Safety practices in surgical pathology: practical steps to reduce error in the pre-analytic, analytic, and post-analytic phases of surgical pathology

Joseph A Tworek

Abstract

The production and interpretation of a haematoxylin-eosin stained slide from a patient specimen is a complex, multi-step process. An error within any of the steps may cause patient harm. The steps in this process can be divided into the pre-analytic, analytic and post-analytic phases. This paper will review benchmarking and published error rates, where available, across all three phases. Practical, evidence-based, methods to reduce errors in all three phases will be discussed with emphasis placed upon the benefits and limits of benchmarking and six-sigma. The concept of striving for zero defects through lean production methods and the Toyota Production System will be discussed as it applies to all three phases of surgical pathology.

Keywords error; lean; Toyota Production System; quality assurance; surgical pathology

Introduction

Given its labour-intensive nature, surgical pathology is prone to errors. Many of these errors are minor or are corrected before final release of the final surgical pathology report, but some errors have the potential to cause devastating clinical consequences. Errors may occur across all phases of the process of surgical pathology.[1] The frequency of many of these errors is often unknown with only relatively few benchmarking studies available. The process of surgical pathology can be conveniently broken down into the pre-analytic, analytic, and post-analytic phases. This paper will focus upon tactics and practical suggestions, some based on concepts from the Toyota Production System, to reduce errors in all three phases. Key elements to error reduction in surgical pathology include understanding where and how frequently errors occur in the process of surgical pathology and to adopt methods to reduce errors. Mapping the production system, measuring errors, and benchmarking error rates can identify potential sources of errors. Once the system is understood, changes can be implemented to improve the process to reduce errors. For this paper, the pre-analytic process includes the process of receiving and preparing the surgical specimen to be analysed by the pathologist. The analytic process includes interpretation of the slide by the pathologist, and the post-analytic process involves conveying results to the clinician.

Joseph A Tworek *MD is at the Saint Joseph's Mercy Hospital, Department of Pathology, 5301 East Huron River Drive, PO Box 995, Ann Arbor, Michigan, USA.*

Mapping the system

Mapping and observing the production process to reduce waste and error is one of the key elements to the Toyota Production System, which is increasingly being applied to surgical pathology.[2,3] The Toyota Production System is appealing as it stresses a zero-defect environment, and has been successfully applied to surgical pathology with a reduction in waste and error.[4,5] A full discussion of this system as it applies to surgical pathology is beyond the scope of this paper, but key elements are discussed and highlighted in a practical often low-tech approach to error reduction. It is the author's opinion that the Toyota Production System need not be adopted in its entirety to effectively reduce error but key elements can be adopted to strive for a zero-defect rate in the critical areas of the histology laboratory such as lost specimens, specimen mix-ups and specimen identification.

Diagrams of workflow pathways should be produced by physically observing all phases of the workflow. This would entail following specimens as they were received within the laboratory through: patient registration; accessioning; labelling of specimen containers with accession numbers; preparing cassettes; grossing and embedding the specimen; specimen microtomy; labelling, staining and delivery of the resultant slides to the pathologist; dictation of the case by the pathologist; and release of the final pathology report. The Toyota Production System emphasises that employees within each part of the production process focus their energies on providing a quality product for their customer.[2] Most immediately their customer is their colleague in the next step of the production process and ultimately is the patient. For example, it is the responsibility of the person preparing the gross of an oriented skin specimen to ensure that a case is properly inked for the person who will be embedding the specimen. The person embedding can then properly orient the specimen within the paraffin mould for the microtomist to cut the block to supply the pathologist with the appropriately oriented sections on the slide so that he or she can properly evaluate the margins of excision.

Observing and mapping this process will generate a list of requirements that each customer needs to provide a quality product. Similarly, a list of potential errors that affect these requirements will also be generated. Once the potential sources of error are identified, process improvement steps can be put into place to minimise the chance of error. An additional benefit of mapping the process is that areas of waste and redundancy may also be identified to help streamline the process. A streamlined process will reduce waste and save energy that can be expended in efforts elsewhere to deliver a quality product.

The zero-defect commitment of the Toyota Production System is the backbone of the lean production system and the concept of six sigma. Six sigma is the ability to produce a product with less than 3.4 defects per one million opportunities, that is, the production process should produce products without defects within a tolerance of variation of six sigmas or six standard deviations.[6] Six sigma is a hallmark of world-class manufacturers, and the six

sigma methodology consists of the steps: 'define, measure, analyse, improve, control'. Average manufactures have a sigma value of about 4, which corresponds to an error rate of 6210 errors per million opportunities. Clinical laboratories typically has a sigma value of 3 (66,807 errors per million) to 4, while the domestic airline industry runs a fatality rate of 0.43 parts per million.[6] This is due to their commitment to zero fatalities.

Measuring error is important to reducing the error rate in the laboratory. A list of potential errors and an error report form from the author's laboratory is listed in Table 1 and Figure 1, respectively. This is modified from Brown in *Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction*.[7] This is an excellent reference and guide to running an anatomic pathology laboratory. Given the many types of error, an error-free laboratory is probably not achievable across all categories. In the author's laboratory, we strive for zero defects in the critical areas of specimen identification, specimen mix-ups, and loss of a specimen or tissue from a specimen. Across the other error categories form Table 1, a laboratory should use benchmarks when available to identify unacceptable performance, and when not available, a laboratory should monitor the rate of defects over time and benchmark against themselves.

Benchmarking

Benchmarking is a powerful tool in the maintenance of quality.[8] It allows comparison of local error rates to an external standard drawn from many laboratories or from a few best performers. It allows for identification of errors, and to determine where best to allocate resources to address the most serious or common errors. By participating in benchmark studies, best practice patterns may also be established to reduce error rates. Furthermore, benchmarking a quality metric allows one to determine over time how change within a laboratory, such as increased specimen volume, affects performance. This may give a laboratory manger objective data to lobby for resources from administration or to compel employees to adopt best practice patterns to reduce error. Another benefit from participating in benchmark studies is that participation in these studies lead to continuous improvement over time. This effect has been clearly demonstrated in the Q-tracks program of the College of American Pathologists (CAP).[9–11] Many benchmarks are not available for quality parameters in surgical pathology. In this situation one should benchmark against one's own laboratory, and seek to improve over past performance.

Some of the potential drawbacks of benchmarking include that often it is not clear from studies what specific factors lead to better improvement. Additionally, there is a risk for complacency by accepting or seeking established benchmarks. This is particularly problematic when dealing with critical errors of patient misidentification, specimen mix-ups, and lost specimens or lost tissue from a specimen. In these categories, the laboratory should strive for zero-defect rate.

Pre-analytic phase

Established benchmarks

In the pre-analytical portion of surgical pathology, some benchmark data are available through the CAP Q-probe and Q-tracks programs for a handful of parameters. These include deficiencies in specimen identification and accessioning, discrepant or missing clinical information and extraneous tissue.

List of potential errors in the anatomic pathology laboratory and their codes

Grossing

G1 No Specimen in container
G2 Mislabelled specimen
G3 Incomplete requisition
G4 Illegible requisition
G5 Incorrect orientation
G6 Tissue pick-up
G7 Mislabelled block
G8 Too much tissue in block
G9 Too much ink
G10 Specimen not completely inked
G10 Staples in specimen
G11 Tissue not completely bisected/dull blade

Fixation/processing

F1 Poor fixation
F2 Inadequate processing

Embedding

E1 Uneven tissue
E2 Air bubbles
E3 Froth artefact
E4 Missing tissue/specimen
E5 Extra tissue outside of cassettes

Distribution of slides and paper work

D1 Gross does not match block
D2 Incorrect paperwork

Microtomy

M1 Knife lines
M2 Chatter
M3 Cracked/torn section
M4 Section too thick
M5 Folds
M6 Uneven spacing
M7 Extraneous tissue/floater
M8 Incomplete section
M9 Thick/thin
M10 Tissue between sections
M11 Slide mislabelled/number not legible

Staining and cover slipping

S1 Staining too light
S2 Staining too heavy
S3 Uneven staining
S4 Air bubble
S5 Cover slip scratched
S6 Section cloudy

Adapted with permission from Brown.[7]

Table 1