AVMA Clinical Negligence Conference
29 June 2018

Lessons learned post-Paterson

A legal & clinical perspective

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action against medical accidents

Paterson: clinical lessons learned

- 200 medicolegal reports for private & NHS Paterson patients since 2011
- 15 reports on Paterson for the General Medical Council
- Prosecution witness at Paterson criminal trial in 2017
- Lead breast surgeon for claimant solicitors & barristers in settlement negotiations with Spire, NHS and defence organisation in 2017.
- Reports on his training, appraisal and MDT working

Post-Paterson: clinical lessons learned

- Lack of training & appraisal
- Cleavage-sparing mastectomy
- Ineffective MDT working
- Misrepresentation of imaging & pathology reports
- Insurance fraud
- Lack of clinical governance

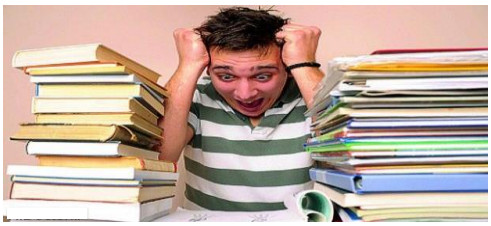
Medico-Legal Issues in Oncology

avma action against medical accidents

30 November 2011, Manchester Conference Centre

10.50 **Breast Surgery**
- Imaging procedures, mammography and ultrasound and misreading of scans
- Breast biopsies
- Staging of tumours
- Complications of surgery-negligent and non negligent treatment.
- Delay in Breast Cancer diagnosis – 'PREDICT'

Professor Gordon Wishart, Consultant Breast & Endocrine Surgeon, Anglia Ruskin University



LESSON 1

Reading the medical records yourself is a non-delegable duty!

Lack of training in breast cancer

Higher Surgical Training

Dec 90 – Sep 91
Lecturer/SR General/Vascular Surgery
Oct 91 – Sep 92
Lecturer/SR General/Vascular Surgery
Oct 92 – Sep 93
Lecturer/SR General/Vascular Surgery

MD Thesis: "The mechanism of lung injury following remote tissue ischaemia"

Lack of training in breast cancer

Societies ✓

- British Microcirculation Society
- NW Injury Research Group
- Vascular Society of GB & Ireland
- Association of Surgeons in Training
- West Midlands Surgical Society

Societies ✗

- Association of Breast Surgeons at BASO
- British Association of Surgical Oncology (BASO)
- British Breast Group
- British Association of Cancer Research

Training in breast cancer

Activity	Vascular	General Surgery	Breast cancer
Courses			
Publications			
Book chapters			
Abstracts			
Presentations			

Lack of training in breast cancer

Activity	Vascular	General Surgery	Breast cancer
Courses	8	8	0
Publications	47	3	0
Book chapters	3	0	0
Abstracts	65	0	0
Presentations	151	0	0

Of the four referees listed in the 1993 CV assumed to be part of his application to Good Hope Hospital, all four are vascular surgeons. None of the four referees are recognised as having an interest in breast cancer

LESSON 2 = UNTRAINED IN BREAST CANCER

Lack of appraisal

- NHS annual consultant appraisal introduced in April 2001
- Clinical performance, service delivery, management issues
- From 2001-2010 only one NHS appraisal document completed, and that was inadequate
- Both private hospitals relied on letters from NHS in 2003, 2006 & 2008 to confirm satisfactory NHS appraisal
- No letters received for 2004, 2005, 2007

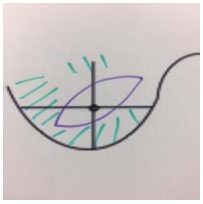
Lack of [illegible]sal

- NHS annual [illegible]ed in April 2001
- Clinic[illegible]ent issues
- From [illegible]ent completed, an[illegible]
- Both privat[illegible] NHS in 2003, 2006 & [illegible]aisal
- No letters [illegible] for 2004, 2005, [illegible]

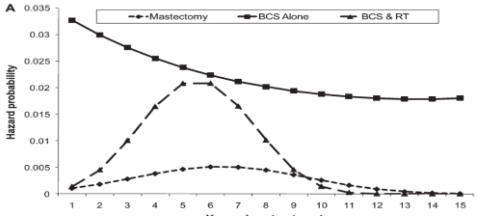
unappraised

Cleavage-sparing mastectomy

- "generous WLE"
- excess breast tissue infero-medially
- increased risk of LR or second primary
- risk of LR higher if RT not given

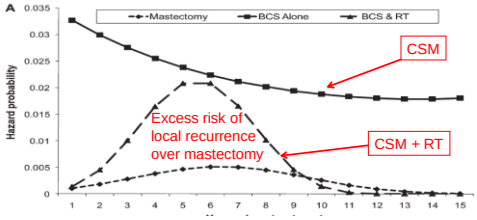


Risk of local recurrence after breast cancer surgery for DCIS



Dick et al, J Natl Cancer Inst 2011; 103: 92-104

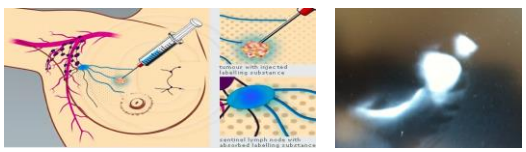
Risk of local recurrence after breast cancer surgery for DCIS



Dick et al, J Natl Cancer Inst 2011; 103: 92-104

Cleavage-sparing mastectomy-lesson 4

- **New surgical procedures must be introduced with patient consent & ethical approval**
- **New surgical procedures must be audited to ensure that they are safe and effective**



Dysfunctional MDT 1

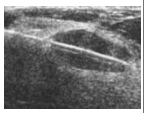
- Only one breast surgeon present (IP)
- Unlikely any other consultants present
- No imaging/pathology results discussed
- No treatment recommendations made

No challenge from colleagues to:

- Surgery without pre-operative biopsy
- Cancer surgery without biopsy confirmation
- Cancer surgery with no cancer found in excised tissue
- Misrepresentation of radiology & pathology reports

Dysfunctional MDT 2

- Lesion seen on breast US but no breast biopsy
- Patient has lump excised as cancer operation (WLE)
- Pathologist finds no discrete lesion in excised tissue.



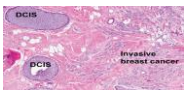
Standard practice if no cancer found after cancer operation:

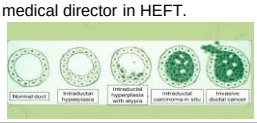
- Pathologist to discuss if cancer has been "missed" with surgeon and radiologist
- Ask surgeon why no pre-op biopsy performed
- Consider repeat imaging to see if cancer still present
- Consider repeat surgery if cancer still present

Dysfunctional MDT 3

If pathologist concerned that standard protocols not being followed in multiple patients:

- Pathologist should have raised concerns with their BUPA clinical director or laboratory manager
- If pathologist also employed at HEFT, thy should have raised concerns about this substandard practice with their clinical director of radiology in HEFT and/or the medical director in HEFT.





Dysfunctional MDT 4

I would expect any breast nurse practitioner or nurse consultant involved in the patient's care to:

- Act as the patient's advocate
- Ask IP why the patient had undergone surgery without a pre-op biopsy
- Ask IP why no abnormality had been identified in the excised tissue
- Explain to the patient that the lesion has been missed and that further investigations or surgery might be required.
- Speak to the Director of Nursing or the Matron in the BUPA Hospital, if this happened

Misrepresentation of facts 1

IP: "*I too was concerned about this irregular lumpy area superior to the areolar margin given her previous history of epithelial instability*"

- Mammograms reported as normal
- Normal breast ultrasound with no suspicious masses in either breast

IP: "*her mammograms today are normal but her ultrasound has shown a rather worrying ridge of different echo texture. We have discussed FNA cytology but Carol would prefer that this was definitively excised*".

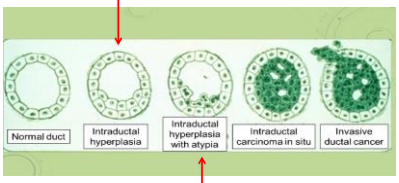
Intentional misrepresentation of facts 2

- Surgery performed without a pre-operative biopsy
- Patient consented to wide local excision
- Wide local excision performed
- Pathology showed stromal fibrosis (nil discrete)

IP: "*The lesion excised from her left breast last week is a benign fibrous lesion rather than a premalignant area as she had previously had on the contralateral right side".*

- Patient continued with unnecessary follow up
- Patient had 6 unnecessary operations in total

“Epithelial instability”



True atypia

Lessons learned 1

- IP was untrained in the diagnosis or treatment of breast disease and in particular breast cancer
- IP practiced unappraised from 2001 to 2011 in NHS & private sector
- Cleavage sparing mastectomy was unproven, untested & unaudited
- The private MDT was dysfunctional
- There was a lack of clinical governance in NHS & private sectors

Lessons learned 2

- Reading the medical records yourself is a non-delegable duty
- Some of the expert breast reports were not fit for purpose
- There are clinicians who claim to be breast specialists who are not
- There are breast specialists who are significantly out of date
- The are breast specialists who stray well beyond their area of expertise
- This should be addressed

Association of Breast Surgery
Key recommendations July 2017

- Staff must approach GMC if concerns not listened to
- MDT working promoted in private practice as for NHS
- Scope of practice should be same in private practice as NHS
- Private practice should be part of annual appraisal
- Private consent process should be as rigorous as NHS
- Guidelines on risk-reducing surgery should be adhered to

"This incident reflects the actions of a single individual surgeon working outside acceptable standards of care and does not represent the current standard of care in the UK."
Mark Sibbering, President of the ABS

ABS ASSOCIATION OF BREAST SURGERY

Independent enquiry January 2018

- Quality of care in independent sector:
- Including appraisal, revalidation, MDT working
- Information sharing/raising concerns between NHS & independent sector
- Role of insurers of independent sector providers and medical indemnity cover
- Report Summer 2019