

Pathology and Muluki Aain 2074

With the implementation of the Muluki Aain 2074, there will definitely be changes how a clinician will practice medicine. The pathologists are no longer exempted from medical negligence and hence will have to change our ways of practicing too. The pathologists too have to maintain a good standard of practice, ensure that laboratory staff follow appropriate guidelines and protocols, have good communication with clinicians, ensure clear documentation of procedures and results, maintain records and subscribe to appropriate, recognized quality assurance programs.

No test is perfect, so incorrect diagnoses are part and parcel of practice in pathology. But how often? This matters. Different studies have shown major errors ranging from 1.5% to 5.7% globally. Error rates vary according to different variables including anatomical site to cultures, countries, legal systems and reimbursement schemes. Error in cancer diagnosis may range from 1.8% to 9.4% and 4.9% to 11.8% of all gynecological and non gynecological cases, respectively.

Time has already come for us to structure our explanatory investigation logically and sequentially in the appropriate direction of time using the familiar chain pre-analytical, analytical and post-analytical errors. Preferably, a national protocol should be available to the experts or legal committees investigating the legal matters.

1. Pre-analytical factors:

The motive for testing

Is the test a screening test or for diagnosis in a symptomatic patient? For example cervical pap smear is for screening purpose not for definitive diagnosis nor to rule out neoplastic lesions of the cervix. The False negative rate of pap smear is fairly high. Due to this reason cervical cytology in a symptomatic woman to rule out neoplastic lesions of the cervix is not a good choice of test which may give false negative results especially in cases of rarer neoplasms like cervical adenocarcinoma.

The appropriateness of the specimen

What kind of specimen was taken in relation to the clinical conditions. How was the specimen handled- was the fixation appropriate? Was the identification number of the specimen correct to prevent mix up? Criteria for suitability of the specimen should be available and the pathologist should report if the diagnostic material is ill-suited for the clinical condition.

The suitability of the clinical information

Pathological diagnosis and clinical history is inter-related. Lack of adequate information may be a source of latent cause of error. What clinical information was available? What is the clinical diagnosis? The form should have adequate information about anatomical site of the specimen, type of specimen and complete history of the patient. This information will guide the pathologist in morphological interpretation as well as use of further ancillary techniques.

2. Analytical Factors

This involves all the logistic and technical processes in the laboratory involved in sampling, tissue processing, slide reparation and appropriate use of ancillary techniques. It should be confirmed that the standard operating procedures are strictly followed which helps to prevent labelling errors and consequent sample/slide mix up in clinical laboratory / histopathology.

3. Post-analytic Factors

After the test is performed or the slide is examined the conclusion is formulated and then the final report is made, clerically processed and delivered to the treating clinicians. How is the report in terms of correctness and completeness? Computerized information systems requires a check on process of verification and authorization, report



format and proper delivery.

Pitfalls in diagnostic decisions

The most critical aspect of the enquiry is the act of diagnosis itself where errors maybe classified into no-fault errors, system errors and cognitive errors. No-fault errors refer to unforeseen errors which is impossible to prevent even by the most careful practitioner. System errors consists of technical and/or organizational failures and also require investigation of organizational factors (equipment, staff, management, standard operating procedures etc). Cognitive errors are the most common source of diagnostic misjudgment. The role of cognitive heuristics and biases in interpretation of microscope slides/results is important for understanding – and – diagnosing – error in diagnostic pathology. 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) ? An important source of cognitive error is premature closure of a differential diagnosis: omitting to ask questions that would help in exploring different differential diagnosis.

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. On an organizational level, pathologists as a professional group should also be prepared.

How should we organize 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.

References:

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