

Confidential

Dear Mike

Thank you for your letter that I received on 4 November 2013.

Dr Mark Newbold, Chief Executive, has apologised unreservedly to the patients and their families and said:

“I share the concerns raised in this programme and when I took up post in late 2010, I felt that much more needed to be done.

“I suspended Mr Paterson and instigated disciplinary proceedings, and I commenced a recall of everybody who had undergone a mastectomy, by this surgeon, in this Trust.

“I also promised the patients and staff that, once the recall had been completed, I would commission a thorough review into why it took so long for the Trust to respond to the genuine concerns raised by staff about the practice and behaviour of this surgeon.

“I asked Sir Ian Kennedy to conduct this review, as he is an expert in the field who is known for his independence of mind. His report will be published in full.

“I have met many of the ladies involved and I have apologised, personally, to them. I have been very open with them, and I am continuing to offer them our full support.”

Regarding your specific points, please find our responses below:

1. We will report that patients are of the opinion that HEFT turned a blind eye to the failures in Mr Paterson’s surgical practice failing to prevent those practices until 2011 despite them becoming apparent in 2003 and 2007 and that HEFT failed to conduct a full recall of Mr Paterson’s patients until 2011.

Following meetings and feedback from patients, the Trust Board commissioned Sir Ian Kennedy in January 2013 to look at its response to Mr Paterson’s so called ‘cleavage sparing mastectomies’ practice.

Sir Ian’s review will be published in full and will critically assess the past actions taken by the Trust. His report is expected to be published within the next few weeks and it is expected to set out a clear timeline of what was known and when, as well as to make recommendations for any further learning for this Trust and the wider NHS, when facing concerns about a clinician’s practice. The Kennedy review will of course explore what action was taken, and when, and how effective it was, or was not. For the record, for accuracy, you are aware that the Trust required Mr Paterson to stop CSMs in 2007. The

analysis of why a focused recall took place in 2008/9, followed by a full recall in 2011/12, will also be covered by the report.

Sir Ian Kennedy is the former chair of the Healthcare Commission and he chaired the review into the Bristol Royal infirmary inquiry. He is known for his patient-focused approach. His review into breast care services at this Hospital has taken into account all of the available paperwork and interviews with staff and patients.

Since Dr Mark Newbold came in to post, he has listened to patient concerns and this has led to a full recall of all of Mr Paterson's mastectomy patients. He has suspended Mr Paterson, initiated an HR investigation and the Trust Board commissioned a full independent Review led by Sir Ian Kennedy.

2. We will report that while working for HEFT, and from at least 1995, Mr Paterson was carrying out an unknown, untested and inadequate surgical procedure (the so-called cleavage sparing mastectomy) which had not been scrutinised by the scientific community or appears in surgical textbooks.

In 2007, an external report requested by the Trust, highlighted that Mr Paterson was carrying out a procedure which had not gone through the correct processes for introducing a novel technique. Mr Paterson was asked to immediately stop this operation and undergo additional training and assessment. His response to that management instruction is an issue which will be reviewed and commented on as part of Sir Ian Kennedy's independent review, as well as forming part of disciplinary proceedings (internal and external).

3. We will report that at least 222 women were operated on in this way and that 33 of these women have gone on to develop cancer which is a rate 50% higher than that normally expected post surgery.

Providing details on local recurrence rates (cancer that has spread to tissue near the breast) for the patients of Mr Paterson who have undergone mastectomy surgery has proved very complex and we have worked very closely with the Cancer Intelligence Network to understand the data.

Over 1,000 women are believed to have been treated with a mastectomy by Mr Paterson between 1994 and 2011. At present, we have only been able to examine the information from these patients, and not from the totality of his practice (ie including the private sector patient cohort). This has added an extra limitation on our analysis of outcomes – in simple terms, the data remains incredibly difficult to read and understand in a comparable way. We have therefore been advised by the Cancer Intelligence Network that great caution must therefore be exercised when interpreting the results.

There is no factual evidence to suggest that the recurrence rate is 50% higher. What we do know at this stage, by clinical teams inside and outside of the Trust analysing recalled patients with single primary breast cancer:

- *152 patients recalled were described as having had a complete mastectomy*
- *237 women the clinical team felt confident that excessive breast tissue remained after the mastectomy operation – this suboptimal mastectomy has been described by some as a “cleavage sparing mastectomy”.*

- 379 patients were individuals in whom the clinical impression was of the potential for there to have been excessive breast tissue after the operation, but not confirmed.

The information we have at the moment suggests that:

Local recurrence rates (at 9-12 years after surgery) are higher in those women where the team felt clinically confident that excessive breast tissue remained after their original operation (6.75% at 9 years and 7.17% at 12 years) than in the other 2 groups of patients (in whom local recurrence rates remained constant at 0.66% and 1.32% respectively between 6 years and 12 years after their initial diagnosis).

Many patients have already had further treatment as part of the recall process. The Trust is continuing to analyse the information to ensure that we are able to understand the impact of the data in order to help guide the treatment of other patients.

Whilst the information made available as a result of this careful review of the recall programme will be helpful in helping guide the decision making, our clinicians are keen to reiterate the need for caution in drawing definitive conclusions. Specialist medical teams will therefore continue discussing the treatment options with patients on an individual basis.

4. Lead Cancer Clinicians Report January 2004. We will report that some members of the Heart of England Breast Cancer Multidisciplinary team were worried about the standard of work in that team and that this led to a report by the Hospital's Lead Cancer Surgeon in January 2004. This report noted concerns that an "*unusually high*" number of patients were being left with "*positive margins*", and about a possible "*negative impact*" on "*relapse rates*".

This point is very concerning, and all of the information we have on it, has been provided to Sir Ian Kennedy, as part of his review. We have also published the 2004 report through our FOIA responses on the Trust website.

5. We will report the concerns of a relative of a now deceased patient that despite this report the operations continued and that HEFT missed an opportunity to stop Mr Paterson's actions.

Of course, we are all very concerned about this issue. It was one of the reasons why Sir Ian Kennedy was asked to undertake an independent review. At the outset we committed to publish Sir Ian's review in full, so that the Trust, its patients and stakeholders and the wider public, can all reflect on any learning it delivers, to try to ensure we, and the wider NHS, learn from these events.

6. Record keeping – we will report that the Trust have expressed concerns about the accuracy of Mr Paterson's record keeping.

One of the key concerns raised by the newly appointed Chief Executive, Dr Mark Newbold, was patient records and consent. This was part of the concern about not being able to feel confident that we had explored the safety of Mr Paterson's practice, because the records did not tell us the full story, hence the decision to conduct a full recall. This issue is being considered as part of the HR investigation and Sir Ian Kennedy's Review.

7. 2007 Report – we will report that some of Mr Paterson's colleagues continued to express their concern about the quality of his work between 2004 and 2007. In 2007, this led to the Trust inviting two outside experts to investigate. These experts were given over sixty patients' notes to review. They concluded that all these patients had been left with excess breast tissue which had unnecessarily exposed them to the risk of cancer returning. In December 2007, Mr Paterson gave an undertaking to HEFT that he would stop performing so-called 'cleavage sparing mastectomies'.

The report in 2007 was led by two experts, one working outside of the organisation and the other from another separate part of the organisation. This reviewed 61 patients' notes. It concluded that Mr Paterson had carried out an unusual procedure and that this should be stopped. It did not conclude that all of these patients had been left with excess breast tissue, but highlighted that potentially half could have been left with excess breast tissue.

This report and the issues it raises will form part of Sir Ian's independent review. We need to ensure that all lessons are learned from previous reports and processes are in place to enable people's concerns to be raised, heard and acted upon. We can reassure current patients that the quality of patient care is our top priority and that our current executive team have totally changed the way we deal with potential concerns over any aspect of care quality.

8. Post 2007 – we will report that despite the above Mr Paterson did not stop performing cleavage sparing mastectomies as undertaken in 2007. We will report the story of one patient who received a Cleavage Sparing Mastectomy in 2010 and who has been paid compensation by the Trust.

The Trust is currently looking into whether Mr Paterson had undertaken the procedure, after he committed to stop in 2007. This is part of a HR investigation and, as such, it would be inappropriate (legally) for us to comment further at this point.

We have put in place with the NHS Litigation Authority a process whereby anyone claiming compensation can have their claim reviewed quickly. Under the leadership of the new Chief Executive, the Trust has made every effort to meet all of the patients who had undergone a mastectomy from Mr Paterson and ensured that they received all the expert advice and support they needed, as quickly as possible.

9. The Recall – we will report that after the 2007 investigation HEFT could have recalled all 1,079 of Mr Paterson's mastectomy patients but, instead, conducted a "targeted recall" which by 2009 had recalled just 12 patients.

A target review of patients did take place following the 2007 review, based on external advice. However, following the appointment of Dr Mark Newbold as Chief Executive, the concerns raised by patients led to the decision to carry out a full review of all Mr Paterson's patients who had undergone a mastectomy.

10. We will report that a 2009 audit found Mr Paterson's re-excision rate was 86% per cent – and this is considerably higher than normally expected.

The report in 2009 is part of the documentation provided to Sir Ian Kennedy and will assist in his review. He will report on this in the next few weeks.

11. We will report one patient's anger that she was not recalled by HEFT until 2011 some 4 years after HEFT's 2007 investigation. This patient is of the opinion that HEFT "were desperate to keep it secret. I think they crossed their fingers and hoped that nothing bad would come from this." She also reports that in her opinion getting information from HEFT about why a full recall was not ordered in 2007 has been "like drawing teeth" and that "they've thwarted me at every turn".

Dr Newbold has met with the patient and shares her concerns and her views. Along with other patients' comments, these were instrumental in Sir Ian Kennedy being asked to undertake an independent review. The complication of a police investigation into Mr Paterson's practices in the private sector, a private sector investigation, a GMC investigation and a HR investigation, and in some aspects, our duties under the Data Protection Act, put legal constraints on the publication of some documentation. We appreciate that this is very frustrating for patients. We have made documentation available for Sir Ian to review so that this can inform his recommendations which will be published shortly.

12. Further criticism – we will report that one patient's records show that Mr Paterson took half an hour to perform what he described in his notes as a bilateral mastectomy. We will report that this speed of operating has been observed in other cases, and that normally a mastectomy would take between 1 – 2 hours.

This is an important issue and, as part of Sir Ian Kennedy's review, he will be looking at what the Trust knew, when and what action was taken as a result. His findings will be published in the report.

13. We will report that the safeguards meant to protect patients like audits of surgical outcomes, annual appraisals and oversight by other experts working as a multi-disciplinary team failed.

This issue is one of great concern to all the current executive team and has been openly discussed at the Board, following the appointment of Dr Mark Newbold and concerns received from patients. It has led to the Board commissioning Sir Ian Kennedy's independent review. He has been asked to leave no stone unturned in order to find out what the Trust knew and whether more could and should have been done to protect patients. We await the publication of his report in a few weeks time.

Yours sincerely

**Surraya Richards
Head of Communications
Heart of England NHS Foundation Trust**