ABS response to the Conviction of Ian Paterson

Ian Paterson was found guilty of 17 counts of wounding with intent and three counts of unlawful wounding at Nottingham Crown Court on 28th April 2017.

The Association of Breast Surgery would like to express its sympathy to the patients who have suffered as a result of Mr Paterson's actions.

Although Mr Paterson has never been a member of the Association of Breast Surgery, the organisation views this incident very seriously. Work is ongoing to review the events that have occurred and identify lessons that can be learnt, both general and those specific to breast surgery. These will be disseminated to our members and those involved in breast care.

We would like to reassure patients that this incident reflects the actions of a single individual surgeon working outside acceptable standards of care and does not represent the current standard of breast care in the UK. The first priority of our members is always the health, wellbeing and safety of patients.

The Association of Breast Surgery constantly endeavours to raise the already high standards of breast surgery by providing members with ongoing education and training with support for research and national audits. These collectively aim to ensure the delivery of a high standard of breast surgery care throughout the UK.

Mark Sibbering (President)

on behalf of the Trustees of the Association of Breast Surgery

31st May 2017

ABS response to the Conviction of Ian Paterson

Summary of Key Recommendations (to date)

For Surgeons

The Association of Breast Surgery Trustees would like to remind all surgeons of their professional responsibilities and duties as highlighted in:

- GMC 2013 guidance, 'Good Medical Practice' www.gmc-uk.org/guidance
- Royal College of Surgeons 2014 guidance, 'Good Surgical Practice' www.rcseng.ac.uk/standards-andresearch/gsp/

Safety and Quality of Care

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. When 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.

Multidisciplinary Team (MDT) Working

It is now widely accepted that breast care should be provided by breast specialists in each discipline and that multidisciplinary teams form the basis for best practice.

The principles of MDT meeting discussion are as follows and should be followed in both the NHS and in private practice:

- the discussion should occur before the final result is communicated to the patient.
- the meeting should be quorate with all required disciplines present. The diagnostic MDT meeting should include a pathologist, radiologist or consultant radiographer in breast imaging, surgeon or breast clinician and breast care nurse.
- The outcome of the MDT discussion should be accurately recorded.

Private Practice

- It is recommended that surgeons should always practise within the area of their specialty training, and that their scope of practice carried out in the private sector should be similar to that carried out in the NHS.

- All private practice workload should be included in annual appraisal discussions.
- All patients who undergo needle biopsy during assessment and all newly diagnosed breast cancer patients should be discussed at an appropriate multidisciplinary team (MDT) meeting.

Benign (non-cancer surgery)

Diagnostic Surgery

With appropriate use of the triple assessment process the number of patients requiring open diagnostic surgery should be minimal. All such cases should be discussed at a MDT meeting prior to the decision for such surgery.

Risk Reducing Breast Surgery

The Association of Breast Surgery has developed / adopted guidance relating to risk reducing surgery in women at increased risk due to a family history of breast cancer and contralateral mastectomy.
www.associationofbreastsurgery.org.uk/publications/guidelines/

The Association of Breast Surgery will look to develop clear guidance relating to risk reducing surgery for histological risk factors that increase breast cancer risk in collaboration with both patients and commissioners.

Consent

It is important to ensure genuine patient consent to treatment with full information, both in the NHS and with the same rigour in private practice.

For Patients

- Patients should not hesitate to ask questions of their surgeons.
- Breast care is delivered by specialist multidisciplinary teams. Individual care should be discussed by that multidisciplinary team and regardless of whether treated in the NHS or privately patients can ask to see documentation of the team discussions relating to their care when an operation or treatment is being recommended.
- Patients should not feel uncomfortable asking for a second opinion.
- If patients have any concerns about their treatment or are unsure how to proceed with a particular treatment, they should not hesitate to ask for a second opinion, and can contact the Patient Advice and Liaison Service (PALS) at their local hospital, who will be able to give guidance on this process.

ABS response to the Conviction of Ian Paterson

Background

Mr Paterson was a Consultant General Surgeon practicing in the NHS at Solihull Hospital (now Heart of England Foundation Trust – HEFT) and carrying out private practice at the Spire Hospitals at Little Aston and Parkway. The convictions relate to the care of 10 private patients who underwent unnecessary breast surgery at the Spire Hospitals.

Between 1998 and 2011 Mr Paterson carried out breast surgery on over 4400 women at HEFT including 1207 mastectomies. He carried out an unknown number of procedures in the private sector during the same time period[1]. Concerns were raised at HEFT from 2003 onwards. Spire Healthcare was aware of these concerns from 2007. Mr Paterson was not suspended from carrying out his NHS or private practice until 2011.

A review of the response of HEFT to concerns about Mr Paterson's surgical practice was published by Professor Sir Ian Kennedy in 2013[2]. An independent review of the governance arrangements at the Spire Hospitals was published by Verita in 2014[3].

In his NHS practice the central concern was that, on occasions, Mr Paterson was leaving behind tissue after carrying out what was supposed to be a mastectomy. Women were giving their consent to mastectomy, but, on occasions, an unrecognised variation of a mastectomy was being carried out; what became known later as a "cleavage sparing mastectomy". The Kennedy Review clearly documents the series of events that occurred and the generic lessons to be learnt.

In his private practice a number of concerns had been raised about Mr Paterson's clinical practice in addition to him carrying out incomplete mastectomies:

- carrying out unnecessary surgery when there was no evidence of malignancy
- giving misleading information about pathology reports to his patients and their GPs
- using cancer codes for non-cancer treatments
- following up patients with more frequent imaging than was accepted as normal
- carrying out procedures for which patients had not given consent
- conducting Spire breast multidisciplinary team (MDT) meetings without a radiologist or histopathologist present, and in which only he and a breast care nurse had access to pathology reports

The carrying out of unnecessary surgery when there was no evidence of malignancy is the area of practice that led to his conviction.

The Verita report made a number of recommendations regarding the governance of consultants working in private practice many of which were general, but some were specific to breast surgical practice.

Lessons to be Learnt

The Association of Breast Surgery has previously reviewed the findings of the Kennedy Review and the Verita report and disseminated the lessons to be learnt to our membership through presentations at our meetings and recommendations published on our website and in our yearbook.

The Trustees will now use the information available from the cases presented in court to identify areas of breast practice where further guidance and recommendations may be appropriate. This work is ongoing.

The recommendations to date are summarised below and these will be updated in due course.

Recommendations for Surgeons

Safety and Quality of Care

The safety of patients and the quality of the care that they receive is a matter of fundamental importance.

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. Trust Boards must ensure that the culture of their organisation is one in which all members of staff know how and with whom to raise concerns and feel safe and comfortable doing so.

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, e.g. the General Medical Council.

Multidisciplinary Team (MDT) Working

It is now widely accepted that breast care should be provided by breast specialists in each discipline and that multidisciplinary teams form the basis for best practice.

The constituent members of the breast team may be conveniently divided into two separate but inter-dependent groups: a) diagnostic team; b) cancer treatment team.

As most patients do not have breast malignancy, the role of the diagnostic team is both to diagnose breast cancer and to treat and reassure patients with benign breast disorders.

The purpose of the MDT meeting is to ensure that patients who have undergone full triple assessment including needle biopsy receive the correct diagnosis and advice regarding management.

The principles of MDT meeting discussion are as follows and should be followed in both the NHS and in private practice:

- the discussion should occur before the final result is communicated to the patient
- the meeting should be quorate with all required disciplines present. The diagnostic MDT meeting should include a pathologist, radiologist or consultant radiographer in breast imaging, surgeon or breast clinician and breast care nurse
- The outcome of the MDT discussion should be accurately recorded

Private Practice

- It is recommended that surgeons should always practise within the area of their specialty training, and that their scope of practice carried out in the private sector should be similar to that carried out in the NHS.
- All private practice workload should be included in annual appraisal discussions.
- All patients who undergo needle biopsy during assessment and all newly diagnosed breast cancer patients should be discussed at an appropriate multidisciplinary team (MDT) meeting[4]. This may be achieved either through formalised arrangements with NHS trusts or the setting up of a private MDT working to the same standards.
- On occasion, patients may seek to shorten waiting times or gain access to treatment not readily available in the NHS by requesting surgery in the private sector. Surgeons are reminded to consider whether their own subconscious treatment biases or the temptation of monetary gain might result in over treatment of their private patients and under treatment of some on the NHS.
- Treatments should follow national guidelines, but where there may be grey areas, a colleague's opinion is advised to confirm the wisdom of undertaking an ad hoc procedure in the best interests of the patient. However, such divergence from established practice should be a rare occurrence. This recommendation is equally applicable to NHS practice, but a more likely scenario in private practice.
- Surgeons should support the introduction of accurate data collection in private healthcare by the Private Healthcare Information Network (PHIN)*.

*PHIN is the approved information organisation for private healthcare, and will publish a range of performance measures allowing potential private patients to compare private hospitals (including NHS providers of private care) and consultants in private practice, to inform their choices.

All operators of private healthcare facilities are required (by an Order of the Competition & Markets Authority) to provide extensive data to PHIN to support this process, including admissions records (similar to NHS HES), adverse events, patient satisfaction and outcome measures.

Consultants are not required to provide data but will be invited to review and approved their data prior to publication, and regularly thereafter, through a secure portal. However, not all hospitals have yet submitted data and data quality is variable. Consultants should anticipate needing to be proactive over the next 12 months to ensure that the data to be published about their practice is of the standard that they would wish. Further information is available at **www.phin.org.uk**

Benign (non-cancer surgery)

Diagnostic Surgery

With appropriate use of the triple assessment process the number of patients requiring open diagnostic surgery should be minimal. All such cases should be discussed at a MDT meeting prior to the decision for such surgery.

Some breast lesions will be assessed as B3 (of uncertain malignant potential) on needle core biopsy. The updated 'Clinical guidance for breast cancer screening assessment'[5] includes guidance on the standardisation of clinical management of B3 lesions. When deciding whether to undertake vacuum-assisted excision (VAE) or open diagnostic surgery, the multi-disciplinary team (MDT) should specifically consider how representative the sampling is and the degree of pathology concern.

Risk Reducing Breast Surgery

The Association of Breast Surgery has developed / adopted guidance relating to risk reducing surgery in women at increased risk due to a family history of breast cancer and contralateral mastectomy.
www.associationofbreastsurgery.org.uk/publications/guidelines/

The Association of Breast Surgery will look to develop clear guidance relating to risk reducing surgery for histological risk factors that increase breast cancer risk in collaboration with both patients and commissioners. ABS will also look to develop educational and decision making tools for clinicians and their patients in relation to communication and documentation of risk in patients with benign conditions that may increase breast cancer risk.

Consent

It is important to ensure genuine patient consent to treatment with full information, both in the NHS and with the same rigour in private practice.

All healthcare involves decisions made by patients and those providing their care. The General Medical Council guidance sets out principles for good practice in making decisions. The principles apply to all decisions about care: from the treatment of minor and self-limiting conditions, to major interventions with significant risks or side effects. The principles also apply to decisions about screening.

Whatever the context in which medical decisions are made, doctors must work in partnership with patients to ensure good care. In so doing, doctors must:

- listen to patients and respect their views about their health

- discuss with patients what their diagnosis, prognosis, treatment and care involve
- share with patients the information they want or need in order to make decisions
- maximise patients' opportunities, and their ability, to make decisions for themselves
- respect patients' decisions

The 2015 ruling of the UK Supreme Court in the case of Montgomery v Lanarkshire Health Board fundamentally changed the practice of consent, shifting the focus of the consent discussion to the specific needs of each individual patient. The Royal College of Surgeons has subsequently recommended the following key principles that underpin the consent process:

- The aim of the discussion about consent is to give the patient the information they need to make a decision about what treatment or procedure (if any) they want.
- The discussion has to be tailored to the individual patient. This requires time to get to know the patient well enough to understand their views and values.
- All reasonable treatment options, along with their implications, should be explained to the patient.
- Material risks for each option should be discussed with the patient. The test of materiality is twofold: whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would likely attach significance to it.
- Consent should be written and recorded. If the patient has made a decision, the consent form should be signed at the end of the discussion. The signed form is part of the evidence that the discussion has taken place, but provides no meaningful information about the quality of the discussion.
- In addition to the consent form, a record of the discussion (including contemporaneous documentation of the key points of the discussion, hard copies or web links of any further information provided to the patient, and the patient's decision) should be included in the patient's case notes. This is important even if the patient chooses not to undergo treatment.

Recommendations for Patients

It is essential that the patient surgeon relationship is founded on trust.

Patients should not hesitate to ask questions of their surgeons. Surgeons who put patients at the centre of their practice welcome discussion to ensure that the patient has genuine informed consent for any proposed treatment or procedure.

Breast care is delivered by specialist multidisciplinary teams which include not only surgeons but also imaging specialists, pathologists, specialist nurses and if

appropriate cancer specialists known as oncologists. Individual care should be discussed by that multidisciplinary team and regardless of whether treated in the NHS or privately patients can ask to see documentation of the team discussions relating to their care when an operation or treatment is being recommended.

A surgeon should not be offended if a patient asks for a second opinion. Patients should not feel uncomfortable asking for a second opinion

Patients should ask their surgeons how many times they have undertaken the procedure they are offered, and their outcomes or results.

Private patients should note that the facilities available in the private sector, including equipment and staffing numbers, may differ from the NHS. Patients may like to ask their surgeon, not only about the risks of a certain procedure, but also whether there may be differences in the care they will receive at the private hospital compared to their local NHS hospital.

If patients have any concerns about their treatment or are unsure how to proceed with a particular treatment, they should not hesitate to ask for a second opinion, and can contact the Patient Advice and Liaison Service (PALS) at their local hospital, who will be able to give guidance on this process.

References

1. Heart of England NHS Foundation Trust. FOI 5157 Breast surgery. http://www.heartofengland.nhs.uk/foi-5157-breast-surgery/

2. Kennedy I. 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. 2013. http://www.heartofengland.nhs.uk/wp-content/uploads/Kennedy-Report-Final.pdf

3. Verita. Independent review of the governance arrangements at Spire Parkway and Little Aston hospitals in light of concerns raised about the surgical practice of Mr Ian Paterson. Executive summary and recommendations. 2014. http://www.verita.net/wp-content/uploads/2016/04/Independent-review-of-the-governance-arrangements-at-Spire-Parkway-and-Little-Aston-hospitals-Spire-Healthcare-March-2014.pdf

4. Best practice diagnostic guidelines for patients presenting with breast symptoms. 2010; www.associationofbreastsurgery.org.uk/publications/guidelines/

5. Clinical guidance for breast cancer screening assessment. NHSBSP publication number 49: Fourth edition November 2016