



Diagnostic errors in pathology

The primary role of the histology laboratory is the provision of a diagnostic service through the preparation, analysis and interpretation of tissue samples. Given that the procedures involved are so complex, it is inevitable that errors will transpire throughout the entire process. Identifying those errors and their root causes in the clinical setting can be perplexing. Often partitioned into clerical, processing, technical and documentation categories, errors in cellular pathology are more traditionally subdivided into pre-analytical, analytical and post-analytical phases. Although there is often confusion as to what stages constitute each phase, pre-analytical phases are generally those processes that are involved from the collection of the tissue samples through to their arrival in the dissecting room following accessioning and data entry. The analytical phase relates to the actual carrying out of laboratory testing from tissue dissection through to the stained slide. Lastly, the post-analytical phase includes those actions that follow the analytical phase such as clinical interpretation, the pathology report and the regulation of storage, retention and disposal of tissue samples.

The pre-analytical phase encompasses many stages including the time prior to receipt of the sample in the laboratory (such as transportation from clinics and operating theatres). Since these stages regularly involve handling of the specimen by countless individuals, pre-analytical stages are related to one of the higher incidences of error and are often more complex to manage. Furthermore, the analytical errors that can occur during the preparation of a single stained and labelled slide from a tissue sample are so significant that the education and training of staff on their occurrences, causes and remedies is paramount (see Table below).

The process known as root cause analysis is a structured investigation often used as a means of identifying not only the source of errors but the actions that are required to eradicate them.

Essentially, the purpose of it is to understand in detail what happened, why it happened and what could be done to prevent it happening again. To be effective, the methodology should be applied to all areas where errors can occur during the entire histological process from the receipt of sample in the laboratory to the typing and dispatch of the final histology report. Any information characterizing the occurrence of these errors is essential in providing strategies for both reducing and preventing them.

Receipt of sample	Data entry	Tissue dissection	Tissue processing	Embedding	Microtomy	Staining	Mounting, QC and dispatch
No tissue received in specimen container	Sample and request form allocated wrong number	Request form and specimen match not performed	Tissue not sufficiently fixed prior to processing	Tissue contaminated during embedding	Tissue lost during section cutting	Oven drying time of slides inadequate	Loss of tissue from slide during mounting
Specimen received without formalin	Sample and request form given different laboratory numbers	Specimen containers wrongly numbered	Tissue processing reagents contaminated	Samples mixed up during embedding	Identification mix-up of block	Staining reagents in the wrong order or out of date	Slides incorrectly labelled
Tissue samples received in wrongly sized containers	Sample and request form allocated to wrong patient on LIMS	Cassettes labelled with different laboratory number to specimen	Tissue processing reagents in the wrong order	Tissue orientation incorrect	Block cut at wrong thickness	Wrong staining programme selected	Slides broken
Number of samples not consistent with request form	Data entered incorrectly on LIMS	Sub-numbering of cassettes incorrect	Tissue processing incomplete	Tissue lost during embedding	Paraffin section floated onto wrong side or slide	Sections detached from slide during staining	Quality control not performed on stained sections
Incomplete or incorrectly labelled request form or specimen		Tissue lost or contaminated during dissection	Incorrect programme selected		Paraffin section mounted incorrectly	Sections contaminated during staining	Slides and request forms wrongly ordered
Labelling on sample and request form not matching		Tissue inadequately fixed or decalcified	Tissue lost during processing		Paraffin section contaminated during floating	Slides broken during staining	Slides wrongly allocated or not delivered

Errors that occur in the histology laboratory

One of the areas that is particularly vulnerable to error in the histology laboratory is the manual entry of digital information whether it is onto laboratory information management systems, specimens, tissue cassettes or slides. Because histology sample numbers during accessioning are consecutive and composed of digits that differ only slightly from those found on adjacent samples, mistakes are inevitable. This predicament is often seen at the microtome where multiple paraffin blocks bearing similar numbers are found cooling on ice trays prior to sectioning, often onto pre-labelled, hand-written slides. The problem, however, has largely been overcome with the introduction of bar-coded labels and scanners into the process, substantially decreasing the errors in this area.

Over the years, pathology laboratories have implemented a variety of control measures aimed at reducing the risk of cross-contamination of tissue. Many laboratories often avoid the serial numbering and dissection of similar specimen types; for example, gastric biopsies would be interspersed with other tissue types in order to reduce the risk of cross contamination during dissection from similar adjacent specimens. Also, the use of different coloured cassettes for specific tissue types can also help to minimize this problem. But without doubt, general tidiness and cleanliness of dissecting tools and benches, microtomes and water baths are often all that are required in preventing the cross contamination of tissue samples. Standard operating procedures pertaining to laboratory testing and analysis of tissue samples are in place as part of the training, accreditation and inspection practices. These standards together with appropriate internal and external quality control schemes are an integral part of quality management systems which together help to eliminate the root cause of errors in the histology laboratory.

The role of the pathologist

Although the histology diagnosis plays an important role in the treatment of disease, errors do occur. Diagnostic fallibility, for example, is an expression of error and when inaccuracies are present in the histology report, they can critically affect the outcome and care of the patient. Errors in fallibility are categorized either as oversights (where significant pathology is missed) or misinterpretations (where changes in pathology are interpreted incorrectly). While fallibility is an expression of error, credibility is the extent to which diagnostic opinions can be believed. In contrast, plausibility questions the consistency that exists between the histology diagnosis and the clinical picture.

Excessive workload and human error are often common factors for potential in diagnostic fallibility. There is always the possibility that an error in diagnosis can give rise to damage accountability and the signature on the histology report will sanction that diagnosis. If the mistake was a consequence of an error of judgement (rather than the result of negligence or incompetence), it would show that the pathologist was exercising the same capability and understanding of that disease process as any other pathologist with the same level of knowledge and experience would have. Not all histology samples have the same diagnostic challenge and with many pathologists having different areas of speciality, it is often a difficult undertaking to be able to compare their levels of expertise.

As part of a risk management strategy, referral of difficult cases, peer review auditing and attendance at multidisciplinary team meetings can all help to improve the diagnostic standards and hence minimize the risks of an incorrect diagnosis. Likewise, the monitoring of technical staff through training, continued competency and proficiency testing in the laboratory is essential in maintaining an error and risk-free environment.

Further reading

1. Achieving high reliability in histology. An improvement series to reduce errors. Heher YK et al. Am J Clin Pathol 2016;146(5):554-560 <https://www.ncbi.nlm.nih.gov/pubmed/28430956>
2. Analysis of errors in histology by root cause analysis: a pilot study. Morelli P et al. J Prev Med Hyg 2013;54(2):90–96 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4718384/>
3. Error and error reduction in pathology. Sirota RL. Arch Pathol Lab Med 2005;129(10):1228-1233 <https://www.ncbi.nlm.nih.gov/pubmed/16196509>
4. Errors: Detection and minimization in histopathology. Karki S. Journal of Pathology of Nepal 2015;5:859-864 <https://www.nepjol.info/index.php/JPN/article/viewFile/15643/12600>
5. Mislabeling of cases, specimens, blocks and slides. Nakhleh RE et al. Arch Pathol Lab Med 2011; 135(8):969-974 <https://www.ncbi.nlm.nih.gov/pubmed/21809987>
6. Specimen labelling errors in surgical pathology. Layfield LJ & Anderson GM. Am J Clin Pathol 2010;134(3):466-470 <https://www.ncbi.nlm.nih.gov/pubmed/20716804>

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