How to deal with pathology errors when legal action is taken. The Dutch experience
Disclosure Information

I hereby declare that I have had business or personal interests in the following industrial enterprises since 1 September 2016:

Name of the enterprise / Nature of the interest

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Some definitions

**Incident:** An unintended event during the care process that has led or can lead to damage to the patient. (GOMA, KNMG et al. 2010)

**Complication:** A negative and undesired effect of a medical treatment which is performed with the correct indication and lege artis. (Chief Inspectorate for Public Health)

**Error:** Negative and undesired effect as a result of an incorrect medical treatment which falls within someone’s scope of responsibility. (Legemaate)
Incidence of errors 1

Case reviews (aim: improvement of quality of patient care)

Meta-analysis of 116 studies by Nakhleh RE et al; Arch Pathol Lab Med. 2016; 140: 29
Guideline from the College of American Pathologists

- *Discrepancy rate* 7.5 – 34.5% (18.3%)
- *Major discrepancy rate* 2.1 – 10.5% (5.9%)

81 different definitions of major or significant discrepancies!
No recommendation for a particular review procedure (insufficient evidence)
Incidence of errors 2


Agreement and error rates using blinded review to evaluate surgical pathology of biopsy material

- Threshold disagreement 6%
- Clinical significant error rate 0.08%

Legal framework

- Complaints law
- Civil liability
- Disciplinary law
Civil liability ("claim")

- There must be damage.
- There must be an attributable error or negligence.
- There must be a causal relationship between “error” and “damage”
Legal standard

Dutch Civil Code (art. 7:453 CC)

The care provider must in his work consider the care of a good care provider and act in accordance with the responsibility resting on him deriving from the professional standard applicable for care providers.
Legal standard

*Ruling of the Dutch Supreme Court 1990:*

For determining liability for medical actions, it must be tested whether “the physician has acted with the care which may be expected from a reasonably acting and reasonably competent physician”… “in equivalent circumstances.”
Legal standard

This check can only be done by the profession itself

- Good Care
- Reasonably competent
- Applicable professional standard
The expert
What can be asked from the expert?

1) A *factual* analysis of the incident
2) An analysis of the *cause* of the incident
3) A *normative* judgment
   * reasonably competent
   * carefulness
   * applicable professional standard
4) Causal connection event - damage
The challenge for the expert

• To distinguish well known diagnostic variation from culpable error

• To unravel the influence of “group statistics” (e.g. FP-, FN- and IOV-rates) versus incidental Individual performance
The reassessment: how wrong is wrong?
The re-assessment, pitfalls

Nothing is so easy as to be wise after the event (Judge Branwell, UK, 1800)

- Hindsight / outcome bias
- Expert / cognitive bias
- Selection / focus / litigation bias
Methods of review

• Blinded vs non-blinded review
• Expert vs non-expert review
• Conference vs non-conference review
• Internal vs external review
• Focussed vs unfocussed review

Expert re-assessment 1

R.M. Austin

Results of blinded rescreening of Papanicolaou smears versus biased retrospective review.


Blinded review: known FN/FP rates

Unblinded review: 60 - 90% abnormal cells found
“Objective” blinded reassessment

Objective re-evaluation procedures in cases of possible error
Objective reassessment procedure

Appoint an “expert” who conducts or organizes the following systematic analysis of the possible error:

- Scientific context.
- Clinical context.
- Process testing.
- Outcome testing with reassessment of the contested examination.
**Scientific context**
- Evidence-based medicine
- “State of the science" at the time of the diagnostic examination

**Clinical context**
- Relevant clinical information
- indication
- "plausibility" of the diagnosis
- Interpretation of data and findings as a whole
Process testing

• Care
• Guidelines/protocols
• Work environment, audits, accreditation

Outcome testing

• Risk of misclassification or diagnostic error
• Reporting: any restriction? Consultation?
• Reassessment
Reassessment of contested examination

- Anonymize the contested examination (practically always sections).

- Compile a set of similar, also anonymized sections (5 - 10).

- Information with these slides exactly the same as the information that was available at the time of the original assessment, incl. any additional examinations on which the original diagnosis was based.
Reassessment of contested examination

- Have the set, including the contested examination, assessed by pathologists who can be considered as “reasonably acting and reasonably competent” (5 – 7) independently of each other and without knowledge of the nature of the possible incorrect assessment and the outcome of the contested case.

- Report by the “expert”/organizer of the panel reassessment and of the broad analysis as described above.
Possible “outcomes” of reassessment by different pathologists:

• *Unanimous* agreement with the originally established diagnosis

• *Unanimous* agreement about the diagnosis, but this differs essentially from the originally established diagnosis

• *No unanimous* agreement about the diagnosis, whether or not in accordance with the original diagnosis
The expert’s – recommendation

The final judicial ruling about liability or attributable shortcoming does not lie with the expert.
The expert’s report should be seen and worded as a recommendation in response to the questions asked for.
The aim of the procedure

The aim of the procedure is not to find or prove the truth (i.e. the ex-post correct diagnosis) by technical or statistical means, but to support the conclusion of the expert whether or not the defendant pathologist has acted as can be expected of a “reasonably competent and reasonably acting pathologist in as much as possible equivalent circumstances”.
Possible queries about the procedure

• More emphasis on the (psychological) cause of the error?
• Influence of size and make-up of set of slides and number of participating pathologists?
• Guide-line for interpretation and legal consequences of outcome re-assessment?
• Agreement with legal and insurance institutions?
Cases revisited
Case 1: F 37 yrs

- Left mammary gland: Palpable irregular ill defined lump, min 3 cm, BIRADS IV
- Thick needle biopsy: infiltrating ductal carcinoma, BR 2,ER/PR pos, Her2Neu neg
- Advice: lumpectomy or mastectomy, SNB
- Histopath mastectomy: (with calponin,p63): complex sclerosing lesion (radial scar?) with infarction. No signs of malignancy
- Internal review biopsy (now with calponin,p63): CSL, no signs of malignancy
- Complaint and claim for compensation because of irreversible surgery due to an erroneous diagnosis
Case 1: F 37 yrs

- Re-assessment on request of insurance company and patient’s lawyer
- Without m-e markers: 0/5 pathologists adenocarcinoma, 5/5 pathologist provisional diagnosis, 3/5 suspect malignant, 2/5 most likely benign, 5/5 m-e markers requested
- With m-e markers: 5/5 pathologists complex sclerosing lesion, no proof of malignancy
Case 1: F 37 yrs

Conclusion re-assessment Case 1

“The pathologist has in this case not acted as may be expected of a reasonably acting and reasonably competent pathologist in as much as possible equal circumstances”

Complaint and liability accepted
Case 2: M 55 yrs

- Pigmented skin lesion left lower leg
- Histopath: Naevus naevocellularis
- Relaps lesion: NN, benign
- 2nd relaps lesion: Malignant Melanoma (histopath) with inguinal gland metastasis (cytopath)
- Expert consultation all 3 lesions: MM, 2x naevoid melanoma, 2nd relaps nodular MM
- Complaint and claim for compensation because of loss of chance of cure
Case 2: M 55 yrs

- Re-assessment procedure requested by insurance company and patient’s lawyer
- 1st lesion: 3/5 pathologists benign NN, 2/5 strong suspicion for MM
- 1st relaps: 2/5 benign NN, 2/5 suspicion for naevoid MM, 1/5 MM
- 2nd relaps: 5/5 nodular MM
Case 2: M 55 yrs

Conclusion:

- “Pathologist has acted as may be expected of a reasonably competent and reasonably acting pathologist”
- No indication for culpable negligence or attributable failure
- Liability not acknowledged
- Accepted by the patient after explanation of the procedure and outcome
Case 3: F 56 yrs

- Clinical suspicion of pulmonary embolism
- Hilar area right lung: tumorous lesion, PET pos
- Brush and washing: consistent with NSCLC, most likely adenocarcinoma
- Bilobectomy (middle and lower lobe R): remnants of haemorrhage with reactive changes and dysplasia of bronchial epithelium. No malignancy.
- Review cytopath: in accordance with original diagnosis of malignancy.
- Mix-up of samples excluded by DNA technology
- Expert consultation: atypical cells, however not diagnostic for malignancy
- Complaint and claim for compensation for unnecessary irreversible surgery due to a wrong diagnosis
Case 3: F 56 yrs

- Re-assessment procedure
- 5/5 cytol.analyst: malignant cells, NSCLC (without restrictions)
- 4/5 pathologists: malignant, NSCLC, most likely adeno (without restrictions)
- 1/5 pathologist strong suspicion for NSCLC
Case 3: F 56 yrs

Conclusion reassessment case 3:

“The pathologist has acted as may be expected of a reasonably acting and reasonably competent pathologist in as much as possible equal circumstances.”

No indication for culpable negligence or attributable failure. Complaint and liability not accepted.

This is not accepted by patient’s lawyer, because of he expert-pathologist’s opinion.  (Case still under discussion)
Overview of reassessment procedures (2000 – 2016)

• 101 expert examinations with re-assessment procedure
• 21 unanimous in accordance with the original (ex-post erroneous) diagnosis
• 65 unanimous not in accordance with the original diagnosis
• 15 not unanimous re-assessments
Overview re-assessment procedures, conclusions

• 39 acted as may be expected of a reasonably acting and reasonably competent pathologist in as much as possible equal circumstances (the reference person)
• 62 not acted as the above mentionend reference person
Origin of the specimens

- Skin (pigmentes lesions) 17
- Cervix uteri (cytology) 15
- Mammary gland (FNA/Histol.biopsies) 13
- Prostate (biopsies) 12
- Head/neck (incl. thyroid) (FNA/biopsies) 9
- Lymphglands (elsewhere, FNA/excision) 5
- Others 30
Take home message

• Design a procedure for expert-examinations in case of diagnostic errors, considering the pitfalls of biases threatening the “objective” re-assessment

• Have this procedure agreed with in your professional organization/society
“Life can only be understood backward, but must be lived forward”

Kierkegaard
What is the cause of the error?

Faulty Diagnosis

- System-related
  - Structures and processes
  - System error

- Human-related
  - Human cognition
    - Cognitive error
    - Faultless error

Graber Arch Int Med 2005;165:1493
Take home message

• Create an atmosphere of openness and reflection about possible erroneous diagnosis.
• Be aware and familiar with the well known risks of erroneous diagnosis of certain pathological examinations and act accordingly (double reading? use of biomarkers, consultation etc.)