Medico-legal Issues in Cytology: A UK Perspective

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Annual cost NHS = £110 billion
Annual cost litigation in NHS = £1.2 billion
NHS Litigation Authority in bid to progressively limit litigation costs
New clinical claims rose by 79% from 2009/10 to 2013/14
Expenditure on new clinical claims rose by 61% from 2009/10 to 2013/14.
Figure 3: Clinical negligence expenditure including interim payments in 2012/13

- Claimant legal costs: £76,489,000 (6%)
- Damages paid to claimants: £274,861,000 (22%)
- Defence legal costs

Total: £1,258,880,000

Figure 4: Damages and costs saved in clinical negligence claims resolved in 2013/14

- Successfuly defended at trial: £67,934,017 (5%)
- Resolved without damages payable: £16,922,080 (1%)
- Legal costs challenged and saved

Total: £1,438,894,721

- £1,354,038,624 (94%)

Figure 13: Clinical claims legal costs as a percentage of damages paid by damages tranche for claims closed in 2013/14

Claimant legal costs for lower value claims are disproportionate to damages payable
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
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

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

*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
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”

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
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
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
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
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.
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.
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’. Thus in the eyes of the law, a missed abnormal smear constitutes a breach of duty of care.
Factors contributing to false-negative and potential false-negative cytology reports in SurePath™ liquid-based cervical cytology


Results: Of 95 samples with subsequent CIN2+, 30.5% predominately contained microbiopsies/hyperchromatic crowded cell groups (HCGs), 27.3% sparse dyskarytotic 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.
Woman

HOW SAFE IS YOUR SMEAR TEST?

Eight top doctors examined Helen Palmer’s slide for cancer ... three said it was positive, five said negative.

READ OUR FULL DISTURBING REPORT ON PAGES 2 AND 3
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?
## The limitations of expert evidence

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<tr>
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<th>CLAIMANTS’ EXPERTS</th>
<th>DEFENDANTS’ EXPERTS</th>
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<tr>
<td></td>
<td>A</td>
<td>B</td>
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<tr>
<td>PENNEY</td>
<td>‘ 4 or 5 inflamed groups of endocervical cells showing changes in nuclear and cytoplasmic morphology. It was not a normal slide’</td>
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<tr>
<td>PALMER 1</td>
<td>Highly abnormal glandular cells</td>
<td>Dyskaryotic endocervical cells</td>
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<td>PALMER 2</td>
<td>Dyskaryotic cells present</td>
<td>Dyskaryotic cells present</td>
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<td>CANNON</td>
<td>Severe dyskaryosis</td>
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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”
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?
- Wells report of relevance: CPA accreditation, good IQC and EQA record may be a valuable defence
LEICESTER AUDIT 2001

- Internal audit of screening history 403 women with cervical cancer
  - 136/403 cervical smears misclassified
    - 97 (24%) false negative
    - 39 (9%) undergraded
  - Small cell and pale cell dyskaryosis; microbiopsies; and scanty dyskaryosis predominanted
  - 20% women had never had a smear

‘people who are diagnosed with cancer outside a screening programme, despite having participated in the programme, often wish to know why this has happened. Audit … can yield this information’

‘offering the suggestion that an abnormality or cancer may have been missed previously should be handled in a flexible manner suited to the needs of the individual patient’
Thank you

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