

# When is the practice of pathology malpractice?

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## ABSTRACT

Because of its complex nature, surgical pathology diagnosis has an appreciable degree of fallibility and is increasingly subject to legal scrutiny. In litigation, the first practical step is to explain why and how this adversity could happen, and the second is the question of apportionment of responsibility and its legal consequences. As pathologists, we have to provide a methodology of investigation allowing a clear distinction between reasonable and unacceptable pathology practice without the twist of hindsight. For that we need to examine the different steps from test ordering to the final report. The most critical aspect of the enquiry is the act of diagnosis itself. What can reasonably be expected and what precautions have normally to be taken? Experts are often requested to re-examine the slides. For that we need a well-devised protocol enabling blinded review. Tort law has two important interconnected goals: compensation for damages and prevention of the same slip ever being made again. We can only properly learn from our mistakes if we carry out an unbiased investigation. Poor normative judgement of diagnostic failures will backfire on the profession.

*Nothing is so easy as to be wise after the event.*

Baron Bramwell, Lord Justice of Appeal (1808–1892)

Diagnostic errors comprise a substantial and costly fraction of all medical errors.<sup>1 2</sup> A wrong diagnosis by a clinical pathologist could lead to delayed or inappropriate treatment and may result in a legal action from the patient who suffered damages.<sup>3–11</sup> In this litigation, the first step is to explain why and how this adversity could happen, and the second is the question of apportionment of responsibility and its legal consequences. The normative ideal is to provide a crystal-clear distinction between reasonable and unacceptable pathology practice without the benefit of hindsight.<sup>12</sup> What obstacles may hinder us from achieving this goal?

Firstly, the most significant psychological difference between people involved in events leading up to a mishap and those called upon to investigate it after it has occurred is knowledge of the outcome, for which we need corrective procedures to achieve debiasing.<sup>13</sup>

Secondly, the victims often assume that unsafe acts arise primarily from aberrant mental processes such as forgetfulness, inattention, poor motivation, carelessness, negligence or recklessness.<sup>14</sup> This results in an inclination to overvalue dispositional or personality traits of the doctor while undervaluing situational explanations for the undesired outcome. A remedy for this is a thorough

examination of all characteristics of the diagnostic situation.

In a tort claim, the complainant must simultaneously prove the following elements: (1) the undertaking from the pathologist is recognised as a form of actionable damage; (2) the pathologist owed the patient a duty of care; (3) the pathologist's conduct was a breach of that duty because it fell below the standard of care to which a reasonable pathologist should conform; (4) the breach was the cause of the injuries the patient suffered; and (5) the injury must not be too remote a consequence of the breach.<sup>15 16</sup> We have to convert these conceptual legal concepts into practical questions. To establish breach of duty, injury and causality, courts commonly require input from an expert pathologist and sometimes other medical experts as well. The court-appointed medical specialist must understand the legal dimensions of their work and appreciate the associated rules.

Tort law has two important and interconnected goals: compensation for damages and deterrence. When a pathologist is legally held responsible for a mishap, this should warn fellow professionals to take due care—the process of adaptive learning from failures. This should prevent the mishap from reoccurring. But if we are prone to an outcome-biased judgement, the deterrence ambition of tort law may also go askew.<sup>17</sup> Poor normative judgement of diagnostic failures will backfire on the profession. The best possible causal explanation for the eventuality is needed.<sup>18</sup>

In this article, I will expound how this causal-explanatory enquiry of a pathologist's presumed wrongdoing should be performed within a legal context and stress the importance of investigating a case systematically from different perspectives. Central is the problem of how to avoid an outcome-biased judgement. Three vignettes will serve as examples of diagnostic failures. They exemplify how recognition of the incident and its subsequent emotions forms the start of a legal procedure.

## THE START: PERCEPTION OF ERROR

Misdiagnosis manifests itself when new information becomes apparent during the course of the illness or from a second opinion indicating a possible morphological misinterpretation. The three examples used here are as follows.

Case 1. A pigmented skin lesion is excised from the left lower leg of a 37-year-old woman and classified as a benign melanocytic naevus, completely excised. Two years later, she notices a swelling in her left groin, and aspiration cytology shows metastatic melanoma. Almost 6 years later, she dies from extended metastatic melanoma.<sup>19</sup>

Case 2. Because of complaints of dysuria, hesitance and a raised prostate-specific antigen level of 10.4 ng/l, prostate biopsies are performed on a 72-year-old man. The diagnosis in all biopsies is high-grade adenocarcinoma, Gleason 5+5=10. Radical prostatectomy follows. Subsequent examination of the resection specimen, however, shows extensive granulomatous prostatitis and no adenocarcinoma.

Case 3. A woman aged 35 visits her general practitioner because of contact bleeding. A cervical smear is taken. The result is Papanicolaou class II. She is reassured, but 8 months later, as the symptoms persist, she is referred to a gynaecologist. A deformed cervix uteri is observed; biopsy specimens are taken showing squamous carcinoma.

A responsible and highly trained pathologist should not make any mistakes and must therefore be held accountable, and this assumption underlies the fundamental attribution error—the victims pervasive tendency to blame bad outcomes on an operator's personal dispositions and inadequacies rather than on situational factors.<sup>20 21</sup> The mishap may also give rise to the counterfactual fallacy. Looking back, the scenario is virtually rewritten, explaining what the pathologist should have done instead, thus undoing the catastrophe ('If only...').<sup>22 23</sup> Firstly, all this leads to a firm framing effect where the occurrence is encased in wilful wrongdoing.<sup>24</sup> This representation of the problem affects the way it will be handled subsequently. Secondly, the counterfactual view of the adversity generates causal attributions and hindsight bias.<sup>25</sup> These reactions from the injured party may handicap the pathologists. The legal process starts with the recognition, definition and representation of the error problem at hand, and decision makers must perform their task unbiased to determine whether the pathologist was really negligent given the diagnostic situation.<sup>26</sup>

### THE DEFINITION OF A DIAGNOSTIC ERROR

The term 'error' is easily used in the belief that we all have the same perception of it and has at least three different action sequence-related denotations: it can mean the cause of something, the action itself, or the outcome of the action.<sup>27</sup> Without proper error definition, it is impossible to accurately count or judge errors in pathology.<sup>28</sup> A simple pragmatic definition of diagnostic error embodies those diagnoses that are missed, wrong or delayed, as detected by some subsequent definitive test or finding.<sup>29</sup> It is the outcome then that signals error, but what actually went wrong? Surgical pathology diagnosis is complex and thus prone to slips at any step in its chain of processes. Making a diagnosis is primarily a cognitive process and invariably characterised as judgement under uncertainty, albeit that the degree of uncertainty may fluctuate with the type of problem.<sup>30</sup> So, even optimally performed laboratory processing and conscientious decision making may end in a wrong diagnosis. Therefore, the result cannot invariably be diagnostic of the process (figure 1).<sup>31</sup>

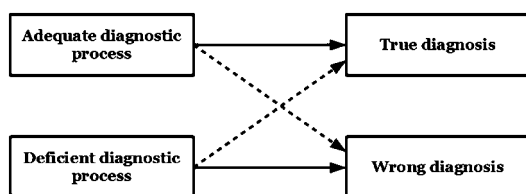


Figure 1 Possible relations between process and outcome.

We must therefore investigate the sequence of steps from the beginning of the diagnostic process—the decision to request a test—to the end—the report as it was sent to the attending clinician. This review process must be logically structured, following the sequence of events forward in time—definitely not rearward—using investigative methods that banish any outcome-related form of bias. The methodology of accident analysis was mainly developed outside healthcare, but is now finding its way into medicine.<sup>32</sup> Taking the position of the pathologist and following their work process over time, we want to find out why that particular conclusion of the diagnostic process made sense to him or her, given the situation.

### THE EPIDEMIOLOGY OF ERROR

There is no perfect test, so incorrect diagnoses are part and parcel of the practice of pathology. But how often? Misdiagnosis in pathology occurs more frequently than previously thought. One report estimates that pathology currently is operating at about a 2.0% error rate.<sup>33</sup> In that review article, major error rates ranged from 1.5% to 5.7% globally for institutional consults. Error rates also varied by anatomical site. In addition, there are also differences between countries with regard to claims against pathologists depending on cultural dissimilarities and diverse legal systems and reimbursement schemes. Reliable data for meaningful comparisons between nations are lacking.

Errors in cancer diagnosis may range from 1.8% to 9.4% and from 4.9% to 11.8% of all correlated gynaecological and non-gynaecological cases, respectively.<sup>34</sup> An analysis of 335 pathology claims gave the following 'top three': a false-negative diagnosis of melanoma was the single most common reason for a malpractice claim against a pathologist, breast biopsy claims were a close second to melanoma, and cervical test claims were third in frequency.<sup>7</sup>

Misdiagnosis is entrenched in cervical cytology, and several meta-analyses have shown an unremittingly high false-negative rate, precluding its use as a test to rule out disease.<sup>35 36</sup> In population screening, an estimated 29.3% of failures to prevent invasive cervical cancer can be attributed to false-negative Pap smears.<sup>37</sup>

An epidemiological perspective of error is important for several reasons. Firstly, quantitative knowledge of test characteristics facilitates the interpretation by the clinician of the outcome in the particular clinical context. All clinicians should be aware of the approximate base rates of false-positive and false-negative test results. Secondly, a systematic search identifies diagnostic problem areas, especially from surveys of medical malpractice claims.<sup>38</sup> Subsequently, we can scrutinise series of erroneous pathology diagnoses and look for possible explanations and putative preventive measures.

### THE AETIOLOGY OF ERROR

While looking into a mishap, we must realise that facts do not accumulate on the blank slates of investigators' minds, and data simply do not speak for themselves, so we may be prone to different types of cognitive biases.<sup>39</sup> There is also a gap between knowing that a phenomenon occurs and understanding why it does. Our possibilities for explanation are sometimes limited: explanations themselves cannot always be explained. Finally, there is the possibility of self-explanation where the phenomenon itself provides an essential part of the reason for believing that the explanation is correct. We may miss the diagnosis of melanoma because microscopic investigation of melanocytic

lesions does not allow proper distinction, but this is circular reasoning.<sup>40</sup>

### Structuring the investigation

As stated, we must structure our explanatory investigation logically and sequentially in the appropriate direction of time using the familiar chain pre-analytical, analytical and post-analytical.<sup>11–41</sup> Preferably, a protocol from a national society of pathology should be available to experts or legal committees.

#### Pre-analytical factors

##### *The motive for testing*

We use a test to either screen for disease in an asymptomatic population or find and classify disease in symptomatic persons. In addition, a test can be used to confirm disease (requires a high specificity) or to rule out disease (requires a high sensitivity). Screening for disease is by definition selecting those persons who will require additional diagnostic testing from those who will be screened during the next round. A screening cervical smear is intended neither for definitive diagnosis nor to rule out neoplastic lesions of the cervix. The false-negative rate of cervical cytology is fairly high.<sup>36</sup> The same holds for the use of smears in symptomatic women. Because of its high false-negative rate, cervical cytology is not suitable for ruling out (pre) neoplastic lesions of the cervix in a patient (case 3). The standard of care to evaluate missing a rare entity such as cervical adenocarcinoma in a Pap test connects screening process criteria with the epidemiological knowledge of an increased chance of failing to notice.

##### *The appropriateness of the specimen*

What kind of specimen was taken in relation to the clinical question and how was it handled (none or appropriate fixation)? Could the specimen be sufficiently identified (prevention of specimen mix-up)?<sup>42</sup> Explicit criteria for the suitability of the specimen in relation to the clinical question should be available, and the pathologist should report if the diagnostic material is ill-suited for the question.

##### *The suitability of the clinical information*

The inter-relatedness between pathology diagnosis and the clinical circumstances is evident. Lack of adequate information may be a source of latent causes of error. What clinical information was available? What is the clinical question? A lymph node biopsy with the question 'Metastatic disease?' in a patient with a history of rectal cancer but now with generalised lymphadenopathy may predispose to missing malignant lymphoma. In addition, is the form adequate with regard to patient characteristics, the anatomical origin and type of specimen and history? This information is essential for guiding the pathologist in both morphological interpretation and the use of ancillary techniques.

#### Analytical factors

This involves the review of all the logistic and technical processes in the laboratory involved in sampling, tissue processing, slide preparation and the appropriate use of ancillary techniques, especially immunohistochemistry. Are protocols routinely being used for defined types of diagnostic procedures—for example, the standard use of  $\alpha$ -methylacyl-coenzyme A racemase and basal cell markers such as 34 $\beta$ E12 or p63 in prostate biopsies<sup>43</sup> (case 2) or periodic acid/Schiff stains in gastric biopsies to help the detection of signet-ring cell carcinoma? What standard operating procedures are in action for proper

laboratory work-up and also to prevent labelling errors and consequent slide mix-up?

#### Post-analytical factors

After slide examination, the conclusion is formulated and then the final report is made, clerically processed and delivered to the attending physician. How is the report in terms of correctness and completeness? Computerised information systems require a check on processes of verification and authorisation, report format and proper delivery.

When assessing all these elements of the three consecutive phases it is equally important to avoid any form of hindsight effects. Laboratory and practice standards should therefore ideally be formulated ex ante to be found in handbooks, review articles or validated protocols (eg, the series of 'My approach' in this journal or the protocols regularly published in *Archives of Pathology and Laboratory Medicine*).

#### Pointing to pitfalls in diagnostic decisions

The most critical aspect of the enquiry is the act of diagnosis itself where errors may be classified into no-fault errors, system errors and cognitive errors.<sup>1</sup> No-fault errors refer to uncertainty about the state of the world and the limitations of medical knowledge. System errors consist of technical and/or organisational failures and also require investigation of organisational factors (equipment, staff, management, standard operating procedures, etc).

Cognitive errors are the most common source of diagnostic misjudgement.<sup>44–45</sup> The role of cognitive heuristics and biases in interpretation of microscope slides is important for understanding—and diagnosing—error in diagnostic pathology.<sup>46–47</sup> Here, we also encounter the competence/performance dichotomy: is this a fundamental flaw in the practice of human reasoning (limitations in competence) or does it reflect other quite different restraints (limitations in performance)?<sup>48</sup> An important source of cognitive error is premature closure of a differential diagnosis: omitting to ask questions that would reject rather than corroborate the current assumption. For instance, during diagnosis of adenocarcinoma of the prostate, Gleason grade 4 or 5 granulomatous prostatitis should be considered in the differential diagnosis and excluded (case 2).<sup>49</sup>

We still have only a fragmentary understanding of why we fail as pathologists and we should invest more in research of this problem.<sup>47</sup> Hitherto ill-understood cognitive phenomena may underlie missing in smears of rare targets such as cervical cancer in diagnostic or screening situations (cases 3).<sup>50</sup>

#### Expert slide review

Expert pathologists are often asked to re-examine the slides. How can the diagnostic operation under scrutiny be replayed without any form of outcome bias? Blinded review has been advocated in non-legal situations as a preferred means of quality control. 'Blinded' does not mean showing the slides to somebody and withholding any information; it means a true rediagnosis as if it was the first examination, and must be organised accordingly.<sup>51</sup> Within a juridical context, knowledge of the outcome may likewise influence the reviewing pathologist. In this situation in particular, a blinded review is a prerequisite for an impartial evaluation—a problem well known in both pathology and radiology.<sup>52–53</sup> On re-examination of missed morphologically determined diagnoses, the type of review can influence the outcome.<sup>54–56</sup> Visual hindsight mechanisms have been demonstrated experimentally.<sup>57</sup>

## Take-home messages

- ▶ Surgical pathology has an appreciable degree of fallibility and is increasingly subject to legal scrutiny.
- ▶ A prerequisite for a fair trial is a transparent and objective causal explanation of the mishap.
- ▶ Without proper error definition, it is impossible to accurately count or judge errors in pathology.
- ▶ Because of the after-the-fact situation, both experts and legal decision makers are prone to an outcome-biased judgement for which corrective procedures to achieve debiasing are needed.
- ▶ The explanatory investigation must be methodical and structured logically and sequentially in the appropriate direction of time using the chain pre-analytical, analytical and post-analytical phase.
- ▶ Since slide review is an integral part of the examination, we need a well-devised protocol enabling blinded review.
- ▶ We still have only a fragmentary understanding of why we fail as pathologists and we should invest more in research of this problem.

Review for legal purposes is often carried out many years after the original diagnosis. A well-established procedure is needed. In the Netherlands, the legal committee of the Dutch Society for Pathology has devised the following method. A coordinator puts five similar cases together, including the case under dispute, from different institutions, and this set of H&E-stained slides together with a form including the original clinical information is used. Then the set is presented to at least five different appropriate pathologist for routine diagnosis, who must independently assess the slides. The examining pathologists are neither informed about the reason for this review nor aware of the original diagnosis, and definitely do not know which particular case is under legal scrutiny. They are asked to examine each case, formulate their conclusion, and, if necessary, state which ancillary tests are needed. The coordinator then collects all information and extracts the five diagnoses of the index case and reports the verbatim conclusions.<sup>58</sup>

The upshot of this objective slide review procedure may be either unanimous or mixed. A varied outcome may, above all, indicate the difficulty of the case, since reasonable pathologists examining the same slide may reach different conclusions. In case 1, after referral of the patient, the slides were first reviewed with knowledge of the outcome in an academic institution where a diagnosis of nodular melanoma was made. In the blinded review procedure for legal purposes, however, none of the five reviewers made a diagnosis of melanoma.<sup>19</sup> In case 2, all reviewers made a diagnosis of granulomatous prostatitis from the H&E-stained sections. In case 3, no review was performed, and the laboratory was checked for compliance with the operating procedures and proficiency of the analysts as described in the protocol for cervical cytology.

Finally, after collection of all the different pieces of information, they must be ordered, integrated and evaluated, leading to the best causal explanation of the misclassification. When this process is carried out meticulously—with the knowledge that it is highly context-sensitive and given its proneness to interpretative bias—it forms the basis for the decision whether the pathologist was acting negligently or dutifully. This should be a concerted effort of a small group of legally trained pathologists

with experience in these affairs. Ideally, this important legal work carried out by experts should be peer-reviewed.

## CONCLUSIONS

Because of its complex nature, surgical pathology diagnosis has a degree of fallibility and is increasingly subject to legal scrutiny. As pathologists, we need to be prepared for this in several ways. On a personal level, any pathologist confronted with litigation should enter the procedure prepared, obtaining both legal and professional advice.<sup>59</sup> On an organisational level, pathologists as a professional group should also be prepared. How should we organise and document our daily work for maximum clarity when we are being held accountable? Do we have an evidence-based and well-tested multidimensional methodology for objective and systematic review of presumed diagnostic wrongdoing which is suitable for legal decision makers? Do we have a pool of trained and certified expert pathologists who can perform their task for the courts? The aim is a transparent causal explanation of the mishap. In this fair and methodical way, we can contribute to the interconnected goals of tort law: compensation and prevention. The famous words of the Danish philosopher, Kierkegaard, are especially pertinent to this situation: 'Life can only be understood backward, but it must be lived forward.'

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