

HBPO Course 2015

Medico-legal aspects and the impact of your reports

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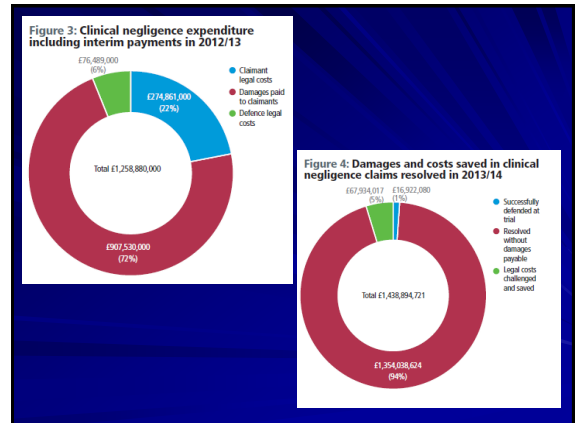
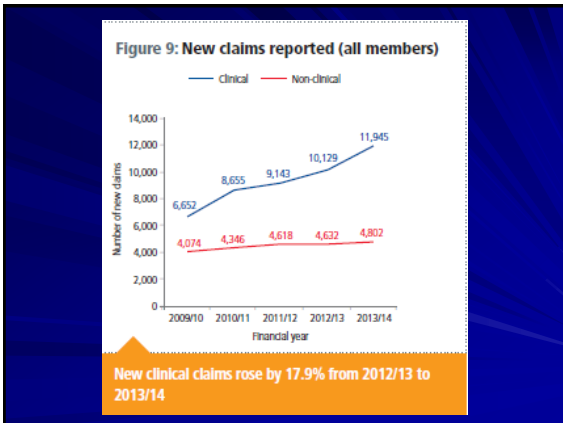
East Pennine Cytology Training Centre Sheffield Teaching Hospitals NHS

Annual Review NHS

- Annual cost NHS = £100 billion
- Annual cost litigation in NHS = £1.2 billion
- NHS Litigation Authority in bid to progressively limit litigation costs

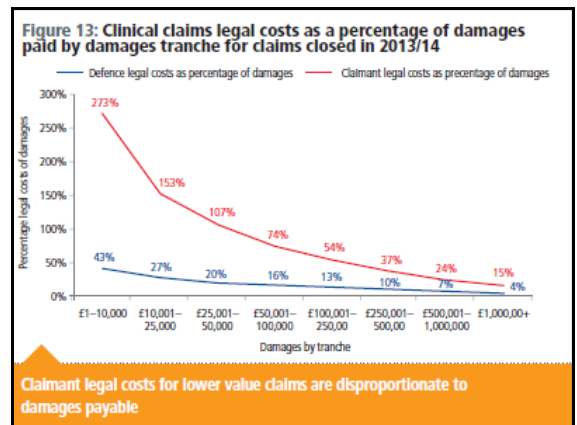
NHS Litigation Authority
Report and accounts 2013/14

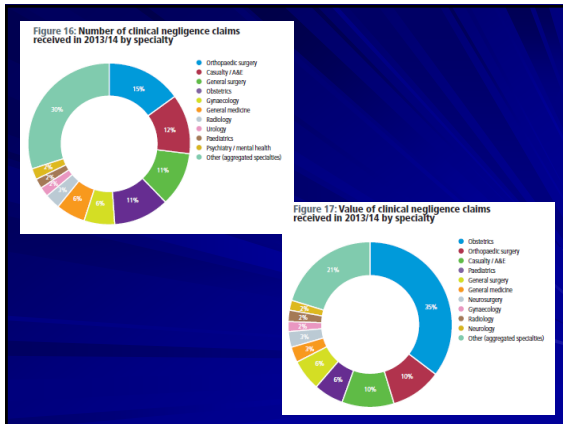
Supporting the NHS



NHSLA success in 2013-14

- Saved over £1.4 billion for the NHS by robustly defending clinical negligence claims
 - 44% clinical claims no payment of damages
 - 79% of cases decided in court successfully defended at trial
- Saved more than £74 million for the NHS by challenging claimant's legal costs – average 28.8% reduction in bills
- Resolved justified claims promptly and efficiently: claimants receiving damages <£25K received compensation in less than a year





Litigation in histopathology and cytology

- 1989-1992 claims frequency for pathology increased from 8.8% to 10%, whereas claims frequency for all specialities decreased by 0.8%
- 62% cases in six categories: malignant lymphoma, melanoma, breast FNA, Pap smears, prostate needle biopsy, expert opinion

Troxel & Sabella, Am J Surg Pathol 1994; 18: 821-831

Litigation in histopathology and cytology - Pap smears

- 25% claims filed with Doctors Company 1987-1992
- Virtually all alleged false negatives
- CLIA 1988 requirement
- 2 cases small numbers
- 2 cases unsatisfactory smears
 - 'negative'
 - 'abnormal cells present, non-neoplastic'

Troxel & Sabella, Am J Surg Pathol 1994; 18: 821-831

Litigation in histopathology and cytology - Pap smears

- 26% of pathology files relate to cellular pathology
- 70% of all cellular pathology files related to alleged misreporting
- 20% related to alleged misreported cervical smears
- File notification generally rising
- File notification for cervical cytology static

Medical Defence Union 1990-99

Why do we have false negative smears?

- Physical screening technique
- The characteristics of the abnormal cells
- Limitations of the visual system
- Lack of knowledge
- Mental screening technique
- Perception
- Judgement

Bowditch, ASC, Canberra, 1997

Physical screening technique

Abnormal cells were not seen because they did not appear in an examined microscope field

- 10-50% of slide never falls into stationary microscopic field of view
- 250-500 fields need to be seen to cover a slide
- Few false negatives explained by incomplete screening: 99.9% chance of at least one abnormal cell being present in a seen field at 50% coverage

The characteristics of the abnormal cells

Abnormal cells were not seen or not recognised because there were few of them, or they were small and pale

- Odds of a false negative report 23.7 times greater if less than 50 abnormal cells on the slide than if more than 200 abnormal cells present
- In false negative smears abnormal cells not represented throughout smear; single; small; finely granular normochromatic nuclei
- "most of the missed abnormalities in our laboratory represent subtle changes that are not detectable under usual screening conditions"

Mitchell & Medley, Cytopathology 1995, 6: 368-375

Limitations of the visual system

Abnormal cells were not seen because they did not enter central vision, or did not have sufficient contrast to enter central vision

- Foveal vision 0.5% microscope field
- Peripheral vision detects an object by size & contrast which is then fixated into central vision by saccade
- Adjust screening speed in low contrast situations
- Bland dyskaryosis

Denton et al. Cytopathology 2008; 19: 162

Lack of knowledge

Abnormal cells were seen but not recognised as such because of lack of knowledge of diagnostic criteria

- small and pale cell
- microbiopsies
- subtle criteria only seen after the alarm raised at screening speed
- inherent aptitude for cytology

Mental screening technique

Abnormal cells were not seen or recognised as such because of fatigue, distraction, lost concentration, divided attention or automatism

- 'microsleeps' when driving
- think about something else
- sleepbank deprivation

Perception

Abnormal cells were seen but not recognised as such i.e., they were recognised as something else, without deep consideration

- short search time and negative default mode
- perceptual bias softens potential alarm signals- same mistake made over and over again
- several abnormal cells need to be seen to reach a threshold of suspicion

Judgement

Abnormal cells were seen, and judged to be something else, after consideration

- If some key feature absent, the risk of error is high
- Once a decision is made, any search for further information is likely to become a search for confirming evidence
- Defer diagnostic decision making until all evidence available

'Many of our "errors" are differences of opinion about the synthesis of subjective observations used to split a biologic continuum into discrete diagnostic categories'

Foucar & Foucar. Am J Clin Pathol 2000

Review of cervical smears from 76 women with invasive cervical cancer: cytological findings and medicolegal implications

D. V. Coleman and J. J. R. Poznansky*

- 50/76 women with invasive cervical cancer found to have had at least one false negative smear
- 209 smears available for review
- 100/209 had been correctly reported
- 97/109 smears contained numerous severely dyskaryotic cells
- 12/109 smears contained <200 severely dyskaryotic cells

Cytopathology 2006; 17: 127-136

Review of cervical smears from 76 women with invasive cervical cancer: cytological findings and medicolegal implications

D. V. Coleman and J. J. R. Poznansky*

English courts an 'acceptable' standard is considered to be that of an ordinary skilled person exercising and professing to have that special skill.² In the context of the cervical screening programme an 'acceptable' standard is usually taken to mean that the smears have been interpreted correctly by a skilled cytologist.

Cytopathology 2006; 17: 127-136

Review of cervical smears from 76 women with invasive cervical cancer: cytological findings and medicolegal implications

D. V. Coleman and J. J. R. Poznansky*

The Courts recognize that mistakes are to be expected when professional persons, however well trained, undertake a particularly challenging task. By the same token, the Courts take the view that the person who has made a mistake cannot escape the consequences of that mistake simply by claiming that the mistake was unforeseeable or rarely occurring or due to fatigue or inexperience.

Cytopathology 2006; 17: 127-136

Review of cervical smears from 76 women with invasive cervical cancer: cytological findings and medicolegal implications

D. V. Coleman and J. J. R. Poznansky*

Their Lordships will not accept the argument that 'a doctor's duty is fulfilled if he provides an adequate service generally and only occasionally falls below the required standard of care'.² Thus in the eyes of the law, a missed abnormal smear constitutes a breach of duty of care.

Cytopathology 2006; 17: 127-136

Factors contributing to false-negative and potential false-negative cytology reports in SurePath™ liquid-based cervical cytology

N. Gupta*, D. John, N. Dudding, J. Crossley and J. H. F. Smith

Results. Of 95 samples with subsequent CIN2+, 30.5% predominately contained microbiopsies/hyperchromatic crowded cell groups (HCGs), 27.3% sparse dyskaryotic cells, 4.2% pale cell dyskaryosis, 6.3% small dyskaryotic cells; 3.2% were misinterpreted cells, 8.4% contained other distracting cells, 7.4% were low contrast, 5.3% were unexplained and 7.4% were true negatives. The mean number of microbiopsies/HCGs in that category was 4.6. The mean number of abnormal cells in the sparse dyskaryotic cell category was 13.8.

Conclusions: Microbiopsies/HCGs were the commonest reason for false negatives. They were usually present in sufficient numbers to be detected but interpretation could be problematic. Dispersed single abnormal cells were usually not identified because of their scarcity or the presence of distracters.

Cytopathology 2013; 24: 39-43

Medical negligence

Breach of the duty owed by a doctor to his patient to exercise reasonable care and/or skill, resulting in some bodily, mental or financial disability.

Negligence

- Defendant owed a **duty of care**
- Defendant in **breach of that duty**
- Plaintiff suffered **harm as a result**
- Extent and quantum of **loss is recoverable in law**

Duty of Care

Doctors in general

R v Bateman (1925)

"If a person holds himself out as possessing special skill and knowledge, and he is consulted, as possessing such skill and knowledge, by...a patient, he owes a duty to the patient to use due caution in undertaking the treatment. If he accepts the responsibility.he owes a duty to the patient to use diligence, care, knowledge, skill and caution in administering the treatment."

Duty of Care

Doctors in NHS

Barnett v Chelsea and Kensington HMC (1969)

"there was here such a close and direct relationship between the hospital and the watchmen that there was imposed on the hospital a duty of careI have no doubt that Nurse Corbett and Dr Banerjee were under a duty to the deceased to exercise that skill and care which is to be expected of persons in such positions acting reasonably....."

Duty of Care

Health authority – primary liability

Hillyer v Governors of St Bartholomew's Hospital (1909)

Hospital liable for negligence of its employees in respect of their administrative but not professional duties

Cassidy v Ministry of Health (1951)

"Where a doctor or surgeon is employed and paid by the hospital authorities[they] are responsible for his negligence in treating the patient."

Duty of Care

Health authority – vicarious liability

Gold v Essex County Council (1942)
Cassidy v Ministry of Health (1951)

"when hospital authorities undertake to treat a patient and themselves select and appoint and employ the professional men and women who are to give the treatment, they are responsible for the negligence of those persons in failing to give proper treatment, no matter whether they are doctors, surgeons, nurses, or anyone else."

Breach of duty of care

Bolam v Friern Hospital Management Committee (1957)

"A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art."

Breach of duty of care

Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital (1984)

"the law imposes the duty of care; but the standard of care is a matter of medical judgement"

Maynard v West Midlands Regional Health Authority (1985)

"a doctor who professes to exercise a special skill must exercise the ordinary skill of his specialty"

Breach of duty of care

Bolitho v City and Hackney Health Authority (1997)

"the court is not bound to hold that a defendant doctor escapes liability for negligent treatment or diagnosis just because he leads evidence from a number of medical experts who are genuinely of the opinion that the defendants' treatment or diagnosis accorded with sound medical practice."

"The court has to be satisfied that the exponents of the body of opinion relied on can demonstrate that such opinion has a logical basis"

Causation

Plaintiff must show:

- i) the harm or injury would not have occurred but for the doctor's negligence
- ii) the harm or injury was a reasonably foreseeable consequence of the doctor's negligence

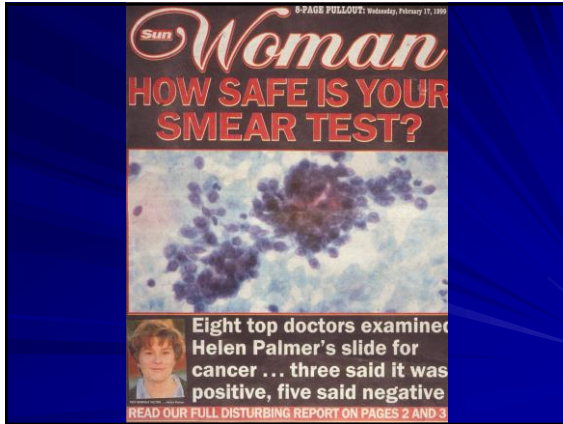
'res ipsa loquitur'

Defence to negligence

- Delegation of duties
 - staff properly trained, qualified and experienced
 - safe system of working and staff familiar with the system
- Contributory negligence
- Voluntary assumption of risk
- Limitation Act 1980

Damages

- General damages
 - Loss of earnings
 - Pain and suffering
 - Reduction in life expectancy
 - Loss of faculty
 - Infertility
 - Death
- Special damages
 - Expenses incurred as result of negligence



Kent & Canterbury: Wells Report

- Cytology laboratory isolated, understaffed, and poorly managed
- Working relations between staff poor
- Poor laboratory performance from 1990-1994
 - considerable underdiagnosis abnormal smears
 - serial misreporting of smears from same woman
- Clinical and diagnostic standards so poor referral made to GMC

Penney, Palmer and Cannon

-v-

East Kent Health Authority

QBD (Canterbury): Judge Peppitt QC, February 15 1999

Key questions in K & C

- What was to be seen on the slide?
- At the relevant time could a screener exercising reasonable care fail to see what was on the slide?
- Could a reasonably competent screener, aware of what a screener exercising reasonable care would observe on the slide, treat the slide as negative?

Kent & Canterbury: Penney

Experts meeting

'4 or 5 inflamed groups endocervical cells showing changes in nuclear and cytoplasmic morphology. It was not a normal slide'

Kent & Canterbury: Cannon

Experts meeting

Cotton: Severe dyskaryosis. Refer
 Krausz: Severe dyskaryosis. Refer
 Boon: Borderline changes in epithelial cells. Repeat
 Hughes: Borderline changes in endocervical cells. Repeat

Kent & Canterbury: Palmer I

Experts meeting

Cotton: Highly abnormal glandular cells. Refer

Krausz: Dyskaryotic endocervical cells. Refer

Boon: Borderline glandular cells. Repeat 6 months

Hughes: Borderline glandular cells. Repeat 3 months

Kent & Canterbury: Palmer II

Experts meeting

Cotton: Dyskaryotic cells present. Refer

Krausz: Dyskaryotic cells present. Refer

Boon: Endocervical cells present.

Negative

Hughes: Endocervical cells present.

Negative

The Bolam argument

For defendants

Bolam principle exculpated HA from negligence

For plaintiff

- pathologists giving evidence not of what they themselves would have done but what screener would have done in times past
- defendants pathologists' views not logical
- defendants expert did not apply the right test

The absolute confidence test

"If the screener has doubt he should pass the slide on to the checker. Anything short of absolute confidence that the smear is within the normal range requires the screener to pass the slide on."

Kent & Canterbury Appeal

- Judge had to decide on fact on these four slides alone
- He had the advantage of hearing the evidence
- He concluded there were abnormalities 'to be seen'
- He did not obviously misdirect himself
- He was thus entitled to come to the conclusions he did

Kent & Canterbury Appeal

- Court of Appeal understood why HA concerned about the Judge's decision
- *Bolam* test does apply to cytoscreeners
- "This case does not decide that negligence by a screener can be established by showing that someone who had a slide labeled negative unfortunately develops cervical cancer"
- the Judge "did not reject the general approach of the Authority's experts in particular Dr Hudson"

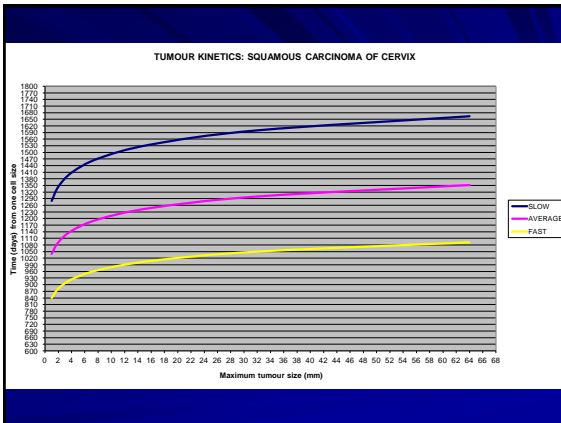
After the K & C appeal

- The limitations of expert opinion must be recognised
- The 'absolute confidence' test suggests errors of interpretation will be much more difficult to defend than errors of detection
- How will the *Bolam* principle be applied in future?
- CPA accreditation, good IQC and EQA record may be a valuable defence

Scenario 1

35 yr old woman. FIGO stage 2B squamous carcinoma cervix diagnosed in Oct 2012. Died Feb 2013

DATE	TRUST	ORIGINAL REPORT	REVIEW REPORT
Dec 2005	A	Negative	Severe
Dec 2008	A	Negative	Severe
Dec 2011	B	Negative	Severe



Scenario 2

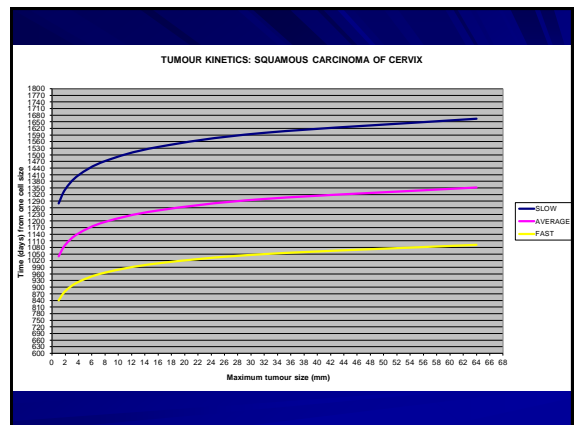
29 yr old woman. Nulliparous. FIGO stage 1B1 squamous carcinoma cervix (9mm wide, 6 mm deep) diagnosed in May 2011. Radical hysterectomy

DATE	TRUST	ORIGINAL REPORT	REVIEW REPORT
Dec 2007	A	Negative	Negative
Dec 2010	A	Negative	Sparse (<30) dyskaryotic cells

Scenario 3

29 yr old woman. Nulliparous. FIGO stage 1B1 squamous carcinoma cervix (9mm wide, 6 mm deep) diagnosed in May 2011. Radical hysterectomy

DATE	TRUST	ORIGINAL REPORT	REVIEW REPORT
Dec 2007	A	Negative	Negative
Dec 2010	A	Negative	Severe dyskaryosis





East Pennine Cytology Training Centre



Overall Winner 2010
Achieving Excellence in Learning, Teaching & Development

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