetings, told me that he "frequently felt the tension" between what Dr Anwar and he were seeking to achieve and the interventions of the solicitors. He commented that some of the responses and Minutes could end up appearing impersonal. In my view, and in the view of some patients, the end product often appeared sanitised, with stock phrases and agreed forms of words taking the place of real engagement.
- 11.31 Mr Rogers described how, in dealing with complaints meetings in other parts of the Trust, the Trust had recently introduced a system whereby the meeting was recorded and the complainant was given a disc of the recording, and a brief letter summarising the key points and any action taken. The feedback from patients had generally been positive, he said. They appreciated the efforts taken by the Trust. But, he went on, "The view of the solicitors on this issue [was] that [the complainant should receive] the Minutes in written form only, rather than [being given] a recording on a disc". There is no doubt that some in the Trust saw the transparency represented by a recording as a step too far in terms of the risk it might expose the Trust to. Rather than making a commitment to open and honest engagement with patients, as reflected in giving the complainant a recording, some in the Trust still clung to the old ways in which patients are told what others decide to tell them.
- 11.32 If he did not feel compromised, Mr Rogers said that he felt at the very least "uncomfortable" with this approach. In my view, it directly challenges the Trust's avowed commitment to openness. It suggests that there is some way to go in understanding what it means to have a truly patient-focussed approach.

<sup>&</sup>lt;sup>76</sup> See, for example, the exchanges between the Trust's solicitors and the Trust in dealing with the complaint made by Mrs Gulati, October 17, 2011.

## Conclusions about the new approach

- 11.33 In the circumstances, it was right to launch a new investigation. Dr Smith was right to include the issue of consent, which had been overlooked by senior managers for eight years or so.
- 11.34 The decision to recall all patients was also right, if belated. It should have been done three years earlier. Dr Smith is to be commended for his decision to write to patients directly. Not only did it respect their right to be informed, but it signalled a commitment to openness and a consequent shift in the culture of the Trust.
- 11.35 Once the recall was decided, the Trust fell into the same error as before and failed to provide the necessary resources, human and material. This led to delays and consequent anxiety for patients. Once recalled, the patients were cared for well and considerately.
- 11.36 The complaints resolution process was an excellent device to reach out to patients, explain the past and apologise. The staff involved were exemplary in their desire to be open and in terms of the dedication they brought to a difficult task. The meetings were overshadowed by doubts and misgivings among the patients that they were still not being told the whole story. This was largely explained by the lack of corporate memory on which the new leadership could draw, not least because of the informal ways of working that had previously characterised how the Trust operated. This led to Dr Smith and Dr Anwar being inadequately briefed and lacking a complete understanding of the past. This led in turn to the recital of the "mantra": that concerns had first emerged in 2007 and that the Trust had then acted on them. While the staff may have thought this was so, many patients believed otherwise which undermined the success of the process.

# 12 CHAPTER XII

# THE QUESTION OF DATA

# The Issue

- 12.1 I turn now to the question of data. As I have said throughout, senior management seemed to adopt what I have called a neutral position. Mr Paterson was doing something no-one else did and which had no professional pedigree, but it did not follow that it exposed patients to an increased risk of recurrence. This led to a continuing preoccupation with data. The thinking seemed to be as follows. The problem, if problem there was, could be solved by analysing the data. This was the objective and scientific way to do things. It would show whether Mr Paterson's way of operating did in fact expose patients to a greater risk of harm, the harm being a recurrence of cancer which could be traced to tissue left behind, rather than to the ill luck which says that there will always be some women whose cancer returns.
- 12.2 Before exploring the issue of data in greater detail, it may help to observe that, on another view of things, as I have frequently pointed out, the real issue was one of consent or its absence. This should have been appreciated from the outset. Had it been, csm would have been stopped much earlier and the elusive search for answers through data would have been avoided in large part. The number of patients exposed to csm would have been much smaller, for a start. Because this was not appreciated, data came to be seen as crucially important for the future welfare of past patients who had been operated on and who now needed to know what risk they were running. But, data on what? The approach adopted was to search for the data which would answer the question about whether there was a risk: an increased risk of recurrence.
- 12.3 As regards the risk of recurrence, on general principles, without needing the data to nail it down, the risk was self-evidently raised if tissue was intentionally, or carelessly, left behind. As far as patients were concerned that was enough. They were not concerned about establishing this with some satisfying degree of certainty. What they wanted was to be examined and "de-risked", whatever that might involve.
- 12.4 And, there is a deeper point. The pursuit of data might be seen, at some point, as some sort of displacement activity. Wrestling with the very human problem of the patient can be postponed while the technical issue about data, which the clinician-scientist is more comfortable with, can be resolved. Indeed, if there is one lesson to be learned from the many occasions when things appear to have gone wrong in the NHS, it is that senior managers and doctors who are reluctant to confront what is actually happening, take refuge in the call for data. The data will give the answer. And, the next lesson of history, of course, is that once data is produced, it becomes the focus of argument: is it valid, is it the right data, is the interpretation valid, is it complete, and so on: an approach captured in the memorable expression, "dissing the data is an art form in healthcare". Time without number, a concern about the welfare of patients is converted into a crypto-scientific dispute about numbers<sup>77</sup>. The

<sup>&</sup>lt;sup>77</sup> The experience of the Healthcare Commission in 2006 in dealing with Mid Staffs NHS Foundation Trust provides a recent example.

result is that doing nothing for the time being becomes the order of the day, justified on the grounds that something (whatever it is) is not clear from the current data and more data/analysis is needed.

- 12.5 It was against this background that senior managers in late 2007 began the search for the data which would answer the question whether Mr Paterson's surgery exposed patients to a greater than normal risk of harm. Of course, Dr Stockdale had carried out his audit in 2003 suggesting that women were at greater risk and the QA Visit of 2004 had expressed similar concerns but these had not become part of the corporate memory. The Trust started again. On September 28, 2007, Mr Budhoo, as Clinical Director, contacted the information team at the WMCIU asking for "any data held by WMCIU on breast cancer cases at Heartlands and Solihull". He continued that he was undertaking a review as Clinical Director and asked to be informed "what information re breast cancer is collected". The WMCIU replied promptly by e-mail, outlining the data it collected and asking what further information was required, giving a telephone contact number. There was no further contact.
- 12.6 The next contact was a request from Mr Cunliffe on November 20, 2007, asking the WMCIU to examine the outcomes of Mr Paterson's patients compared with those of other surgeons at the Trust. Some preliminary data was sent to Mr Cunliffe on November 29, 2007 drawing particular attention to cases where there appeared to have been second or repeat operations after mastectomies.
- 12.7 The senior managers, meanwhile, persevered in their attempt to answer the question about the risk of recurrence, not generally, but in the particular case of csm. They were immediately faced with several problems. First, as I have pointed out a number of times, it was not possible to establish which patients had had a csm. Mr Paterson recorded that his patients had had a mastectomy. He did not record whether they had, in fact, had csm. Secondly, recurrence usually occurs after a lapse of several years, such that the incidence of recurrence was difficult to measure, except as regards those who had been operated on sometime previously (between, for example, around 1998-2004) when it would be even more difficult to determine whether the patient had had csm. Thirdly, it was difficult to separate patients who might have received "mitigating" radiotherapy and other treatment from other members of the breast team, from those patients who had just had what was recorded as a mastectomy, without any further intervention. And, of course, the regimen of adjuvant treatment might modify the potential risks of the surgical treatment that they had been exposed to. Fourthly, a rate of recurrence involves dividing the overall number of patients by the number of incidences of recurrence. But, it was very difficult to determine just how many patients in total Mr Paterson had operated on. He did not, it was said, always accurately record what he had done, and, of course, there were the large number of patients whom he had treated in the private sector, the precise number of which was not known (and there was no obligation to make any report to the NHS Regional Cancer Registry, the WMCIU, such that their data might be significantly incomplete).
- 12.8 In the face of this uncertainty, it was not possible, it was said, to establish from the data the degree to which women might have been put at risk. More data and

analysis, it was said, were needed.<sup>78</sup> And, to remember the context, what was at stake here was who should be recalled, prior to the decision to recall everyone in mid-2011. Senior managers regarded the answer to the question lay in the data on recurrence. It would show whether there was a risk and, if so, where it lay.

12.9 The issue of risk rumbled on for several years. There are still echoes now. But, it should not have rumbled on. As I will explain, there was some data quite early on. It did not say anything specific about csm because csm was not a recognised procedure, so obviously no data was collected. But it did show two things: the increased level of risk associated with the incidence of immediate reconstruction, and with "shaves after mastectomy".<sup>79</sup> It also demonstrated that, more generally, Mr Paterson exposed patients to a significantly greater risk of recurrence than his peers.

#### Mr Paterson's rate of recurrence

- 12.10 The data relating to increased levels of risk arising from Mr Paterson's practice was contained in communications between Mr Cunliffe and the WMCIU. Dr Lawrence sent it to the Trust in early 2009. I will examine it shortly. At this point, it is important to notice the third of the issues I just referred to: Mr Paterson's overall rate of recurrence compared with that of his peers. To be clear, this data allows for a judgement as to whether Mr Paterson's surgery generally met the appropriate level of performance. It is not about csm or the other improper procedures he carried out. It was to play a major part in how the Trust dealt with patients, staff, outside agencies such as the GMC and the public, over the next several years. It is a very important and, perhaps, revealing episode.
- 12.11 The Trust took for the benchmark for performance the Association of Breast Surgery's <sup>80</sup> Surgical Guidelines for the Management of Breast Cancer (2009). The relevant guideline has as an objective "To minimise the development of local recurrence after mastectomy for invasive cancer". The outcome measure to evaluate achievement of this measure is that as a minimum standard "<5% of patients with primary operable breast cancer should develop local recurrence within 5 years following mastectomy", with a target of <3%. Relying on this, the Trust has routinely, right up to the present, been able to claim that Mr Paterson's performance (which showed a rate of recurrence as regards all surgery of around 4.0%) was within the norm of performance of his peers.<sup>81</sup>
- 12.12 But, as early as 2005, the Director of WMCIU, Dr Gill Lawrence and colleagues had presented data at a National Conference of the Association of Breast Surgery which told a different story: that the norm as regards local recurrence after mastectomy was 1.38% and was 2.75% after breast conservation surgery. She explained to me that

<sup>&</sup>lt;sup>78</sup> So, when Mr Paterson was ultimately excluded from the Trust, he was not excluded on the basis of exposing women to increased risk of recurrence. He was excluded on the basis of the grounds of the new investigation launched in early 2011.

<sup>&</sup>lt;sup>79</sup> It is important to note that the WMCIU made it clear that they could not carry out an audit of shaves, because no records of such operations were collected by them, nor could they be readily identified from the pathology data that the Trust sent them. Thus, what was analysed by WMCIU was lists of patients identified by the Trust as having had shaves, the identification having been made by Mr Paterson. This left Dr Lawrence unsure whether the data was, and is, entirely accurate.

<sup>&</sup>lt;sup>80</sup> Then associated with the British Association of Surgical Oncology – BASO.

<sup>&</sup>lt;sup>81</sup> See the statement issued to the press on November 3, 2010 for its first public appearance.

the minimum standard proposed by the Association of Breast Surgery of <5% to <3% had no scientific basis. Indeed, when Mr Cunliffe cited it, she described it to him in a note as "rubbish; it's been pulled out of the air [by the Association]; it's meaningless".

- 12.13 Dr Lawrence, indeed, had been at pains as early as 2007 to draw Mr Cunliffe's attention to the data on the norms of recurrence that she presented in 2005. She did so in an e-mail dated December 4, 2007, at the time that the Trust was wrestling with what to do with Mr Hennessey's report and was awaiting Dr Polson's Interim Report. She even enclosed the slide presented at the Conference in 2005. Dr Lawrence sent a further e-mail, again attaching her presentation, on March 3, 2009 to Mr Cunliffe reiterating these norms. Six years after the first e-mail and eight years after the presentation, her concerns remain unheard, or un-listened to, by the Trust.
- 12.14 When newspapers quoted the Trust's press release in November 2010 to the effect that Mr Paterson's rates of recurrence were within the national standards (on the basis of the ABS' guidelines), Dr Lawrence told me, "I was very cross actually. I was very angry when I read the newspaper article". But, she said, "I didn't do anything really. I just despaired".

# The WMCIU and the Trust

- 12.15 I will return to the data shortly. Before I do, I need to notice that it is clear that relations between the Trust and WMCIU were and to an extent remain less than ideal. This had and still has a number of serious implications. Mr Paterson continued to operate until 2011, two years after Dr Lawrence sent her report to the Trust. The Trust is still seeking to understand the range of risks that past patients may have been exposed to. And, the process of recall may yet have to expand further. It is essential, therefore that working relations should be as good and supportive as possible. Unfortunately, they have not been. This is not in the interests of patients.
- 12.16 During my conversations with senior managers, they complained of difficulties in getting answers to the questions that they were concerned with and the slow pace at which WMCIU responded. For her part, Dr Lawrence accepted that relations were less than satisfactory and that she was equally responsible, not least as regards the pace at which WMCIU had dealt with the Trust. The pace "was far too slow", she admitted. She explained that it was partly because no-one was appointed in a dedicated way to do the analysis.<sup>82</sup> Such a decision was for the Trust to make and it did not. "It should have been much better planned at the beginning. ... I think I didn't know the whole picture of what was going on". This was probably due to the same concerns about confidentiality arising from the HR process which governed all of the Trust's actions. It also reflected a recurring pattern of not allocating sufficient resources to do things efficiently.
- 12.17 Moreover, Dr Lawrence expressed three significant concerns on the part of WMCIU. First, the Trust, in her view, failed properly to take account of the warnings set out in the reports and accompanying correspondence sent to the Trust in February and June 2009. Relations are affected if one party thinks that the other is not paying

<sup>&</sup>lt;sup>82</sup> The Trust paid a member of staff overtime for a short period to assist with WMCIU's initial report produced in February, 2009, but this did not cover the full-time commitment called for.

attention, particularly when the warnings were serious and, rather than being isolated, were part of a background of concern which had been growing over the years. Secondly, she made the important point that the Trust wanted WMCIU to come up with a rate of recurrence for Mr Paterson, while not understanding nor accepting that a rate of anything cannot be calculated without an agreed denominator (the number of operations carried out). Since, no-one knew how many operations in total that Mr Paterson had performed, far less how many csm operations he had carried out, it was impossible to talk in terms of rates of recurrence. As Dr Lawrence explained to me, "I have been pressed for recurrence rates for the surgeon and I am very reluctant to do that because I don't believe I've got all the cases.... I could provide recurrence rates [for Mr Paterson] ... in the NHS because I've probably got those. ... But the rest of his practice is in the private sector and I have never been fully convinced that I had all the cases from the private sector and his private sector cases may have no recurrences or they may all have recurrences, which is going to change the denominator and the recurrence rate, so I have been very reluctant to do that". She described it as "my basic principle and nobody seems to understand that in the Trust.... I find it quite frustrating that I have to keep saying over and over we cannot do ... rates".

- 12.18 That said, her Reports did actually offer an estimate of Mr Paterson's rates of recurrence. And she did describe it as being within the Association of Breast Surgery's guidelines. But, her position is that while this is accurate and so had to be stated, it is also meaningless and the Trust knew this. Her concern, therefore, is with the Trust's choosing to latch onto a number that served its interests rather than use the number she had pressed on them for years.
- 12.19 Between the Trust and WMCIU, therefore, there was something of a dialogue of the deaf: the Trust seeing "the answer" as lying in data on rates of recurrence; the WMCIU seeking to make clear that it was not as simple as that. Clearly, when so much was at stake and when, at least on one view, data, properly understood, could help to identify what the Trust should do, this continuing tension between the Trust and WMCIU was unfortunate at best.
- 12.20 Meanwhile, it has to be said that despite all that has gone on at the Trust over the past decade or more, the Trust itself has still not carried out its own audit of the outcome of the surgery in the breast team. The audit carried out by Dr Stockdale in 2003 remains the only one.

## The data

- 12.21 The data available to the Trust is of great significance in assessing the response of the Trust to Mr Paterson's surgical practice. It asks questions about the approach to the process of recall and about Mr Paterson's continued practice. It should be remembered that he continued to operate until 2011, eight years after Dr Stockdale's audit and more than two years after data was sent by WMCIU to the Trust. For this reason, I will need to examine it carefully.
- 12.22 It is as well to recall what I am considering here. The previous Reports commissioned by the Trust pointed to Mr Paterson's deviation from accepted and proper practice. The question that senior managers posed for themselves was whether there was any particular risk, greater than the general risk which all patients were exposed to, as regards the procedures which were particular to Mr Paterson while being unknown to other surgeons: csm and "shaves at mastectomy". These were the procedures Mr

Paterson had been required to stop at the end of 2007. Senior managers were looking for data. They were seeking to determine which patients should be recalled.

- 12.23 An exchange of e-mails between Mr Cunliffe and Mr Jewkes (a breast surgeon at Good Hope Hospital) can serve as a starting point. Mr Cunliffe was made aware of data from the WMCIU that raised significant questions about Mr Paterson's practice, nearly two years before Dr Lawrence's reports in February and June 2009. The exchange took place in December, 2007, while Dr Polson and Mr Hennessy were carrying out their investigations. On the one hand, it can be understood as part of the Trust's attempt to determine whether Mr Paterson's surgery posed the sort of risks being advanced by Mr Ingle and the oncologists. To this extent it lent emphasis to Mr Hennessy's recommendation that csm and "shaves at mastectomy" should cease.
- 12.24 But, the exchange can also be understood as providing further background to the discussions about to be embarked on concerning the recall of patients. Recall was premised on risk. The initial recall was limited to, or focussed on, a small number of patients deemed most at risk of recurrence. I have suggested that the identification of such a category of patients was not feasible, even though it was the chosen course of action. Mr Jewkes' e-mails suggest that the policy behind the recall was not only unfeasible but ill-conceived: that the risk was more extensive, based on the evidence (data) that Mr Jewkes was bringing to Mr Cunliffe's attention.
- 12.25 Mr Jewkes remarked first on the high proportion of mastectomies followed by immediate reconstruction carried out by Mr Paterson and wonders whether this related to a "strong enthusiasm" for this procedure. Recourse to immediate reconstruction had been a contentious issue in the MDT for years. Some of the members of the MDT thought that it was being recommended inappropriately by Mr Paterson and that the dissenting voices of others were simply being overridden. It was one of the matters identified in Mr Wake's report in January 2004 and by the QA visit in 2007. Mr Wake had recommended that selection criteria be agreed in accordance with regional and national guidelines. Mr Jewkes referred to "increasing numbers of recurrences in reconstructed breasts" as "more worrying". Here was evidence. Recurrences were being identified. And, this particular issue is particularly problematic, and was so at the time. If breast tissue is being left behind and there is an immediate reconstruction, the tissue left behind constitutes a potential ticking time bomb, undiscoverable unless specifically looked for,
- 12.26 Second, while he regarded Mr Paterson's recurrence rates as "acceptable" at around 5 8%, (which, it will be noted, is significantly higher than the minimum standard in the Association of Breast Surgery's guidelines issued two years later and much higher than Dr Lawrence's figure presented in 2005), Mr Jewkes remarked on the unusually high numbers of cases where the resection margins were involved (that is, that there was not as clear a margin as appropriate between the area where the cancer was and the rest of the breast). "You would expect higher local recurrences", Mr Jewkes argued, "and poorer outcomes eventually". Though this is not evidence of recurrence, it is evidence of the circumstances which would lead to recurrence. And, it referred to Mr Paterson's surgery more generally, not just to the two particular procedures. It was a clear warning about what the future might bring and, thus, what action might be called for then.

- 12.27 Mr Jewkes then drew Mr Cunliffe's attention to the "high excision rate" after reported mastectomy, which he described as "very unusual <sup>83</sup>. ... [T]his would suggest that significant amounts of breast tissue were being left behind after mastectomy **on a regular basis** [my emphasis]". Indeed, he pointed to the fact that there was "a significant difference in the weight of mastectomy specimens" between Mr Bala and Mr Paterson: 672 gm compared with 385 gm. This "might suggest that breast tissue is being left behind during mastectomy by ISP [Mr Paterson]". Here again there was evidence: the "high" rate of excision ("shaves after mastectomy") with all its implications.
- 12.28 The importance of this exchange of e-mails lies in the fact that, if, in the period between 2007 and 2010, the senior management were concerned to establish the facts before taking action about recalling patients, the facts being the risk to which patients were exposed, they already had some pretty significant pointers in 2007. They may indeed have formed part of the background to the decision to restrict Mr Paterson's practice. But, this restriction related only to csm and "shaves at mastectomy". The concerns over immediate reconstruction and margins remained as they had since 2003 and before. Mr Jewkes was providing evidence that these practices were continuing and with them came higher risks. And, most significant of all, he was providing evidence of "partial" or "incomplete" mastectomies. He may not have been presenting data of the sort that might emerge from some particular, focussed study. But, he was providing evidence to go alongside what others had been arguing for years. He was providing evidence alongside that of Mr Hennessy and Mr Lee that Mr Paterson's surgery **generally** was of concern.
- 12.29 Mr Jewkes' concerns do not seem to have registered with sufficient force. They certainly do not seem to have been understood as arguing strongly for the two things that have been a recurring theme: that Mr Paterson should stop operating till the full scale of the risk could be assessed, and that all, not just a few of his patients should be recalled.

## The WMCIU's Reports

12.30 Whatever else the Trust had by way of evidence and data before then, by early to mid 2009 senior managers had data in the form of a report from the WMCIU. The report was requested initially by Mr Cunliffe on May 22, 2008 as one of the consequences of Mr Hennessy's Report. It looked at the whole of Mr Paterson's practice in the NHS (and later sought to include those of his patients from the private sector who could be identified). It was headed "Breast Cancer Audit Summary Report". Mr Cunliffe asked that the WMCIU's Data Quality Manager "perform an audit of breast cancer cases treated surgically" by Mr Paterson and the four other surgeons currently or recently operating on patients, based on two datasets of patients that Mr Hendrickse, the Clinical Director – Surgery, provided. Submitted in February 2009, as her initial report, Dr Lawrence particularly remarked on "unusual

<sup>&</sup>lt;sup>83</sup> Dr Lawrence at the WMCIU was unaware and not made aware of these exchanges between Mr Jewkes and Mr Cunliffe, but independently made the same point two years later in her June, 2009 Report.

combinations of operations" including "mastectomies after mastectomies".<sup>84</sup> It appeared, the report stated, that there was a higher incidence of recurrence in this category of patients. She told me that "What the report actually unearthed was these very odd operation combinations which was not what I was told we were looking at to begin with but I had a sense might be what we were looking at because I knew about the background". "The background", of course, reached back as far as Dr Stockdale's Audit six years earlier and certainly was causing concern to the QA team in 2004.

- Dr Lawrence submitted a revised, final Report of June, 2009. The Trust's senior 12.31 management did not appear to regard her report as being of such significance that it should change the approach either to the process of recall or to Mr Paterson's continuing to operate. Dr Lawrence remarked that "The June Report ... disappeared as far as I know". In fact, Mr Cunliffe's response was to challenge the data, as I will describe later, or subject it to further scrutiny. One thing that was not done was to make the WMCIU's report available more widely. Fellow surgeons and others in the breast team were not aware of the analysis. Had they been aware, they would undoubtedly have expressed views as to the way forward. Instead, the interview with me was the first occasion on which they were aware, in the case of the surgeons, that their performance had also been analysed so as to compare it with Mr Paterson's, and that the WMCIU had drawn attention to the significant risk of recurrence in particular cohorts of Mr Paterson's patients. On seeing the report they were, at best, surprised that it had not been made available more widely.<sup>85</sup> There was also a sense of vindication.
- 12.32 Given that the issue is the Trust's search for data on which to base their actions, I asked Dr Stockdale whether the limited recall, which was still the planned form of action in 2009, could continue to be justified in the light of the WMCIU's June report. He replied, "Absolutely not. ... It is quite clear that there were substantial [numbers of] patients at risk and it is quite clear that the Trust choosing to believe that only 12 were at risk was at the very best naive and at the very worst totally culpable." Dr Stockdale, while arguing that "Unless you see [the patients] face-to-face you can't tell so you've got to recall everybody", took the view that "there were two groups <sup>86</sup> from the outset who should have been recalled", suggesting a limited, albeit more extensive recall than that initially decided on. "[B]ut", he went on, "as soon as you have that from the Cancer Registry you've got to recall everybody".
- 12.33 It is difficult to understand why Dr Lawrence's report, which I regard as highly significant in the evolution of what the Trust could and did do, was not shared more widely. The only plausible answer must be that the senior managers were of a mind that the answer to whether Mr Paterson's surgery posed a risk to patients lay in the data. And, once in this mindset, it became important, indeed crucial, to make sure that the data was sound and reliable. The WMCIU's report was challenged and

<sup>&</sup>lt;sup>84</sup> The Report states that "There were 75 patients with unusual combinations of operations. ...In 2004–2007 86% of the conservation operations after mastectomies and all the mastectomies after mastectomies were performed on patients operated on only by IP [Mr Paterson]. ...In 1994-2003, 73% of the conservation operations after mastectomies and 67% of the mastectomies were performed on patients operated on only by IP. 90% of the former operations were carried out on patients where IP was the first surgeon".

<sup>&</sup>lt;sup>85</sup> Mr Bala, when I showed him the report, said, "I've never seen this. ... I should have known. At least there's some very valuable information for my own ... performance".

<sup>&</sup>lt;sup>86</sup> Patients who had had multiple mastectomies and those with positive margins.

examined for flaws. A flaw was identified, as I shall set out. The significance of the report as a whole could then be doubted. The oft-repeated pattern of "dissing the data" could be played out again. The status quo could be maintained. Mr Paterson could continue to operate. The search for answers could continue.

12.34 It had fallen to Mr Cunliffe to assess the importance of Dr Lawrence's report. He had commissioned it and now he had to decide what it meant in terms of the impact, if any, it should have on the Trust's actions. Perhaps it is worth making the point here, a point reflected in the views expressed to me by a number of members of staff, that managing what was becoming an increasingly challenging exercise was something that should not have been placed on Mr Cunliffe's shoulders. He was described to me as a "really personable chap, very nice guy, [who] dealt with it to the best of his ability". But, it may have been a challenge too far. "He is an eye surgeon", I was reminded. Debating with the Cancer Registry was, it was put to me, "completely outside his expertise and remit. ... If he wanted to know whether Cancer Registry data was significant he should have asked a breast specialist or a cancer intelligence specialist. ... It was not for him to argue the case". Of course, Mr Cunliffe did take advice and regularly was in touch with specialists. But, the burden lay on him. And, the suggestion is made that in bearing that burden he was "heavily influenced by the Chief Executive and the wider considerations of the reputation of the Trust".

## A Dispute

- 12.35 The evidence and cautions expressed in the WMCIU's report (which I will set out more fully shortly) do not appear to have prompted the Trust into any particular action. They were seen as part of the background and needing more work. The report did, however, have one wider impact which I need to mention.
- 12.36 Dr Lawrence had sent a covering e-mail with her Report. On casual reading <sup>87</sup>, its opening paragraph, though not the rest of the e-mail, far less the Report itself, could be thought to indicate that Mr Paterson's surgical performance was within acceptable standards. To those reading this paragraph, it could set the context within which the later remarks and the Report could be understood. It could be read that Mr Paterson's surgery was broadly acceptable, and the more particular issues referred to (the "problematic" operations) could be regarded as statistical "work in progress".
- 12.37 When the GMC began to deal with the complaints raised by patients against Mr Paterson, they called for statements from the Trust. Dr Smith, the Acting Medical Director, submitted a statement to the GMC on December 21, 2010 in which he wrote, "The Trust has collated audit data in conjunction with the West Midlands Cancer Network [sic], and to date Mr Paterson's outcome data does not appear particularly outside reasonable rates of recurrence for the relevant period. Further work is however needed to ensure that the data accurately reflects the csm patient outcomes....."

<sup>&</sup>lt;sup>87</sup> It goes without saying that what I call a "casual" reading, if it is accurate, is entirely inappropriate, given the importance of the issues and the apparent desire of the Trust to understand what was happening. It also overlooks the fact that in the very sentence in which she describes Mr Paterson's performance as being within the norm, Dr Lawrence flags up "exceptions" which she goes on to address later in the e-mail. More than anything, it perhaps reflects the desire to find good news even in the most unlikely places!

- 12.38 In making his statement, which was repeated word for word six months later in a letter to the GMC from Dr Anwar on July 6, 2011, Dr Smith relied on the opening paragraph of Dr Lawrence's e-mail that I just referred to. She compared Mr Paterson's performance with the established norm. She reported that Mr Paterson's overall recurrence rate "... lies between the minimum standard and the target". This paragraph was to have considerable significance in what followed.
- 12.39 When Mr Paterson appeared before the GMC in a preliminary hearing, the Panel of the GMC had Dr Smith's statement before them. The Panel decided not to order that Mr Paterson be suspended. They did so citing the evidence, relied on by his counsel, that the Trust had stated that Mr Paterson's performance was not outside the accepted range and, presumably, therefore, he remained fit to operate, all other things being equal. As I have said, Dr Smith's evidence was based on an entirely innocent misunderstanding: there was no intention to mislead. It did not, however, reflect the known views of Dr Lawrence at the WMCIU. It gave, therefore, a false assurance to patients and to the GMC. But, it entered the corporate memory of the Trust such that the new Medical Director, as I have said, wrote, again innocently, to the GMC in precisely the same terms six months later. Clearly, for the future, it is important that the GMC is aware of the discrepancy between what the Trust was saying and the real and previously expressed view of WMCIU.
- 12.40 What led to this discrepancy? Dr Smith told me that he did not read beyond the first paragraph of Dr Lawrence's e-mail which accompanied the report. So, he did not read on to discover the reference to the significant risk of recurrence to which patients undergoing two particular procedures had been exposed. Nor did he take account of Dr Lawrence's reference in the second paragraph (!) of her covering e-mail to the data she presented in 2005. She wrote that recurrence rates "... could and probably should be lower than the > 3% target": they should be "... 1.4% for those having a mastectomy. ... If those data do prove to be correct," she went on, "then IP's [Mr Paterson] recurrence rates may actually be relatively high". His rates were 3% for recurrence after mastectomies and 5% after breast conserving surgery, as regards NHS patients (where the data was more reliable). And here she was referring to his overall rate of recurrence, not to those operations where she had identified high rates of recurrence. These were "shave after mastectomy", where she identified a "very high recurrence rate" albeit in a small number of patients, and operations for an immediate reconstruction where she identified a "relatively high recurrence rate".
- 12.41 When I drew Dr Lawrence's attention to Dr Smith's statement to the GMC she replied, "I am stunned that he can say that". She went on, "I don't think the Trust is being honest about it and, I mean, I don't know why they did that. Sorry I mean, I am astounded. ... [A]II along it has not so much been about recurrence rates, as unusual operations which potentially could have higher recurrence rates. ... I had been at pains ... to say that we do not actually know what his recurrence rates were, but if we look at particular groups of patients with unusual operations, or with particular types of operations, then the recurrence rates were worrying and these sort of operation sequences [where the patient has more than one 'mastectomy'] should not be possible".
- 12.42 For my part, I do not for a moment accept that there was any dishonesty on the part of Dr Smith or the Trust. Rather, there was a misunderstanding. At the same time, however, I do not see an appropriate level of engagement with an issue which had been dogging the Trust for years and as regards which the Trust had just received a major Report. In my view, Dr Smith's statement was the product of an incomplete

briefing, a limited grasp of what had become a complex story, and, as a consequence, too cursory a reading of the e-mail from Dr Lawrence to which he did not give the attention it demanded. But, most of all, I am drawn to the view that, like others, Dr Smith chose to see something that looked like good news: that there was no evidence that Mr Paterson's surgical practice was exposing women to increased risk. Dr Lawrence's e-mail and, more important, her Report deserved and demanded better. It did not get it. The desire to believe that, after all, things are not bad prevailed; a preference for good news over true news.

- 12.43 The view adopted and passed on to the new senior management had the effect of perpetuating the notion that, while there may be problems about certain operations that Mr Paterson carried out, these had been stopped at the end of 2007. Otherwise, there was no reason why he should not carry on operating while the Trust works out whom to recall, by looking for the right data.
- 12.44 There was a further effect arising from the Trust's approach to the opening paragraph of Dr Lawrence's e-mail. Mr Cunliffe wrote on September 7, 2009 to the Hospital Director of one of the private hospitals at which Mr Paterson operated, in response to a request from her about the audit of breast surgeons which the WMCIU had carried out. Mr Cunliffe set out Mr Paterson's overall recurrence rate as reflected in the opening paragraph of Dr Lawrence e-mail. In so doing, he appears to be confirming what the Hospital Director said in her earlier letter to him of August 7, 2009. She wrote that she and a colleague "have discussed the best way forward ... with our Medical Director and advised him that the recurrence rates for Mr Paterson were within the normal range". Mr Cunliffe would be aware that the reality was more complex and that the assurance that the Director appears to find in the figures is illusory. After all, Dr Lawrence had contacted him on several occasions in 2007 and later, and gone to the trouble of attaching the data from the 2005 Conference to her correspondence. Yet, it was left there.

# WMCIU's Report of June 2009

- 12.45 I turn now to examine what Dr Lawrence's report of June, 2009 told the Trust and Mr Cunliffe. First, it is important to notice the exchanges that took place between February when the initial report was submitted and June. The report in February did not include any reference to "shaves at mastectomy", because no such data was collected, nor did it refer to patients treated in the private sector. Mr Cunliffe accepted that private patients should be included in the Report (to meet the need for a denominator) and that a list of patients would be provided. The list was to be checked against the WMCIU's data base. Data on cases not registered with WMCIU was to be provided by Mr Paterson, something that Dr Lawrence considered to be less than ideal.
- 12.46 In the June Report, Dr Lawrence presented data to Mr Cunliffe based on whatever private hospital data WMCIU had about Mr Paterson's patients. The June Report also contained data about "shaves after mastectomy". The fact that the data on shaves was to be provided by Mr Paterson, since no-one else knew or could find out who the patients were, again created uncertainty about the accuracy of the data. Moreover, when the WMCIU received the data on shaves, they did not distinguish between "shaves after mastectomy", which would be very unusual, and shaves after breast conserving surgery, which was good practice. This meant that in its analysis, WMCIU did not distinguish between the two categories of shaves. This, in turn, led Mr Cunliffe to dispute the recurrence rates arrived at.

- 12.47 Mr Cunliffe was right to dispute the conclusions drawn about the risks arising from shaves: that the numbers were small and included patients who should not have been included. But, although he was right on this particular point, the bigger picture was clear. Mr Paterson was an outlier in terms of his general rate of recurrence and evidence was emerging that patients undergoing at least one particular procedure and, perhaps, others were at a high risk of suffering a recurrence. Dr Lawrence's advice was arresting. "I would say", she wrote, "that ... 2000 2007 patients are **at significant risk** of having a recurrence and should be monitored carefully over the next few years". She added that "As two of the 9 patients having a shave mastectomy in 2003 have already had a recurrence, the remaining patients in the 1994 2003 cohort who had shave mastectomies should also be kept under **close surveillance**... [my emphasis]".
- 12.48 As regards patients who had undergone an immediate reconstruction, Dr Lawrence warned that "These data [showing a relatively high recurrence rate] would again suggest that all patients treated with immediate reconstruction in 1995 2003 and 2004 2007 who have not already had a recurrence should be kept under close surveillance". To what extent this warning was acted on is part of the story of the slow unravelling of the process of recall. Certainly, in 2009, the Trust's initial process had only identified 12 patients for recall, while others were being picked up serendipitously in clinics.
- 12.49 On April 14, 2011, Dr Lawrence wrote to the Director of Breast Screening for the area, sending a copy of her letter to senior figures in the NHS in the West Midlands, asking that patients not be referred to Mr Paterson. This provoked a flurry of letters from, for example, the Medical Director of the West Midlands Strategic Health Authority and from the Primary Care Trust. They were asking, in effect, what was going on: what clinical concerns there were and what risks to patients. It may be thought remarkable that these bodies did not know and were only informed by the Director of the WMCIU, rather than by the Trust where Mr Paterson worked and where the patients they sent were treated. It was only a month later that Mr Paterson was excluded from the Trust.<sup>88</sup>

## WMCIU's Report of 2013

- 12.50 In July, 2013, Dr Lawrence produced a further Report for the Trust. This too had taken a long time. Dr Lawrence wondered aloud whether there had been a sufficient sense of urgency on the part of the Trust in providing all the necessary information, given that one of the stated aims of the Report was to seek to identify patients who might still be at risk based on the characteristics of their tumour and the time of their operation.
- 12.51 The Report is the first one that concentrates specifically on csm. It describes an analysis of "Recurrence after Cleavage Sparing Mastectomy". It focuses on csm and its effect on patients. It is able to do so because, by the time of the study, much more was known about which women had undergone csm. The precise numbers were still unknown, however, so the study divides patients into three cohorts: a cohort who, according to the Trust, had a csm; a cohort who, the Trust stated, did not have a

<sup>&</sup>lt;sup>88</sup> Subsequently, as the Minutes of the Meeting of the Board of November 8, 2011 record, Dr Anwar reported that "External agencies have been kept informed", including the GMC, the Medical Director of the breast screening programme, and the Medical Director of the Strategic Health Authority.

csm; and a cohort described by the Trust as of unknown csm status. In essence, what the report is seeking to do is indicate whether the concerns and warnings of the previous Reports were becoming reality.

- 12.52 What does Dr Lawrence's Report tell us? In the Executive Summary, Dr Lawrence was anxious to warn that great care should be taken in the interpretation of the data because of major differences in the characteristics of patients and the tumours involved and in the follow-up times for the three groups of patients compared. But, that said, the concerns that she expressed in her previous Reports about the risk of recurrence are borne out. She described the work as "looking exceptionally worrying. ... I have never seen anything like this before [my emphasis]".
- 12.53 "Local recurrence rates", she writes," were significantly higher in women treated with csm compared to women known not to have been treated with csm or for whom the csm status was unknown. ... Whereas local recurrence rates in women not treated with csm or with unknown csm status remained constant at 0.66% and 1.32% respectively between 6 years and 12 years after their initial diagnosis, those in women treated with csm increased sharply after 5 years reaching 6.75% at 9 years and 7.17% at 12 years". Thus, she found that the rate of recurrence in the case of patients who had csm extended over a longer period, such that the "... true longer term local recurrence rates in these women may therefore be higher than those reported".
- 12.54 The work was initiated to ensure that all the patients who needed to be recalled had in fact been seen by the Trust, and to provide some possible estimate of the risk of recurrence for them, some sort of predictive guide, depending on the operation carried out on them. The Trust is now wrestling with the implications of this latest Report.

# **Final Thoughts**

- 12.55 It may well be that Dr Lawrence's warnings in 2009 were not so backed up by data as to point irresistibly to conclusions about the recall process. But, they went a long way in that direction. Had they been heeded, against the background of what Mr Jewkes was saying, the approach to the recall of patients may well have been different, as may the continued welfare of some patients. Quite apart from the question of recall, the data presented in 2009 also demonstrated that Mr Paterson was outside the range of acceptable performance (according to the 2005 data) in terms of the recurrence of cancer in his patients. This was clear, yet the Trust continued to describe Mr Paterson's performance as being within national standards for the next several years. While strictly accurate by reference to the Association of Breast Surgery's standard, it painted too optimistic a picture.
- 12.56 Of course, there will be those who argue that until the position regarding the data was clear (and the current analysis of 2013 can still be regarded as 'work in progress', if one were so minded), it was proper to proceed cautiously. But, the case for a total recall was there to be made in 2008/9, if not earlier. The data five years on is not the wisdom of hindsight. It is the realisation of fears expressed much earlier in the form of warnings backed by emerging evidence.
- 12.57 Dr Lawrence told me that she personally wrote the conclusions of the two reports in February and June 2009. "I was trying to alert him [Mr Cunliffe] to the fact that there could potentially be patients who were at high risk of recurrence". Two strands of

analysis were emerging. First, as regards csm, she could still not say anything specific in 2009, because no data existed. But, plenty of other people were making the case for a total recall, given that intentionally leaving breast tissue behind after a "mastectomy" inevitably left patients at a higher risk of recurrence, and no-one knew who had had csm. Secondly, as regards the patients on which there was data which pointed to an increased risk, she described the way in which she expressed her conclusion regarding patients treated with immediate reconstruction as "strong for me. That [conclusion] is saying 'I think you've got to recall these patients". As regards the patients treated with a "shave after mastectomy", she said that she was "basically saying, 'You need to seriously to think whether to recall them". "I'd written those conclusions," she added, "in the way that a Medical Director ... would take notice of it, a Chief Executive would take notice of it". But, as I have pointed out, the message was not received.

- 12.58 Referring to the compilation of the report in 2013, Dr Lawrence again expressed concern at the way in which things had been dealt with over the previous several years. "Things as important as this should not be done in the way that this has been done. ... That is a lesson to be learned. You should set up a proper project to do it".
- 12.59 Such a project could have been launched with real vigour at least after Mr Hennessy's report; properly resourced, properly focussed and with all those who could contribute being drawn in. This is not what the Trust did. Had a proper project management process been put in place and sufficient resources allocated, the terms of the exercise would have been clarified and agreed, with both parties working together, confusion would have been avoided, and the process would have been finished in a much shorter time. As it was, the exchange of often exasperated e-mails became the order of the day. And, as a consequence, women were harmed.

#### Conclusions about data

- 12.60 The issue of data is complex, or made to appear complex. It was the chosen ground on which to fight concerns about Mr Paterson's surgical practice. It was the chosen ground because it is where clinicians feel comfortable: an answer will emerge which is indisputable. But, the route to the answer is by way of data which is almost infinitely disputable if someone is so inclined. So, the pursuit of the answer becomes the business of the day And, while it goes on, often for years, the real point, the care of patients, becomes something to get back to once everyone can agree on the data.
- 12.61 Of course, as I have repeatedly made clear, the response to Mr Paterson's surgical practice did not need to depend on data. He was operating on women without their proper consent. This was reason enough to require him to cease operating the moment it became clear. But, the issue of data occupied centre stage.
- 12.62 In essence, however, there were two questions that the Trust needed to answer: should Mr Paterson continue to operate after concerns were expressed; and, once it was accepted that he was carrying out procedures which were irregular, did these procedures expose patients to any risk of harm and if so which patients were exposed so that they could be recalled for further examination and assessment.
- 12.63 There was data by the end of 2003 that identified that Mr Paterson's surgery posed risks to patients. The QA Visits also had pointed to concerns. Mr Hennessy's Report persuaded the Trust to require Mr Paterson to cease carrying out two specific procedures on the grounds that they were not recognised procedures and entailed

risks to patients. Mr Hennessy and Mr Lee both expressed wider concerns about Mr Paterson's surgery prompting the Trust to require Mr Paterson to demonstrate his ability to carry out a mastectomy. Data emerged from the WMCIU in 2009 that Mr Paterson's rate of recurrence generally was higher than that of his peers. The criterion used was the data presented at the National Conference of the Association of Breast Surgery, and subsequently at Regional QA meetings in the following weeks in 2005. Senior managers preferred to compare Mr Paterson's performance with the national standard allowing them to say that his performance was within this standard. They did so despite the several efforts made by Dr Lawrence to indicate that the national standard was not an appropriate indicator of performance. The continued reference to Mr Paterson's being within this standard is to be regretted. It misled the GMC. It gave false assurance to patients.

- 12.64 There were reasons enough in 2004 and 2007 to require Mr Paterson to cease operating until the range of concerns, including his clinical competence, could be addressed in a calm and considered manner. The data (or evidence) seen by Mr Hennessy demanded the cessation of the named procedures. It could have been interpreted as demanding that Mr Paterson cease completely for as long as necessary. The data emerging from the WMCIU in 2009 raised sufficient concerns about Mr Paterson's overall performance again to justify action by senior managers; whether to stop him from operating altogether or attach further conditions to those already in place. Senior managers chose not to do so. In my view, in the light of everything that had gone on before, they should have done so. In the event, Mr Paterson continued to operate in the NHS and the private sector until 2011 and when he was excluded by the Trust he was excluded for reasons other than his surgical performance. In my view, had the Trust adopted the perspective of the patients, there was enough data or evidence, leaving aside the issue of consent, to call a pause in Mr Paterson's surgery generally from late 2007 onwards.
- 12.65 The second question was whether there was a risk of harm to patients arising and if so, what to do. Dr Stockdale had presented evidence of increased risk arising from inappropriate surgery in 2003 as had the QA Visit of 2004. By 2007, Mr Hennessy had left the Trust in doubt that certain operations should cease, but senior managers were still asking themselves whether the particular operations exposed patients to an increased risk of harm. They were concerned to know this so as to decide whether to recall any patients and if so whom. To answer this they sought data first on who had received csm and then on the rate of recurrence in this subset of patients. Both of these exercises were misbegotten. It was impossible from the data to discover who had undergone csm. It was impossible to work out a rate of recurrence regarding csm because it was not a recognised procedure such that no data was kept.
- 12.66 The WMCIU was frustrated by being asked to answer questions that it could not answer, not only about csm but more generally about rates of recurrence in the absence of an agreed number of operations performed by Mr Paterson in the NHS and the private sector. In the event, the WMCIU's Report of 2009 presented enough evidence to prompt a much more extensive recall than that which was under way. Their Report of 2013 confirmed the fears expressed in the earlier Report. From a precautionary perspective, given that the abiding concern should have been the welfare of the patients operated on over the years by Mr Paterson, the judgement should have been made much earlier to extend the recall process. In fact, the total recall was not begun until mid-2011. Valuable time was lost. There were patients at risk. The data, when taken with everything else, was strong enough to say they must be recalled. They were not. They should have been.

# **13 CHAPTER XIII**

# THE PRESENT AND THE FUTURE

- 13.1 The Trust is now dealing with the fallout from Mr Paterson's surgery. He has been excluded from the Trust.<sup>89</sup> The catalyst for the decision to exclude him appears to be the enquiries received by Dr Anwar from the Primary Care Trust responsible for commissioning care from the Trust and other local interested parties. They told him that they had been informed by the QA team of "issues" about Mr Paterson and sought reassurance that there was no cause for concern. Dr Anwar told me that he interpreted the queries as amounting to the question "... 'is this guy safe to work' and the answer is no and that was when we stopped him...".
- 13.2 The HR process to which Mr Paterson is subject grinds on. The Interim Orders Panel of the GMC on July 6, 2011 imposed conditions on his registration for a period of eighteen months forbidding him from carrying out breast surgery amongst other things. The GMC will soon begin to hear the complaints made against him. The private hospitals where he operated have launched their own investigations. The Trust is dealing with the very many legal actions brought by patients against the Trust. And, I was told, the Trust is wrestling with the further challenge of whether to recall patients who have undergone procedures other than mastectomies or csm, for instance, a lumpectomy or a wide local excision. The concern is obvious: given what is known about the patients already reviewed, does the Trust have a duty to look at all other patients (around 3,500), to reassure both the patients and the Trust that there no further areas of concern?
- 13.3 Mr Rogers told me that he had been given the task of taking this process forward. His observations are worrying. They suggest lessons are not being learned. He told me that "... given everything we have said about ... the mass recall not being properly thought through and resourced. ... I guess my concern is we are embarking on something else on a larger scale and are not clear on what we are actually seeking to achieve or find ... it needs to be properly planned and regularly reviewed". Some might even say that the Trust was going into things on a wing and a prayer! I would have thought that one of the more obvious lessons to be learned from the past is that Mr Rogers' warning should be heeded.<sup>90</sup>
- 13.4 The Trust must deal with all of the fallout from Mr Paterson's surgical practice and how it responded to it over the years. At the same time, the Trust must look after all of the patients who continue to come through the door every day. It is a very challenging state of affairs. Being so, it is important in dealing with this fallout to maintain the right perspective and not be caught up solely with the day-to-day

<sup>&</sup>lt;sup>89</sup> It is clear that communication within the Trust is still not, or is perceived not to be as it should be despite the various changes in leadership. I was told by one senior member of the breast team that, "even up to the point where Mr Paterson stopped working, no-one actually told us. He was working one week, then suddenly he wasn't there and then a week later there was a locum in his place but no-one actually said this is happening. ... They made an announcement but all they said is that he's not here anymore. They didn't say why. You had to read the Solihull Times to see he has been excluded from working". The explanation may lie in the fact that the HR process is still going on and its attendant confidentiality still determines the Trust's behaviour.

<sup>&</sup>lt;sup>90</sup> I was told subsequently by the Trust that appropriate resources are being allocated.

management of a very difficult set of circumstances. And the right perspective, as ever, is concern for patients past and present. The financial cost to the Trust is very significant: meeting claims, dealing with regulators, managing the recall process, and dealing with complaints. And, it continues to rise. But, the human cost, to patients and their families is incalculable. The Trust, through its new leadership, is seeking to do all it can for those patients who have suffered. But, the scale of the task should not be underestimated.

- 13.5 Very many patients whom I met felt betrayed by HEFT. <sup>91</sup> Their ability to trust the clinicians has been tested to destruction. Many say that they could not contemplate being treated by the Trust should they fall ill. HEFT has a huge task on its hands to win back some measure of confidence. And, since HEFT looks after a community, many of whom will need its services, it must also reach out to persuade the community that it has done the right thing in the case of Mr Paterson and has in place all the necessary and appropriate measures to ensure that such events will not happen again.
- 13.6 Of course, patients, though they are the most important constituency that the Trust must take account of, are not the only one. Many staff at the Trust involved in the care of women treated for breast cancer feel bruised. They too have lost confidence in the management of the Trust. They too feel betrayed: that no-one listened to them; that things were allowed to go unchallenged for so long; that they cannot trust those charged with leading the Trust, even the new leaders; that they were kept in the dark, unaware of information which would have lent support to their concerns. This lack of trust and, indeed, bitterness were almost palpable in my meetings with some of the staff most closely associated with Mr Paterson and the care of women with breast cancer. So strong was their lack of trust that, just as with some patients, it extended to me and the Review I was charged with carrying out. I was asked by the Trust to conduct it, and was being paid by the Trust, so it followed that I would do the bidding of the Trust. They saw this bidding as continuing what they viewed as an exercise in containment, whereby the preservation of the Trust's reputation was the primary goal. I sought to reassure them that I would do the job I was asked to do to the best of my ability. This Review is the result. It is for others to judge.
- 13.7 Such attitudes among members of staff demonstrate how corrosive the erosion of trust can be. If these clinicians are to be reintegrated into the Trust spiritually and emotionally as well as physically, the new leadership needs to act promptly and decisively.
- 13.8 Finally, the Board must readdress its function and focus. It is clear that the present senior management see themselves as having a duty to ensure that the Board is formally kept of abreast of developments relating to Mr Paterson. This is evident from the Minutes of the Board for April, 5, 2011, when Dr Anwar gave an update, July 5, 2011 when he reported that Mr Paterson had been excluded from the Trust, and May 1, 2012 when he gave a further update. On September, 4, 2012, Dr Anwar gave a detailed account of the history of concerns about Mr Paterson and the Trust's response. The significance of the case and its implications for the Trust were clearly recognised, both by the senior management and by the Board under its new

<sup>&</sup>lt;sup>91</sup> One patient, typical of many, described herself to me as being "very, very, very angry".

Chairman <sup>92</sup>. I was equally reassured by the current Director of Workforce that, whatever the level of communication between the Executive and the Board in the past (and I have pointed to the lack of formal reporting in the years up to 2011), the regular reporting to the Board by the Medical Director is supplemented by regular briefings. These tend, I was told, to focus on the continuing matters arising from the HR process, but also cover concerns about patients.

- 13.9 That said, the narrative that was initially developed for the new senior management was not without its own problems. I say "for" the new management, because, as I have pointed out, they were new to the Trust and initially only knew what they were told. They were effectively in the hands of others. As a consequence, they were associated with the prevailing reluctance to row back from the assertion that Mr Paterson's overall surgery, in terms of the rate of recurrence of surgery, was within accepted norms, and that 2007 was "year zero". Dr Anwar, the Medical Director, wrote a letter to all GPs in the area served by the Trust, on August 1, 2011. The purpose was to put them on notice that the Trust was about to recall all of Mr Paterson's patients rather than a smaller "at risk" group. He began by reiterating the standard view that "concerns ... were originally raised in 2007. ... At that time a review of the cases highlighted a cohort of at risk patients and after extensive consultation including an external expert review the decision was made that this specific cohort of patients should be recalled for further medical assessment and review. This was immediately instituted".
- 13.10 There is no mention of the fact that the limited nature of the recall was hard to defend and that it began to implode very soon. There is no reference to the disquiet expressed by the three external experts brought in to advise in 2008. Everything is made to look controlled and well reasoned whereas another view could readily and persuasively be advanced. Dr Anwar's letter then goes on, "As an additional precaution we ... are now recalling all patients who have been discharged and have had breast surgery under Mr Paterson, in order to provide them and us with reassurance that no further intervention is required". It might be thought that, in the circumstances, this is less than the whole story, particularly the reference to the recall being "an additional precaution" rather than a clear necessity.
- 13.11 The letter concluded that "The current evidence [in August, 2011] suggests that those patients, who were under the care of Mr Paterson, have outcomes which were within the recognised national limits". Well, it did not and had not for a long time.
- 13.12 Dr Anwar's leadership and commitment to openness shine out, since he joined the Trust. I can only conclude that such a guarded and frankly misleading letter was put before him at a point at which he knew no better. Clearly, some may have thought that such a letter coming from the Medical Director was important for the reputation of the Trust and for retaining the confidence of local GPs. But, such a view is wrongheaded. Ultimately, openness means what it says. To start a new chapter, the old one has to be closed.
- 13.13 In a sense, what I am referring to is a commitment to truth, to a duty of candour. I am not referring to a duty of candour as it applies to clinicians and staff. The very large majority of clinicians, particularly in the field of caring for those with cancer, have to

<sup>&</sup>lt;sup>92</sup> Lord Hunt, appointed on April 1, 2011

present bad news to patients every day. To them, talk of a duty of candour is superfluous. For them, it is not a question of whether to tell the truth but how to tell it. But, they find themselves in organisations which, for a range of reasons, find it hard to part with the truth. For the future, talk of a duty of candour must be addressed to organisations and their leaders, as Robert Francis QC recommended in his Report on Mid Staffs NHS Foundation Trust. It is they who owe this duty to patients. And, the duty must entail, among other things, the creation of an environment in which their clinicians can speak to whomever, without fear or favour. I have no doubt that the current senior managers understand and embrace this view. They must persuade their colleagues and the wider community of this, against a background of years during which candour was not always greatly in evidence.

- 13.14 As I said at the outset of this Review, the issues thrown up by an examination of the Trust's response to concerns about Mr Paterson's surgical practice are well-known and well-recognised. They are, in the well-rehearsed term of countless Reports, questions of culture and leadership. They include the ability of an organisation which is large and complex to ensure that oft-recited commitments to the safe care of patients are realised in practice. They include the ability of an organisation to take safe care as seriously as it apparently wishes, in the face of other pressures, not least funding and the lack of sufficient, and sufficiently trained, staff. They include the ability of an organisation to enforce standards of conduct on members of staff, particularly senior clinicians, who have a mind-set in which they condescend to do what is asked of them, but on their terms. They include the creation of a culture of caring shared by all who work in the organisation. And, they include the need for trained leaders who can resolve these issues.
- 13.15 While the Trust has recently begun to make efforts to change the prevailing culture, it is clear from what I was told that it still has some way to go before it can be thought to be addressing successfully the challenges of providing safe care and of establishing a culture in which such care can prosper. It must get beyond doing what is passable and do what is possible. There is still a tendency to react rather than act, and to react in a formula-driven way. This does not achieve change. What is needed, and is the challenge for the Board and senior managers to embrace, are leaders who think, talk and breathe safety. Only then do improvements follow. And, they follow by making it clear that safe care is everybody's business, not just someone with a job marked "safety".
- 13.16 From my conversations, I formed the view that the culture until recently was one characterised by organisational drift: over a period of time, standards alter and the abnormal becomes the norm. The Trust introduced a "culture improvement programme", and instituted standard approaches to changing culture, such as bringing all the members of the team together to identify their problems and to confront them. But, it is not clear that they were successful. To be successful, staff of all types and stripes must be engaged, silos must be broken down, and, crucially, the Board must be engaged. Clinicians in particular cannot any longer be indulged. They cannot be allowed by leaders to be part of the problem rather than part of the solution.
- 13.17 Dr Anwar's response is important for the future behaviour of the Trust. He talked of "the fascinating thing in the NHS ... performance management. We have very, very strong robust frameworks around financial performance management ... we have people who are escalated [referred upwards] through the organisation all the way to the Chief Executive because they are not delivering on their finance. Then I look at

the quality and outcomes bit. ... we do not do that with quality, we do not do that with outcomes.... I would like my Clinical Directors, my doctors to be brought to my office ... for us to have a discussion around quality shortfalls and how we go about addressing those and actually people being as au fait with outcomes as they are with pennies."

- 13.18 The culture of an organisation is shaped by the people in it. I was keen to explore with Dr Anwar, the Medical Director, the appointment of Mr Paterson and any lessons that might flow from it. He told me that, given what was already known of Mr Paterson, he would not have been the kind of person the Trust would want to appoint. "I would hope", he said, "although we need to work on it, that you shortlist on technical ability and appoint on values". He agreed that a wider lesson for the NHS is that, in making appointments, an assessment of personal qualities, capacity to work in a team, the capacity to listen, and some kind of psychometric testing might be important. "The consultant body is extremely influential in ... set[ting] the cultural tone for the organisation. ... They not only influence today, they influence what happens tomorrow, next week and next year. ... The juniors are sitting with us now. We have to be setting the right cultural tone now".
- 13.19 I stress the reference to the culture of the organisation because of what I said as I began the Review: that I am concerned with the systems which operated, the manner in which the Trust was led and managed, rather than focus solely on the tempting but ultimately unhelpful tendency to look for people to blame. Furthermore, it is not my role to seek to hold people to account. That is for others. My role is to provide as true an account as I can of the relevant events, so that others may make informed judgements.
- 13.20 That said, in terms of accountability, there are clearly matters which need to be addressed. The list is long.
  - Senior managers did not respond effectively to concerns expressed about Mr Paterson's surgical practice until late December 2007 and then their response was neither sufficiently robust nor sufficiently rigorous.
  - Other clinicians in the breast team, fellow surgeons, oncologists, radiologists and pathologists, continued to work with Mr Paterson for years. They did not go to the GMC or the regulator, even though they felt that they were getting nowhere in the Trust. The oncologists worked in a separate Trust so could have gone to the senior managers of their Trust.
  - The breast care nurses saw the operations he carried out but accepted Mr Paterson's assurances.
  - The process for gaining consent from patients was trivialised and sold patients short.
  - Mr Goldman, as Chief Executive, appeared to leave the problem to others, but was clearly closely involved.
  - Senior members of the Executive decided to instigate an investigation into Mr Paterson's surgical practice under the disciplinary procedures. In doing so, they ensured that concerns would be investigated in confidence and from the perspective of the clinician rather than the patient.

- Mr Cunliffe, in conjunction with Mr Goldman, clamped down on communication, sought to contain the fallout, chose not to stop Mr Paterson from operating on women with breast cancer, and chose to initiate a very limited recall.
- Those responsible for Safety and Governance did not play any formal or prominent role in the Trust's response to concerns about Mr Paterson's surgical practice, despite the crucial nature of their responsibilities.
- The Board was excluded and made no formal effort to be involved.
- The designated Board member "overseeing" investigations did not keep the Board advised.
- The Board and Executive did not meet proper standards of good governance.
- The Trust's "organisational memory" was impaired through informal ways of working.
- The senior managers' approach to audit and collecting data was patchy and poorly administered.
- 13.21 The contribution of these various individuals is woven through this story. But, as I have said, the real story concerns the systems in place through which the Trust was led and managed over the relevant years. I have sought to provide as full an account as possible of these so that any judgements about the lessons to be learned can be informed and considered.
- 13.22 I have repeated many times that the Board is responsible for the welfare of every patient in the Trust. I have reminded the Board, particularly the Executive members, that what happens at the bedside and in the operating theatre begins in the Boardroom. The Board sets the tone, by what it does and, importantly, by what it does not do. The Board must show a much greater interest in what happens to patients. To offer one example, I spoke to a patient who had considerable experience in managerial roles and in public service. She itemised a series of things which underlie the notion of service and which are so obvious that it might be thought that they do not need to be said. But, they do.
- 13.23 They boil down to what is a familiar refrain in the NHS, familiar yet still routinely ignored: that patients wish to be seen and cared for as people and not cases. They find the depersonalisation of the exchange with the clinician or nurse merely piles on more distress. The patient's critique began with the first encounter; "your appointment is, say, two-o-clock and you are still sat there two or three hours later. ... people coming, people going ... some poor sod has just been told they have got cancer. ... So it is awkward. ... you are sat there in this pokey little corridor and people are walking past; you see tray after tray of cups of tea and coffee going past. You think 'Hang on a minute'. Even if they had a coffee machine there and you could get a cup yourself, that type of thing – the whole personal thing. ... it is like a cattle market really". She went on, "There are people wandering around, shouting your name. People who are told they have got breast cancer are taken from one room to another and they have got to walk across this corridor where everyone else is sat. ... who are probably waiting to hear the same piece of information themselves. ... You are in a trance. ... There is no privacy. ... I think they should realise that ... they are dealing with people and people's feelings and ... state of anxiety".

- 13.24 Many patients whom I spoke to returned again and again to the theme that the Trust must reach out to patients, support them and create an environment of empathy and understanding, an environment that they felt was still seriously lacking. This perspective, the perspective of the patient as a person, should, of course, be at the centre of the Trust's arrangements for caring for patients. It may be said in reply that the important thing is the care provided and all this other stuff is fine but not the first priority. If this is said, it could not be more wrong. How the Trust cares **about its** patients is a central feature of how it cares **for** them.
- 13.25 To begin to meet the objectives that I have set out, the Board must demand of its senior Executives that they identify what is relevant in determining that the care provided to their patients is safe and of good quality. The Executive must be required to provide all the necessary information to determine whether such care is being delivered. Standards already exist nationally. It is open to the Trust to expand on these so as really to get under the skin of the Trust's performance. Patients and clinicians must be engaged in developing such standards. Information on how it is meeting the standards must be published routinely, not just to let everyone know how the Trust is doing, but also as a way of signalling that the Board accepts that it is accountable.
- 13.26 Not only will this bode well for the future but it will serve as one of the ways of indicating the Trust's determination to learn from the past. It will allow the Trust to begin to meet the significant challenge of winning back the confidence of patients, staff and the wider community.
- 13.27 This is a Review of the care of patients. It is fitting that the last word should go to a patient whom I spoke to, whose metastatic cancer is now widespread:

"... some of us will always have rotten bad luck and carry on and the disease will develop, that is going to happen, but rotten bad luck is easier to live with than the thought that your surgeon may have damaged you. .... You have this gnawing suspicion that maybe if you had woken up with a nice flat chest wall the day after the operation, maybe you would be feeling well now, but I'm never going to know", Mrs Shena Mason.

# 14 LESSONS TO BE LEARNED AND RECOMMENDATIONS

- 14.1 Much of what follows is addressed to the Board of the Trust since it is the Board's responsibility to ensure that the lessons that I have identified and the recommendations that I make are considered and, where appropriate, implemented. To the extent that they are relevant, they apply, of course, to the Boards of all Trusts.
- 14.2 I also add a number of matters which are for consideration by the NHS more widely.
- 14.3 I would expect the Board to consider my recommendations and publish its response. I would also recommend that the Board should routinely (every six or twelve months) report publicly on the progress made both in addressing the recommendations and, more generally, in securing care for patients which is both safe and of good quality.

# THE BOARD

- 14.4 The Board is made up of Non-Executive and Executive members. What I say here is addressed largely to the Non-Executive members. Because they are Non-Executives, they are not involved, nor should they be, in the day-to-day operational management of the Trust. Thus, in what follows, I set out recommendations relating to structures and processes that should be put in place. Implementation is for the Board, and then for the Executive, answering to the Board. Crucially, therefore, the structure and processes put in place must include ways in which the Board can assess whether the Executive is, in fact, doing what has been agreed.
- 14.5 Much of what I say will already be familiar to the Board. Some of the measures recommended may already be in place. My brief was to identify the lessons that can be learned from what I describe in the Review. Clearly, what I will recommend was **not** in place at the relevant time, or was not properly implemented. If it had been, much of went wrong would have been avoided.

# The Safety and Quality of Care

- 14.6 It is the Board's primary responsibility to ensure that the care provided to patients is safe and of good quality. To discharge this responsibility, the Board must be engaged. It must not be ignored, side-lined or kept less than well informed. It cannot just be the passive recipient of what the Executive chooses to tell it. It must be able to hold the Executive to account. It must identify a range of information on which it routinely seeks assurance from the Executive. The Board cannot do its duty to serve patients' best interests if important matters are not brought to its attention and if it does not seek to inform itself.
- 14.7 The safety of patients and the quality of the care that they receive is a matter of fundamental importance to the Board. The Board must agree with the Executive a range of information about the safety and quality of care which must be reported to it and which will inform the Board about the Trust's performance. This information will include matters called for by regulators, but will go further to cover all matters agreed by the Board and between the Board and the Executive.

- 14.8 The Board must publish the range of information that it has agreed upon. It should then publish all the information it receives concerning the safety and quality of the care received by patients on a regular basis. There must be a standing item on the Board's agenda to receive and discuss the information received.
- 14.9 The Board must be active in its pursuit of information about the care of patients and the welfare of staff. It is not sufficient to wait to be advised by the Executive. The Board should also make clear that it can and will call for information on any matter of concern to it.
- 14.10 Part of the process of gaining information on performance is the routine carrying out of audits. The Board must ensure that audits are carried out and that resources are made available for the purpose. The data produced must be made available to the Board and published routinely.
- 14.11 In establishing a suitable framework relating to information, the advice of external agencies should be sought and the experience of high-performing Trusts studied. The Board should routinely receive and comment on the periodic reports of such external bodies as Quality Assurance teams.
- 14.12 To carry out its proper role of scrutiny of the Trust's performance as regards the safety and quality of care, the Board may need to ensure that it has suitably qualified Non-Executive members, who are able rigorously to interrogate the information supplied by the Executive.

# Expressing Concerns

- 14.13 Members of staff must be able, and feel able to express concerns about the safety and quality of care provided to patients and be listened to. Clinicians often regard senior management and the Board as remote and barely relevant to their everyday care of patients. This means that when they need to engage the attention of the Trust to address what they see as serious matters, they do not know how to go about it. As a consequence, they may become frustrated and feel ignored, and, as a consequence, become disengaged.
- 14.14 Staff throughout the Trust cannot serve the interests of patients if they choose to be ignorant of the managerial structures of the organisation within which and for which they work. Equally, the Board must ensure that the culture of the organisation is one in which all members of staff know how and with whom to raise concerns and feel safe and comfortable doing so.
- 14.15 When members of staff feel that their concerns are not being addressed appropriately within their organisation, they have a duty to raise them with the relevant professional regulatory body, eg the GMC.
- 14.16 The Board must create an environment in which members of staff feel able and free to raise matters of concern regarding the care and treatment of patients. This involves leadership from the Board and particularly the Chairman. The Chairman must demand of the Board and the Executive a commitment to openness and candour. The extent to which this is reflected in everyday practice must be measured regularly through such devices as surveys of staff and patients. The results of such surveys must be published and reported as a regular item on the Board's agenda.

- 14.17 The Board also has a duty to connect effectively with staff at all levels and require the Executive to do so. The Board must satisfy itself that clinicians and others understand the Board's role and responsibility. It must create ways in which clinicians and other staff can gain access to Non-Executive members, and Non-Executives can gain access to staff. Periodic descents onto wards and the like are not substitutes for genuine engagement, so that staff come to understand the management of the Trust and its relevance to them and their patients.
- 14.18 The concerns of staff can be dealt with best within the relevant team or unit. All staff should be encouraged by managers to raise concerns and must be listened to. Rank, hierarchy, or professional allegiance must not be allowed to stifle the raising of concerns. Any action taken, or the reason for not taking action, must be reported to the team or unit. If the matter meets a criterion of importance agreed between the Board and the Executive, the Board must be notified formally.
- 14.19 The Board must establish and make all staff aware of mechanisms whereby staff can raise concerns if they are reluctant to do so with their colleagues, or feel that they are not being listened to. One mechanism should be the appointment of someone who is completely independent of all managerial control, (some sort of Ombudsman), whose job it is to be available and listen to staff's expressions of concerns. Any such conversations must be confidential. The person appointed should have direct and unrestricted access to the Chief Executive and the Chairman and any other relevant manager so as to convey the concerns. The person appointed should be entitled to request information on what action has been taken and express an opinion on it. Ultimately, the "person appointed" must be entitled to request a meeting of the Board if s/he judges it necessary. In some Trusts, this role has been assigned to the senior independent director on the Board. Though this is a welcome recognition of and response to the problem, it may be that a member of the Board may appear too much a part of the system of management to be seen to be truly independent and to be trusted. Boards in such cases should reflect on whether an appointment in the form that I have set out would be preferable.

The Board and senior management must make it clear that to tolerate unacceptable performance in colleagues is itself unacceptable.

14.20 When members of staff are of the view that their concerns are not being addressed appropriately within their organisation, it should be made clear to them that they have a duty to take their concerns to the relevant professional regulator as part of their duty to ensure that the safety and welfare of patients are safeguarded.

## Working Formally

- 14.21 The Board's memory and, thus, its capacity to exercise proper governance are impaired if it does not work formally, recording decisions and disseminating them. Failure to do so means that the Board cannot draw on previous experience and existing knowledge, except through the memories of individuals. It means that versions of the past can gain currency without any record to check them against. It also means that operations and projects may not be carefully thought through, with input from all affected, nor appropriately planned and, thus, not well-executed.
- 14.22 The Board must establish formal ways of working in accordance with the requirements of good governance. While informal discussions are a necessary element of management, all matters of substance should be recorded for the benefit of current and future members of staff and Board members, particularly if they relate

to the safety and quality of care provided to patients. Decisions should be recorded and plans set out, with appropriate objectives, resources and timescales. The use of Sub-Committees is a valuable device to distribute the Board's workload, but reports on and concerns about the safety and quality of care must always be brought to and dealt with by the Board. The Minutes of meetings should be published routinely and be sufficiently explicit to allow others to understand what is being discussed and what decisions have been reached. This is one of the fundamental responsibilities of the Chairman of the Board.

# **Responding to Concerns and Conducting Investigations**

- 14.23 The Board should be informed when an investigation is launched. The Board must be made aware of the results of investigations conducted in its name if it is to be able to exercise its responsibilities. Concerns over the safety and quality of care ought not to be investigated through the disciplinary procedures. These procedures should be concerned with personal misconduct. They may be run in parallel but recourse to them as a means of investigating concerns about the safety and quality of care brings a whole apparatus of confidentiality which prevents such investigations from being open. The organisation will only learn necessary lessons if investigations into the safety and quality of care are conducted in an open manner with the engagement of all.
- 14.24 The Trust should ordinarily appoint external experts or the relevant Royal College to carry out investigations into the safety and quality of care. It must also allocate sufficient resources to allow investigations to be completed as promptly and efficaciously as possible. Delays give rise to anxiety in patients and can lead to distrust as to the commitment of the Board. The Governance and Safety Committee, as a sub-committee of the Board, should involve itself in such investigations and be the channel for providing the necessary assurance to the Board concerning the conduct and outcome of them.
- 14.25 The establishment of investigations must be reported to the Board. Thereafter, the Board should receive progress reports on a regular basis. The Board should receive copies of the Reports produced at the end of investigations. These are necessary requirements to enable it to discharge its responsibility. Investigations under the existing disciplinary procedures should be confined to the consideration of personal misconduct by a member of staff. They may run in parallel with but should not be used to investigate concerns about the safety and quality of care provided to patients. The requirements of confidentiality associated with disciplinary procedures must not be used as a means of keeping everyone except a few insiders in the dark. The Board have a right to know what is being done in its name as regards its employees. Members of staff equally are entitled to know what is being done. Lessons cannot be learned and remedial steps taken if nothing is disclosed because of concerns about confidentiality.
- 14.26 The Board must be alert to ensure that Reports which are produced from reviews and investigations are shared widely. The aim must be to avoid piecemeal and disjointed responses and actions. The risk must be avoided that only a few Executives have the relevant knowledge and understanding of the whole picture, making it difficult for other staff and the Board to act effectively. The Board must ensure that proper records are kept, that they are shared with those inside the Trust and with external experts advising the Trust, and are seen by the Board.

- 14.27 In deciding how, in the future, the Board will work with the Executive to address concerns, including the conduct of investigations, the Board should adopt the perspective of the patient rather than that of the clinician/professional. It is important to be fair to the clinician/professional. It is vital to take proper account of the interests of patients. Adopting the perspective of the patient will mean that, when circumstances warrant it, the current approach implicit in the disciplinary procedures, intended to re-integrate the clinician/professional back into practice, should not be adopted. Such an outcome may not, on occasions, be in the interests of patients. To reflect the perspective of patients, the Board should introduce a mechanism for involving one or more patients when addressing concerns or carrying out an investigation regarding the safety and quality of care.
- 14.28 The Governance and Safety Committee is a vital Sub-Committee of the Board. Besides its other responsibilities, it should serve as the channel of communication between the members of staff, the Executive and the Board in the case of investigations and other such matters which relate to the care of patients. In playing this role, the Committee should not limit itself to organisational or structural issues, but also concern itself, where appropriate, with individual cases.
- 14.29 Whenever an investigation is launched, sufficient resources, in terms of funding and people, must be made available so that it can be concluded as quickly and efficiently as possible. Periodic reports on progress should be made to the Board.
- 14.30 Once the examination of concerns or an investigation has been completed, the Board should establish a formal follow-up process to ensure that any lessons have been learned and appropriate action taken.

#### **Communication and Openness within the Trust**

- 14.31 It is crucially important that the Board and members of staff are made aware of what is happening in the Trust generally, and as regards their area of activity or responsibility in particular. This is especially so when concerns have been expressed and staff wish to know, and are entitled to know, what is being done. In the absence of accurate information, rumour, gossip and speculation fill the gap. These are very destructive to the morale of staff and of the Trust as a whole. They damage the reputation of the Trust. They undermine the confidence of patients. They create concern and disquiet in the community served by the Trust.
- 14.32 The Board has the responsibility to ensure that the Executive report routinely to it those matters of importance that it has been agreed should be put before the Board. The Board also has the responsibility to ensure that proper mechanisms exist for keeping members of staff informed on developments within the Trust. This is an essential feature of the Board's wider commitment to openness. When concerns have been raised, and when they are being looked into, a commitment to openness means that the Board must have in place procedures whereby members of staff can be kept informed of developments. The requirements of confidentiality in any particular case should not be allowed to keep staff in the dark. While it is important to be fair to those whose conduct is being called into question, this cannot be used as a reason for not keeping staff informed.
- 14.33 The Board should require the Executive to present to the Board the procedures in place to achieve good communication and openness and to report on their operation periodically. The Board must regularly conduct a survey of staff which should ask,

among other things, whether there are matters on which staff wish to be informed or better informed. The results must come to the Board and should serve as one mechanism for holding the Executive to account as regards their leadership of the Trust. The results should be routinely published within the Trust and made available to the public.

14.34 The Board must expect of its Executive that it provide the Trust with the necessary operational leadership. Where the leaders are clinicians, the Board must ensure that, as managers, they act as managers. They must not act as clinicians, still part of the system of hierarchies and tribalism which characterises healthcare. Indeed, one of their roles as leaders should be to breakdown these hierarchies as healthcare becomes increasingly a team enterprise. The Board must be vigilant to identify failures in leadership, such as staff feeling bullied, or not listening to unwelcome news. Again, this requires the Board regularly to seek the views of staff and be seen to act on them.

## **Communication and Openness with Other Bodies**

- 14.35 No Trust is an island. Many other bodies are affected by and need to know about what is happening in the Trust. It is part of the Trust's responsibility to keep the wider healthcare community appraised if concerns are being considered which have implications for that community.
- 14.36 It is wrong, as well as pointless, to seek to control the flow of information to outside bodies so as to contain the impact of any particular event or set of circumstances. It prevents others from taking appropriate measures. It ensures that partial information will emerge in an unsystematic manner, thereby damaging patients and the Trust much more than would be the case with full, open communication. And, most important, it is a breach of trust.
- 14.37 The Board must ensure that all relevant agencies are informed when events occur which have implications for the Trust's patients, other patients, or other services. This should form part of the regular report on the handling of concerns which the Board should require of the Chief Executive. Those bodies which may need to know include regulators, commissioners of services, GPs, screening and other such services.
- 14.38 Openness is essential. The Chief Executive's routine report to the Board should include copies of the information provided to all other relevant bodies. This will enable the Board to hold the Executive to account.

## Appointment of Consultants and managing them thereafter

- 14.39 The process of appointing consultants is critical if the Trust is to achieve its vision for caring for patients.
- 14.40 It is not easy to challenge and confront improper behaviour or poor performance, particularly if the person to be challenged is an established member of staff. This must not serve as a reason for doing nothing. Failure to confront, or "working around" a difficult colleague or member of staff entrenches problems, sends wrong signals to other members of staff, and puts patients at risk.
- 14.41 Any potential appointee should be shortlisted on the basis of technical skills but appointed on the basis of values. Once appointed, consultants should be supported in their pursuit of care which is safe and of good quality. They must be managed

robustly if there is evidence that they are not caring properly for patients or not working appropriately with colleagues.

- 14.42 A person appointed may be technically sound but have personal qualities or characteristics which mean that s/he will not best serve the interests of patients and the Trust. This may be because of her/his attitudes to colleagues or to patients, or both. Modern healthcare is pre-eminently a team-based exercise. If a person is not a team player, the team is disrupted and the care received by the patient is less than the best.
- 14.43 The process of appointing consultants is traditionally concerned almost exclusively with their technical skills and background. The process should be supplemented by tests designed to identify relevant personality traits, not least collegiality, empathy, and dedication to service and to patients. If a candidate demonstrably lacks these, s/he should not be appointed. The Board must have in place a process which gives effect to this. It may be said that it is hard to recruit in particular fields at particular times, such that anybody is better than nobody. This is not a position which patients would endorse. At the very least, a probationary period can be used during which a consultant can be required to attend appropriate training as a condition of being retained.
- 14.44 A consultant is a leader. S/he trains others, leads teams, represents the unit or team at larger gatherings. If any particular consultant behaves in a way which shows poor leadership, s/he must be confronted immediately and managed robustly. Failure to do so risks putting the care of patients at risk. The Board should satisfy itself that robust procedures exist for identifying and dealing with apparently aberrant behaviour. The notion of "working around" difficult consultants has no place in the NHS. They should be confronted and required to change their behaviour. Their performance should then be monitored and action taken if there is no improvement in behaviour.
- 14.45 The Board must make the Trust's position clear to every member of staff: that it will not stand for inappropriate behaviour and will provide all necessary support to whomever is responsible for taking action. The Board can only do so if it is made aware of the need. To that end, a mechanism should exist whereby the Chairman is made aware by the Chief Executive in cases where action is not so far having the necessary effect. The member of the Executive responsible for acting must be made aware that a failure to do so will constitute a breach of her/his duty, owed to the Trust and to patients. Those in positions in which they must confront consultants or others as regards their behaviour should receive suitable training and support to carry out what may be a difficult task.
- 14.46 The Board should ensure that disciplinary procedures should be used to deal with matters of personal conduct and inter-personal tensions or conflicts. Their rationale is the re-integration of the professional into the workforce as an effective member. These procedures should not be used when the issues involve the safety and quality of patients' care, not least because they shroud everything in confidentiality, they inhibit open discussion of disputes which might profit from discussion, they drag on for a long time, and they may make prompt action on behalf of patients difficult to take.

### Recall

- 14.47 Though they are uncommon, when they take place, processes for recalling patients are very important for patients, the Trust and all others affected. They must be properly thought through, properly resourced, and properly managed. A number of Trusts have organised recalls and their experience should be taken account of. Patients should be treated with great sensitivity. Good communication and openness are essential.
- 14.48 The Board should commission a short study of other recalls within the NHS to see what can be learned.
- 14.49 The Board should be informed when a decision is made to recall patients. The Board is responsible for the reputation of the Trust and so needs to know. The Board should have in place a process which can be smoothly and promptly adopted in the event that the Trust decides to recall patients. Ideally, the patients recalled should be seen by staff who are not part of the Trust. This engenders confidence in past patients, ensures independent assessment and decisions, allows the Trust to draw on external expertise, and means that the process can be carried out expeditiously. In many cases, the relevant Royal College can be engaged.
- 14.50 Adequate resources, both as regards finance and people, must be allocated.
- 14.51 If staff within the Trust are involved in a recall, they must be supported so that they can give proper attention to it, by, at the very least, being relieved of their routine clinical duties. Enough staff must be deployed to avoid delays. Patients caught up in a recall suffer considerable anxiety. This makes it imperative to move with all due speed.
- 14.52 Once a decision to recall patients is made, the Board should ensure that the decision and the reasoning behind it are communicated promptly and widely to patients, GPs, regulators, other relevant bodies, and the media. The media can assist in the process. Thereafter, the Board should ensure that regular updates are provided internally within the Trust, to patients, and to the media.

### Patients

- 14.53 Respect for patients is at the heart of what the Board does and stands for. The perspective adopted when making decisions affecting the care of patients should be the perspective of the patient. Patients are what the Trust exists for: to serve them to the best of its ability.
- 14.54 It is not enough to declare these sentiments in a vision statement and then move on to the business of the day. Caring for patients is the business of every day.
- 14.55 Patients should be treated with respect in their dealings with clinicians. It is crucial that the central importance of seeking patients' consent before treatment is respected. When things go wrong, they must be given honest information, supported in a caring and understanding way, and looked after promptly. Information should be readily available to patients in a range of accessible forms. Lack of information and delays are doubly intolerable when they involve the anxiety of recalls.
- 14.56 The physical environment in which patients are looked after should be designed with the needs of patients as the paramount consideration, rather than the convenience of

the staff or of the organisation. The views of patients should be routinely sought and reported to the Board. Relevant action should be taken in response to these views and made public.

- 14.57 Members of the Board, led by the Chairman, must ensure that the commitment to respect for patients is not empty rhetoric but is reflected in all that is done throughout the Trust, particularly in the way in which they and staff behave. The Board must identify, in consultation with patients, the information about the Trust's performance which allows it properly to assure itself that the needs of patients are at the centre of what the Trust and its staff are doing. This information should be recorded, reported routinely to the Board, and published. The watchword for all staff should be "I exist to provide for you" rather than "This is what I as a professional do and this is where I do it".
- 14.58 The physical environment in which patients are cared for should be reassessed from the perspective of patients. Particular attention should be given to waiting areas, places where bad news can be broken and explored in privacy, the journeys that patients have to make between one source of treatment and another, and to such facilities as coffee machines and drinks dispensers. The Board should convene a group consisting of patients and staff to examine the physical environment and make proposals concerning its possible redesign or development.
- 14.59 Patients are entitled to be told the truth. This applies both to their own condition and to any expression of concerns which touch on their condition or treatment. When there are concerns or developments, such as a change in routine or redeployment of staff, the Board should ensure that the Trust has effective policies in place to ensure that information is provided to patients in a timely and understandable fashion. These policies should be published. The use of plain English, rather than jargon (whether medical or managerial), should be insisted on: jargon excludes the very people whom it is intended to include. The performance of the staff in complying with these policies should be measured and reported to the Board.
- 14.60 The Trust has, by and large, a good system for dealing with complaints. There is room for improvement as regards seeking permission from patients before nonclinicians, or clinicians not associated with their care, have access to patients' notes and records with a view to dealing with complaints, but measures are being taken to address this. The system should operate in all contexts. It should not be impeded by concerns over disciplinary procedures. The Board should adopt a duty of candour as an organisation and ensure, through appropriate measurement, that it is complied with. In meeting this duty, the Board must ensure that complaints and related expressions of concern are dealt with promptly. Unwarranted delay is corrosive of trust and increases anxiety. The Board should have an appropriate performance measure for dealing with complaints with the results reported routinely to the Board and made public.
- 14.61 A central feature of respect for patients is the need to seek their consent before embarking on any treatment. This is both an ethical and a legal requirement. It makes it clear that patients are entitled to have the last word about what happens to their bodies. A growing practice has emerged of talking in terms of "consenting" patients. This is wrong. It trivialises what is a central feature of the relationship between patients and healthcare professionals. It completely undermines the respect that patients are due. It reflects a complete failure of understanding on the part of professionals about the nature of the transaction between them and their patients. It

seeks to reduce a matter of great ethical significance to the level of an administrative chore. The Board must as a matter of urgency address this issue. It is important in its own right and in its symbolic significance about the place of patients. It should issue instructions to the Chief Executive and Medical Directors to take such measures as are appropriate to root out the current practice.

14.62 Clinicians confronted by poor care carried out by colleagues should draw it to the attention of others who can take action. To this end, clinicians should ensure that they are familiar with the ways in which concerns can be raised. If they are not satisfied with the response, they should take advantage of the procedure proposed earlier whereby they can escalate their concerns to the independent "person appointed". While not abandoning patients, the clinicians should not compromise the care they provide so as to compensate for the poor care of colleagues.

## THE WIDER NHS

### Regulators

- 14.63 Regulators played a passive role as regards the actions of the Trust in addressing concerns about Mr Paterson's surgical practice, receiving periodic communications when the Trust chose to inform them. To that extent, they denied themselves the opportunity to look more closely at the actions being taken so as to satisfy themselves that they were appropriate to safeguard the interests of patients.
- 14.64 I have made a series of recommendations about how Boards should set out measures of performance as regards the safety and quality of the care provided, which are in addition to those matters currently required of them by statute or regulation, how they should monitor them, how they should routinely publish information on compliance. Regulators should consider how they might incorporate into the standards by which they assess the performance of Trusts, a Trust's own measures of performance, and its compliance with them. Doing so would enable regulators to be more active. They would be able to track compliance and intervene in an appropriate manner when necessary.

### **Commissioners of Services**

- 14.65 The commissioners of services for breast cancer continued to commission care from HEFT, unaware, at least formally, of growing concerns about Mr Paterson's surgery. Commissioners of all forms of care need to have up-to-date information about the performance of the services that they commission and of those providing them. If they do not, they may expose patients to the risk of harm. Trusts have a duty to provide that information. They also have a duty to advise commissioners of concerns about any particular area of care, what measures are being taken to address them, and regularly update them.
- 14.66 Commissioners should actively require regular reports on performance from those they commission services from. These reports should include information on compliance with the standards set by the regulators in the area of the safety and quality of care (reflecting the earlier recommendation addressed to regulators). Commissioners must make decisions as to what services to commission, and from which Trust, in the light of information received from the Trust and regulators. Trusts

have a duty to inform commissioners when concerns exist about the safety and quality of care being provided, and to advise what they propose to do. When a Trust launches an investigation into concerns about the care of patients it must advise commissioners and report the outcome.

14.67 There should be regular "joined-up" exchanges of information according to agreed protocols between commissioners, regulators, Quality Assurance teams, Royal Colleges, and related organisations in healthcare and social care on the one hand, and Trusts on the other, about the safety and quality of care provided by the Trust.

### **QA** Visits

- 14.68 QA Visits allow for a careful external assessment by experts of elements of a Trust's performance. Their recommendations are intended to identify matters needing attention and to improve the performance of the service. They can, however, be ignored, since their recommendations are not backed by any sanction for failing to heed them.
- 14.69 To have any real effect, QA Visits should form part of the regime of standards operated by regulators and must be backed by appropriate remedies for non-compliance, including sanctions. Consideration should be given to including the reports and recommendations of QA Visits into the regime of inspection carried out by regulators. Non-compliance could then be identified and appropriate action taken by the regulator.

### **Disciplinary Procedures and the National Clinical Assessment Agency (NCAS)**

- 14.70 Resort to disciplinary proceedings to address concerns relating to the safety and quality of care being provided to patients means that the investigation of those concerns is shrouded in confidentiality, staff immediately affected by decisions may be left in the dark about developments, patients may equally be kept unaware and at risk of being exposed to poor practice, and progress towards resolution is measured in years. Engagement of the NCAS means that the underlying premise is that the issues to be resolved are inter-personal, and that the aim is the re-integration of the clinician into the Trust. The perspective, therefore, is that of the professional, not that of the patient. In cases of concerns about the safety and quality of care this approach is inappropriate.
- 14.71 Disciplinary procedures against a particular clinician are appropriate in appropriate circumstances. Where the issues facing the Trust concern the safety and quality of care, particularly the former, other procedures should be adopted to ensure that the issues are examined openly, promptly and rigorously. They must above all be open. The Board, staff and patients should be kept informed of progress and developments. Any disciplinary procedures should be managed separately or organised in parallel.

### Data in the private sector

14.72 The assessment of the performance of clinicians and information for the benefit of patients depend on the collection, analysis and dissemination of data. Organisations in the NHS are required to submit data regarding activity and outcome to national and regional databases. There is no parallel obligation on organisations in the private sector to collect or submit such data. This means that patients may not be well-

informed about a particular clinician's overall performance, when s/he works both in the NHS and the private sector. When things go wrong, it may be difficult to determine the scale of the risk that patients are exposed to if the data is incomplete because performance in the private sector has not been reported. Should patients need to be recalled, the process of doing so – whom to recall –is made more difficult and complex.

14.73 Organisations in the private sector should be required to submit data on patients to relevant national and local registries: the form of treatment and its outcome. This data should be available to the public. The regulator should make it a condition of registration that organisations in the private sector submit such data.

# 15 APPENDIX I

# WITNESSES

### Patients

Carol Bird

Lynne Bowyer

Lynn Bullock

Ann Butler

Georgia Christoforou

**Clare Crouch** 

Catherine Gulati

Elizabeth Grant

Lynda Johnson

Gail Lawrence

Pamela Mahon

Sheena Mason

Diane McKay

Mr Nash

Tracey Smith

Karen Stone

Jacqueline Tranter

Sue Walton

Nikki Watkinson

Gillian Wood

Yvonne Wood

### **Current Staff**

Dr Aresh Anwar, Medical Director

Mr Balasubramanian, Consultant Breast Surgeon Clare Bate, Breast Care Nurse, now Lead Clinical Nurse Specialist Iona Belgrove, PALS Officer Mr Ian Cunliffe, ex-Medical Director - Surgery Susanne Duddy, Breast Care Nurse Dr Chris Fletcher, Consultant Radiologist Mr Mark Gannon, ex-Medical Director - Surgery Alison Greenwood, Breast Care Nurse Hazel Gunter, HR Director Mr Charles Hendrickse, Consultant Surgeon Sue Hyland, Head Nurse, now Deputy Chief Nurse Mr Hemant Ingle, Consultant Breast Surgeon Amanda James, PALS Officer Dr Sabeeha Karim, Consultant Histopathologistt Dr Anne Keogh, Director of Medical Safety Jill Kneale, Breast Care Nurse, now Lead Breast Nurse Alison Money, HR Manager Dr Francis Murray, Consultant Anaesthetist Dr Mark Newbold, Chief Executive Dr Brendan O'Connor, Consultant Anaesthetist Dr Rex Polson, Consultant Physician Neil Rogers, General Manager, Surgery Dr Steve Smith, Acting Medical Director, now Associate Medical Director Mr Jon Stewart, Consultant Surgeon Dr Bruce Tanchel, Consultant Histopathologist Elaine Wilkes, Breast Care Nurse Dr Sarah Woolley, Director of Safety and Organisational Development

### **Past Staff/Others**

Faye Baillie, ex-Acting Chief Nurse Helen Barlow, MDT Coordinator Mr Misra Budhoo, Consultant Breast Surgeon Anna East, ex-Non-Executive Director Dr Indy Fernando, Consultant Oncologist Mr Mark Goldman, ex-Chief Executive Anne Gynane, HR Director Mr Colm Hennessy, Consultant Breast Surgeon/External Reviewer Paul Hensel, ex-Non-Executive Director Gaynor Hill, General Manager Mr Alan Jewkes, Consultant Breast Surgeon Dr Gill Lawrence, ex-Director, West Midlands Cancer Intelligence Unit Mr Martin Lee, Consultant Breast Surgeon/External Reviewer

Dr Andy Stockdale, Consultant Oncologist

Chris Wright, ex-Matron

# 16 APPENDIX II

# TIME LINE

- 1998 Mr Paterson appointed
- 2001 Mr Goldman appointed Chief Executive, previously Medical Director from 1993 Ms Bello appointed and leaves after 7 months

Mr Bala appointed

- 2002 Mr Taylor leaves
- 2003 Mr Hendrickse appointed Clinical Director Surgery
  - Dr Stockdale carries out audit of 100 patients
  - Dr Stockdale and Dr Fernando express concerns
  - Mr Wake begins investigation
- 2004 Mr Wake Reports to the 3 Medical Directors

Mr Gannon introduces measures designed to improve working of MDT

**Quality Assurance Visit and Report** 

Quality Assurance Follow-Up Visit

2005 National Cancer Peer Review

Mr Gannon ceases to be Medical Director - Surgery

Mr Cunliffe appointed Acting Medical Director - Surgery

National and Regional Conferences on breast surgery – Dr Lawrence presents evidence regarding rates of recurrence

- 2006 Mr Cunliffe appointed Acting Medical Director Surgery
- 2007 Mr Ingle appointed

Quality Assurance Visit and Report

Cross-cover by breast surgeons introduced

Mr Ingle and others express concerns

Mr Cunliffe appointed Medical Director – Surgery

Investigations set up under the Disciplinary Procedures

Dr Polson invited to carry out investigation into inter-personal tensions

Mr Hennessey invited to carry out investigation into

Mr Paterson's surgical practice

Board advised of investigation

Ms East, as Non-Executive appointed to "oversee" investigation

Dr Lawrence draws 2005 data to Mr Cunliffe's attention

Dr Polson submits Interim Report to Mr Cunliffe

Mr Hennessey submits his Report to Mr Cunliffe

Six Clinicians write to CEO expressing continuing concerns

Meeting between six clinicians and Chief Executive and subsequent letter

 $\ensuremath{\mathsf{Mr}}$  Paterson requested to cease csm and "shaves after mastectomy" and agrees to do so

Mr Goldman writes to a local private hospital advising that Mr Paterson had been required to cease two types of surgery and that an investigation had been launched

2008 Mr Goldman meets six clinicians about investigation and action taken and follows up with a letter. He subsequently advises them that the letter is confidential and that they may not discuss Mr Paterson's position

Dr Polson submits his Final Report

Meeting to discuss Dr Polson's Report

Action Plan drawn up for Mr Paterson in collaboration with National

**Clinical Assessment Service** 

Mr Goldman writes to PCT and private hospitals

Mr Paterson agrees to comply with the Action Plan

Mr Lee observes Mr Paterson's surgery and submits a Report

Limited recall of patients decided

External advisers comment on limited recall

Decision taken to stop sending trainees to the breast unit

Mr Jewkes steps down as Clinical Lead

2009 Limited Recall begun

West Midlands Cancer Intelligence Unit submits Reports in February and June

2010 Mr Goldman steps down as Chief Executive
Mr Cunliffe steps down as Medical Director – Surgery
Newspaper stories appear
GMC begins to receive complaints
Board advised of recall and concerns about Mr Paterson's surgery
Dr Smith appointed Acting Medical Director
Dr Smith submits statement to GMC
GMC decides not to place limits on Mr Paterson's registration
Dr Newbold appointed Chief Executive
2011 Dr Anwar appointed Medical Director

Total recall decided and begun

Mr Rogers appointed General Manager - Surgery

Mr Paterson excluded from Trust

Mr Paterson's registration made subject to conditions by the GMC

Board advised regarding matters relating to Mr Paterson

Complaints Resolution meetings begun

2012 Final recall clinic held

Board receives regular updates

Mr Paterson suspended by GMC

Mr Paterson's salary stopped by the Trust

Board commissions Kennedy Review

2013 West Midlands Cancer Intelligence Unit submits Report on csm and rates of recurrence

Trust considers further recalls

Kennedy Review submitted to Trust

# 17 APPENDIX III

# DR STOCKDALE'S NOTE TO MR CUNLIFFE OF 2007, ENCLOSING HIS AUDIT OF 2003

14 September, 2007

Mr Ian Cunliffe, Acting Medical Director, Birmingham Heartlands Hospital Bordesley Green East BIRMINGHAM B9 5SS

#### **PRIVATE & CONFIDENTIAL**

Dear Mr Cunliffe

I am writing following recent concerns about breast surgery at Solihull / Heartlands raised by my colleague Dr. Fernando

I can confirm that I first formally raised my concerns at my appraisal with Dr Milligan, Clinical Director in November 2003.

Prior to this I had completed an audit of 100 consecutive patients referred to me by the breast surgeons from 1<sup>st</sup> January 2003.

My particular concern was about patients with positive margins following surgery. 34% (14 out of 41 patients) had a persisting positive margin following mastectomy and 11% (6 out of 55 patients) had a persisting positive margin following local excision.

Concerns were also raised about multidisciplinary team working and about selection of patients for primary breast reconstruction.

At some time following this, a meeting was convened in the Education Centre at BUPA Parkway hospital and an audit to be co-ordinated by the Pathology Department was promised.

I am not sure if this was every completed. The results were certainly not disseminated.

Further concerns were noted at my appraisal in May 2005

I have recently kept notes of individual patients about whom I continue to have clinical concern.

The particular issue is the repeated incomplete resection of breast tissue following an operation described as mastectomy.

Of particular concern is the technique of completing a mastectomy and then taking a "shave" from the adjacent remaining tissue to confirm the margins are satisfactory. By definition after a mastectomy there should be no remaining tissue from which to take a shave.

I have identified 12 patients treated by mastectomy, with either obvious gross residual breast tissue or whose management includes shaves, a number of whom also have positive margins.

I have identified a further 8 patients who have had a mastectomy and were left with sufficient tissue for either a second mastectomy or further surgery for other indications. Surgery was for local recurrence in four of these patients.

Against this background of incomplete primary surgery, I have great concerns about selection of patients for immediate reconstruction following mastectomy.

Regrettably there are no surgical guidelines in place for this procedure but a generally agreed surgical principle is that patients should be selected who are unlikely to require either post-operative radiotherapy or adjuvant chemotherapy, i.e. patients with small node negative tumours that can be widely excised.

When a reconstruction is created following a mastectomy it is impossible to assess the volume of residual breast tissue.

I am aware of 9 patients left with positive surgical margins following "mastectomy and immediate reconstruction", 3 of whom have relapsed.

Though cases are discussed at the multidisciplinary meeting, it is often not possible to assess the completeness of surgery until the patient is reviewed in clinic.

Cases with positive margins are discussed but if a shave has been taken it is not always clear that the shave taken from the cavity corresponds with the positive margin on the excision specimen. The response is frequently that no further surgery is feasible which may or may not be the case.

There is very clear evidence in the literature that positive surgical margins are associated with an increased risk of local relapse which cannot be completely compensated for with radiotherapy. In addition local relapse is associated with an increased risk of metastatic disease and hence of dying from breast cancer.

Having initially raised my concerns in 2003 I believe that the time has now come for an external review of breast surgery at Solihull Heartlands and I would appreciate your advice. I am of course in a position to forward individual patient details for review.

Yours sincerely

Dr A D Stockdale Consultant Clinical Oncologist

cc Dr I Fernando Consultant Clinical Oncologist Heartlands Hospital Bordesley Green East BIRMINGHAM

> Mr. M. Budhoo **Clinical Director** General Surgery Birmingham Heartlands Hospital Bordesley Green East BIRMINGHAM B9 5SS

### BREAST CANCER AUDIT

100 consecutive patients referred to Consultant Clinical Oncologist, Solihull Hospital from January 1<sup>st</sup> 2003

21 screened; 79 symptomatic

1 patient male breast cancer

8 symptomatic patients locally advanced metastatic or relapsed disease therefore excluded

All screened patients operable

4 patients bilateral disease

#### SURGERY

The study is of 92 patients who had surgery for 96 primary breast cancers

	Mastectomy	Wide local excision
23 screened	7 (30%)	16 (70%)
73 symptomatic	34 (47%)	39 (53%)

#### MULTIPLE OPERATIONS

21 patients - 2 operations; 1 patient 3 operations (23% 2 or more operations)

### REASON FOR SECOND OPERATION

1 screened	}	No pre-op diagnosis 13/96 (	14%
12 symptomatic	}		
9 patients		Positive margins 9/96 (S	9%)

Of 9 patients who had a second operation with positive margins; 5 wide local excision; 4 mastectomy (1 remained margin positive)

### **POSITIVE MARGINS**

20 patients had persisting positive margins (22%)

34% mastectomy positive margin (14/41)

11% wide local excision positive margin (6/55)

17 out of 73 symptomatic (23%)

3 out of 23 screen detected (13%)

	Mastectomy	Wide local excision
23 screened	2	1
73 symptomatic	12	5

9 patients positive margin cleared by shave

2 patients positive margin uncertain clearance following shave

3 patients referred back by oncologist for further surgery ?outcome

#### SELECTION FOR CONSERVATIVE SURGERY

4 elderly or unfit patients declined radiotherapy following local excision (83,82,79,68 years)

#### TRIAL PARTICIPATION

All patients requiring chemotherapy and radiotherapy were considered for a clinical trial;

TACT trial - 3 patients entered; 1 declined; 1 ineligible (positive margins)

SECRAB study - 10 entered; 0 declined; 6 ineligible (positive margins); 1 ineligible prior malignancy

DELAY FROM DATE OF OPERATION AND DATE OF REGISTRATION WITH ONCOLOGY

3 out of 92 (3%) were registered with oncology prior to further surgery (2,6 and 44 days)

Average delay from operation to oncology clinic appointment; 30 days (range 19 to 61 days)

Average delay from oncology to the start of chemotherapy; 9 days (range 6 to 14 days)

Average delay from oncology to start of radiotherapy; 59 days (range 28 to 133 days)

PATIENT	AGE	No OP	DATE ONC	DATE FINAL	WLE	MARGIN MM	TNM	POS		DATE 1ST DXT	GRADE
UMBER			REG	OP	MX					CHEMO REG	
1	74	1	07/01/03	28/11/02	MX	3	T3 N1	2	9	DXT 14/3/03	
2	72	0	07/01/03	an publicant Adar at 200							
3	57	1	14/01/03	12/12/02	WLE	1.5	T1 N1	2	10	CMF 21/1/03	111
4 ``	83	1	14/01/03	05/12/02	WLE	8	T2 NX		0	DXT REFUSED	11
5	63	2	14/01/03	05/12/02	WLE	0+ RE-EX	T1 N0		12	DXT 21/3/03	III(MED)
6	54	1	14/01/03	05/12/02	WLE	POS	T1 N0		10	DXT 13/3/03	. 111
7	90	1	14/01/03	05/12/02	WLE	7	T1 N0	0	6	DXT 17/3/03	
8	74	0	14/01/03								
9	67	1	14/01/03	12/12/02	WLE	0+ SHAVE	T1 N0		7	DXT 3/4/03	
10	58	1	21/01/03	18/12/02	MX	POS	T3 N1	2	19	EPI/CMF 28/1/03	
11A	67	1	21/01/03	(L) 18/12/02	MX	POS	T3 N1		13	CMF 28/1/03	
11B	67	1	21/01/03		WLE	1	T1 NX		0	CMF 28/1/03	1
12	57	1	21/01/03	20/12/02	MX	10	T2 N1	10	18	FEC/TAX 30/1/03	III
13	48	1	21/01/03	19/12/02	WLE	0+ ?SHAVE	T1 N1	2	10	CMF 4/2/03	11
14	51	1	21/01/03	18/12/02	MX	10	T2 N1	5	5	FEC/TAX 30/1/03	11
15	42	1	28/01/03	19/12/02	MX	10	T3 N1	6	10	EPI/CMF 6/2/03	
16	76	1	28/01/03	03/12/02	MX	15	T4 N1	4	9	DXT 1/4/03	
17	63	1	28/01/03	19/12/02	WLE	0+ SHAVE	T1 N0	0	14	DXT 24/3/03	1
18	60	1	28/01/03	19/12/02	WLE	0+ ?SHAVE	T1 N0	0	11	DXT 9/4/03	11
19	78	0	28/01/03								
20	83	0	04/02/03								
21	62	1	04/02/03	06/01/03	MX	3	T1 N0	0	13	DXT 27/3/03	
22	89	1	04/02/03	05/12/02	MX	POS	T4 N1	1	9	DXT 31/3/03	11
23	46	2	04/02/03	18/12/02	MX	0+ RE-EX	T2 N0	0	13	TAM ONLY	
24	61	1	10/02/03	16/01/03	MX	5	T2 N1		15	EPI/CMF 18/2/03	
25	40	1	10/02/03	16/1/03	WLE	POS	T1 N0	0	11	DXT 9/4/03	11.
26	56	1	10/02/03	16/01/03	WLE	3	T1 N0	0	9	CMF 18/2/03	
27	66	0	10/02/03								
28	82	1	11/02/03	03/01/03	WLE	14	T4 N1	1	13	UNFIT DXT	11
29	58	2	11/02/03	09/01/03	WLE	0+ RE-EX	T1 N0		8	RT 2/4/03	N/S
30	78	2	11/02/03	03/01/03	MX	0+ RE-EX	T2 N1		9	RT 7/4/03	11
31	52	1	11/02/03	16/01/03	WLE	4	T1 N0		21	RT 24/3/03	11
32A	71	1	11/02/03	(R) 12/12/02		5	T1 N0		16	RT 31/3/03	11
32B	71	2	11/02/03	(L) 16/1/03	WLE	0+ RE-EX	T1 N0		13	RT 31/3/03	
33	71	1	11/02/03	09/01/03	MX	10	T2 N1		10	DXT 11/3/03	111
34	56	2	25/02/03	30/01/03	MX	POS	T3 N1		13	4/3/03 CMF	II (LOB)
35	63	1	25/02/03	30/01/03	WLE	2.1	T1 N0		11	23/4/03 RT	III
36	70	1	25/02/03	29/01/03	MX	POS	T4 NX		0	12/5/03 RT	II (LOB)
37	87	1	25/02/03	09/01/03	MX	POS	T3 N0		4	29/4/03 RT	II (LOB)
38	61	2	25/02/03	30/01/03	MX	COMPLETE N/S	T2 N1		10	11/3/03 EPI/CMF	1
20	45	1	04/03/03	06/02/0	MX	POS	T2 N1		11	11/3/03 EPI/CMF	
·	69	1	04/03/03	13/02/03	WLE	6+ SHAVE	T2 N0		18	6/5/03 RT	1

ER	TRIAL	COMMENTS
ER+	~	
		INOPERABLE
ER+ *	INELIGIBLE SECRAB	CA OVARY DYSGERMINOMA
ER+	•	٠
ER+		
ER+		50F53
ER+		
		METASTATIC RIP 12/04/03
ER+		
ER-	INELIGIBLE SECRAB	POS MARGINS
ER-	INELIGIBLE SECRAB	BILAT DISEASE/INELIGIBLE POS MARGINS
ER-		
ER-	TACT	
ER+	SECRAB	
ER+	TACT	
ER+	TACT	
ER+		
ER+		
ER+		CLEAR SHAVE/AXILLARY RELAPSE
		METASTATIC
		INOPERABLE
ER+		MALE
ER+		FUNGATING AT PRESENTATION. NEO ADJ ARIMIDE
ER+		
ER+	SECRAB	
ER+		
ER+	SECRAB	
		METASTATIC
ER+		SKIN INVOLVED; TAMOXIFEN ONLY
ER-		
ER-		CA(R)86 RT@QE
ER-		or in you will be the gal
ER+		
ER+		
ER+		
ER+	INELIGIBLE SECRAB	
ER+		
ER+		NEO ADJ ARMIDEX
ER+ (WK)		NEO ADJ ARMIDEX
ER+	TACT DECLINED	
CR-	INELIGIBLE TACT	
<i>u</i> -	INELIGIBLE TACT	INELIG' E POS MARGINS

PATIENT	AGE	No OP		DATE FINAL		MARGIN MM	TNM			DATE 1ST DXT	GRADE
NUMBER			REG	OP	MX					CHEMO REG	
41	40	1	04/03/03	06/02/03	WLE	1.5	T2 N0		15	23/4/03 RT	11
42	69	1	04/03/03	06/02/03	WLE	1+ SHAVE	T1 N0	0	14	12/5/03 RT	1
43	76	0	04/03/03								
44 .		1	11/03/03	13/02/03	WLE	4.5+ SHAVE	T1 N0	0	12	12/5/03 RT	11
45	56	1	11/03/03	20/02/03	MX	5	T1 N1	3	14	18/3/03 EPI/CMF	II (LOB)
46	49	1	18/03/03	20/02/03	WLE	POS	T1 N0	0	8	19/5/03 RT	- 11
47	65	1	18/03/03	20/02/03	WĹE	0+ SHAVE	T1 N1	1	9	30/4/03 RT	11
48	66	1	18/03/03	18/02/03	WLE	N/A+SHAVE 10	T2 N0	0	12	12/5/03 RT	111
49	60	2	25/03/03	06/03/03	WLE	N/A+SHAVE 4.3	T1 N0	0	12	19/5/03 RT	11
50	64	2	25/03/03	27/02/03	WLE	13	T1 N0	0	11	28/5/03 RT	II (LOB)
51	63	2	25/03/03	27/03/03	MX	1.4	T1 N0	0	13	TAM ONLY	1
52	77	1	25/03/03	27/02/03	WLE	1	T1 N0	0	7	11/6/03 RT	111
53	55	1	15/04/03	27/02/03	MX	POS	T1 N0	0	9	REFERRED BACK	DCIS
54	69	1	15/04/03	13/03/03	WLE	1.4+ SHAVE	T1 N1	1	7	16/6/03 RT	I (LOB)
55	48	1	15/04/03	06/03/03	MX	8	T2 N1		12	29/4/03 CMF	1
56	57	1	15/04/03	06/03/03	MX	13	T1 N0		12	TAM ONLY	111
57	51	3	15/04/03	20/03/03	MX	15	T2 N1		10	29/4/03 EPI/CMF	111
58	78	1	15/04/03	20/03/03	WLE	7	T1 N0		5	16/6/03 RT	1
59	62	2	22/04/03	13/03/03	WLE	0+RE-EX	T1 N0		6	16/6/03 RT	1
60	79	1	22/04/03	06/03/03	WLE	5+ SHAVE	T1 N0		7	30/6/03 RT	i
61	70	0	29/04/03								-
62	59	1	29/04/03	26/03/03	WLE	11	T1 N0	0	7	23/6/03 RT	11
63	79	2	29/04/03	25/03/03	WLE	13	T1 N1		15	17/6/03 RT	11
64	65	1	29/04/03	27/03/03	WLE	0+ SHAVE	T1 N0		16	7/7/03 RT	1
65	95	1	29/04/03	20/03/03	MX	4	T4 N0		1	DXT UNFIT	III
66	74	1	06/05/03	03/04/03	WLE	6+ SHAVE	T1 N0		13	18/6/03 RT	1 .
67	67	1	06/05/03	03/04/03	WLE	2	T1 N0			1/7/03 RT	1
68	62	2	13/05/03	14/04/03	MX	9	T2 N1		14	CMF 20/5/03	
69	62	1	13/05/03	24/04/03	WLE	2+SHAVE	T1 N0			18/06/03	1
70	58	2	20/05/03	24/04/03	MX	0+ RE-EX	T3 N1			CMF 27/5/03	u li
71	79	1	20/05/03	22/04/03	WLE	2	T1 N0		6	REFUSED DXT	ii ii
72A	78	1	20/05/03	(R) 24/04/03	WLE	POS	T3 N1		13	DXT 28/7/03	
72B	78	1	20/05/03	(L) 24/04/03	WLE	5	T2 N1			DXT 28/7/03	11
73	65	2	20/05/03	24/04/03	WLE	2+ SHAVE	T1 N0		7	10/7/03 DXT	
74 .	73	2	20/05/03	24/04/03	MX	2+ SHAVE	T4 N0			4/7/03 DXT	0
75	55	1	27/05/03	01/05/03	WLE	0+SHAVE	T1 N0		11	2/7/03 DXT	11
76	59	1	27/05/03	01/05/03	WLE	0+SHAVE	T2 N0			23/7/03 DXT	111
77	86	1	27/05/03	01/05/03	MX	POS	T2 N1		11	22/7/03 DXT	11
78	60	1	27/05/03	01/05/03	MX	3	T2 N1			10/6/03 EPI/CMF	
79	36	1	10/06/03	08/05/03	MX	POS	T2 N1		11	EPI/CMF 17/6/03	111
80	65	1	10/06/03	08/05/03	WLE	N/A +SHAVE 5	T2 N1			DXT 2/9/03	11
-	63	1	10/06/03	08/05/03	WLE	N/A+ SHAVE 8	T2 N0		5	CMF 17/6/03	

ER	TRIAL	COMMENTS
ER+		
ER+		TRIAL NOT ACTIVE
		METASTATIC
ER+		TRIAL NOT ACTIVE
ER+	SECRAB	
ER+		anti
ER+		NO CHEMO MICRO METS
ER+		
ER+		DUKE C 1998
ER+		1ST SURG 22/1/03
ER+		
ER+		PREV RT (R) BREAST 98
ER+		NEO ADJ TAMOXIFEN
ER+		
ER+	SECRAB	
ER+ 5%		CT DECLINED, NO RT
ER+	SECRAB	
ER+		
ER+		
ER+		
		NODES L AXILLA/CA R BREAST OXFORD
ER+		
ER+		
ER+		
ER-		
ER+		
ER+		
ER+	SECRAB	
ER+		
ER+		NO DXT
ER+		
ER+		
ER+	200000000000000000000000000000000000000	
ER+		
ER+		
ER+	11 11 11 11 11 11 11 11 11 11 11 11 11	
ER+	1 4 4	REFUSED CT
ER+		
ER-	SECRAB	PMH I.T.P. + DIABETES - NOT FOR TACT
ER-	INELIGIBLE SECRAB	
ER+		DEC NED CHEMO
	SECRAB	

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	AGE	No OP	DATE ONC	DATE FINAL	WLE/MX	MARGIN MM	TNM	POS	TOT	DATE 1ST DXT	GRADE
NUMBER			REG	OP	MX			NODE		CHEMO REG	
82	55	2	17/06/03	15/05/03	WLE	0+RE-EX	T1 N0		9	DXT 22/7/03	11
33A	68	1	17/06/03		WLE	POS	T2 N1		12	REFUSED DXT	1
З́В _	68	1	17/06/03	(L) 22/05/03	WLE	2	T1 N0			REFUSED DXT	li
4 `	48	2	17/06/03	21/05/03	MX	POS	T4 N1			20723/6/03	in .
5	73	1	17/06/03	15/05/03	MX	20MM	T4 N0		10	DXT 13/8/03	11
86	73	2	24/06/03	29/05/03	MX	0+SHAVE	T1 N1		6	TAM ONLY	1
87	83	1	24/06/03	29/05/03	MX	7MM	T2 N0		1	03/09/03 DXT	111
88	89	1	24/06/03	29/05/03	MX	2.5	T3 N1		12	T.I.T.A.	
89	69	1	24/06/03	22/05/03	WLE	5	T1 N1			02/09/03/DXT	11
90	78	0	01/07/03							01100.00.0/(1	
91	59	1	08/07/03	18/06/03	WLE	8	T2 N1	12	15	EPI/CMF 15/7/03	111
92	47	1	08/07/03	21/08/03	MX	POS	T3 N1			DXT 28/10/03	11
93	48	2	15/07/03	31/07/03	MX	0+ RE-EX	T3 N0		12	DXT 25/11/03	
94	90	1	22/07/03	26/06/03	WLE	0+SHAVE	T2 NX		0	REFERRED BACK	1
95	75	2	22/07/03	26/06/03	WLE	POS	T1 N0		6	22/9/03 DXT	1
96	68	1	22/07/03	26/06/03	WLE	0+SHAVE	T2 N0		3	29/8/03 DXT	1
97	74	1	22/07/03	26/06/03	MX	POS	T2 N0			2/9/03 DXT	1
98	55	1	12/08/03	17/07/03	MX	POS	T2 N1			19/8/03 CMF	11
99	90	1	12/08/03	10/07/03	MX	1	T4 N1			DXT UNFIT	
00	74	1	12/08/03	03/07/03	WLE	3+ SHAVE	T1 NX			DXT 0NFTT DXT 24/9/03	11
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and the second											

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