Quality assurance in anatomic pathology

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Abstract

We are in the midst of major changes in our discipline. New technologies and regulations, are poised to fundamentally change the way that pathologists interact with and utilize data. Nowhere is this more apparent than in the realm of anatomic pathology (AP) quality assurance (QA). QA efforts in the AP laboratory today are often limited by the batched assembly line-like nature of the workflow and data trapped within rigid laboratory information systems (LIS). Middleware with progressive business intelligence platforms have helped close this gap by automatically extracting LIS data, and making it easier to manipulate and combine with data from other information systems. Employing informatics tools such as tracking systems in the AP lab minimizes human involvement in repetitive processes which in turn drives down errors, standardizes processes and drives workflow. Scanning barcodes directly inputs data into the LIS which is available for real-time QA monitoring. The use of synoptic reporting, computerized provider order entry (CPOE), and newer technologies such as whole slide imaging also help improve quality in AP. This article reviews current issues and future trends related to AP initiatives in the preanalytic, analytic, and postanalytic phases of laboratory testing. Special emphasis is placed on new technologies that are poised to disrupt the practice of AP in the near future.

Keywords aplis; cpoe; informatics; process management; qa; qc

Introduction

Production processes are — as a rule — iterative mechanisms by which raw materials are progressively converted into end products. The production processes of medicine are no exception to this rule; though each clinical workflow has unique features, they are all related by which observations, tests, and procedures get converted into knowledge, action, and (ideally) better patient outcomes. Manufacturing industries — particularly the automotive industry — have historically taken the lead in applying workflow analysis and quality management tools to their production processes, thereby reaping the benefits of increased efficiency, consistency, and decreased waste. Medicine has historically lagged behind in this regard, but with the ubiquitous presence of computerized data and analytic as well as tracking systems being embedded in our workflow, we have recently seen tremendous innovation and advancement in medical quality management.[1]

Nowhere is this more evident than in our discipline of Pathology. Of all medical workflows, ours perhaps bears the most similarity to industrial production processes: we convert certain raw materials — *e.g.* human samples — into end products — *e.g.* pathology reports with actionable clinical knowledge — in a series of well-defined steps. Of these steps, the vast majority are pipelined batch processes that perform modifications (*e.g.* formalin fixation, paraffin embedding, microtomy) on raw material (*e.g.* a surgical pathology tissue block) until said raw material has been transformed into a microns-thick layer of stained human tissue mounted on a coverslipped glass slide. It should come as no surprise, then, that this inherent similarity between industrial production lines and the pathology test process has encouraged widespread adoption of industrial quality management and improvement initiatives in pathology laboratories around the world.[2—4]

The specifics of any given production process are largely dependent on the nature of both the raw materials and the desired end products. Hence, different pathology specialties have somewhat different associated workflows. However, all pathology workflows have the following characteristics in common:

- Test process involves three phases:
  - Preanalytic
  - Analytic
  - Postanalytic
- Workflow consist of a series of intermediate steps of variable complexity
  - Some steps can be automated
    - Example: printout of a labels
  - Some steps follow a rigid algorithm, but require human intervention
    - Example: case assembly (matching slides with related paperwork)
  - Some steps require a large amount of manual work by a skilled artisan
    - Example: gross examination of a specimen
- Test process has certain unavoidable built-in waiting periods
  - Example: formalin fixation time
- Workflow is supported by a laboratory information systems (LIS)

Currently, electronic medical record (EMR) systems — anatomic pathology laboratory information systems (APLIS) among them — are predominantly monolithic units sold by individual vendors who have little interest in providing the end user with flexibility or interoperability (even among products *sold and supported by the same vendor*). As such, quality assurance (QA) projects in pathology (and indeed in medicine in general) are almost always as much about working around the rigid limitations of the system, or exporting data out of these systems for easier manipulation and analysis as they are about actual improvement in workflow. This fact represents one of the great ironies — and tragedies — of our story: we have, in a very real sense, become

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slaves to the very systems that supposedly make our — and, through us, our patients' — lives easier.[5] Nevertheless, given that most of our data is housed in databases within the APLIS this is where we need to mine our data in order to obtain information about particular quality indicators. For example, the timeliness of specimen transportation can be assessed by comparing the date of specimen procurement recorded in the LIS with the date received by the laboratory. Turnaround time for any laboratory test, including a frozen section, is often considered to be a significant quality component in the laboratory service industry.

Anatomic Pathology (AP) has, largely due to the nature of its specimens and the operations that must be performed on those specimens, traditionally lagged behind Clinical Pathology (CP) in its quality management. With the relatively recent advent of technologies such as barcoding and radiofrequency identification (RFID) tagging, as well as digital imaging, new possibilities for quality improvement have opened up. Indeed, certain pathology departments — most notably the one at the Henry Ford Hospital System (Detroit, Michigan, USA) — have now developed and adopted quality management programs that bear a striking resemblance to those seen in the automotive industry.[6] There is much that we can learn from the successes — and, just as importantly, the failures — of these quality management programs.[7] This review article will proceed through the successive steps in the AP workflow (preanalytic, analytic, and postanalytic phases) noting areas for (and barriers to) possible quality improvement.

Preanalytic phase

The AP preanalytic phase involves the handoff of a medicolegal entity (the specimen) from one system with a very specific set of priorities (the surgery team) to another system with an often very different set of priorities (the AP team). In the operating room or clinic, information critical to proper handling and routing of specimens is recorded by individuals who (a) are often not doctors and (b) likely have had no training in pathology (*e.g.* nursing staff) — and who thus cannot be expected to understand what clinical information would be most relevant to the downstream pathologist. Errors that arise from this — including improper labelling and improper orientation of specimens — are often beyond the power of the AP team to catch at the time they are made, unless the AP team was to take the unprecedented step of embedding someone trained in properly accessioning and orienting specimens in every operating room, clinic or doctors' office from which specimens are received. Though this would have obvious benefits, the manpower costs, especially in large facilities, is prohibitively high. For certain laboratories, interaction with specimens may occur prior to accessioning when couriers collect containers at distant sites which already have pre-printed labels on them generated by the APLIS.

Therefore, the first interaction the AP team has with a specimen is customarily at the time of its receipt in the AP laboratory, usually with a printed requisition. Once the case is received, a human is required to manually accession the case, during which (a) the APLIS assigns it a unique accession number and (b) related information from the requisition is entered into the APLIS. In multipart cases, each part is entered and documented separately.

Errors that arise during this phase fall within the following categories:

- Patient identification
- Patient history
- Specimen identification
- Specimen adequacy
- Specimen handling
- Specimen transportation
- Accessioning

In other words: during a flawless execution of the preanalytic phase, the proper specimen is taken from the proper patient; this specimen is then properly identified, labelled, handled, and transported to the AP lab; finally, the specimen is properly accessioned. Currently, every single step in this sequence of events requires at least some (and in many cases, extensive) human intervention, and is thus fraught with opportunity for error. Further complicating this is the fact that most errors in the preanalytic phase (except for those associated with accessioning) occur before the specimen ever reaches the pathology department, providing limited opportunity for QA. While this is technically true, it speaks to the need for laboratory information systems to be very tightly integrated with not only the hospital system's EMR, but also positive patient identification technologies supported by said EMR.[8,9]

Patient identification

Modern (primarily barcode-based) positive patient identification technologies are well-studied, and are known to demonstrate a tangible decrease in error rate when implemented. The ubiquity of barcode-based identification systems — as well as the inherently non-integrated nature of most EMR solutions — often leads to situations in which the point-of-care EMR and the LIS generate barcodes that look very similar, but encode entirely different kinds of data. The resultant proliferation in non-unified patient identification bands and stickers is known to be a persistent source of error, and efforts to standardize positive patient identification have been shown to significantly decrease error rates — by almost 50% in some studies.[10]

The shortcomings of positive patient identification technologies are largely confined to the following scenarios:

- The identification medium is degraded to the point that there are read errors
- The system that holds the patient identification data is offline
- Different barcoding systems with similar symbologies are in use by different clinical subsystems, resulting in the wrong barcode being read into the patient identification system
- The patient identification data in the system are incorrect
- The wrong wristband/sticker is applied to the patient/patient record

The first scenario represents a shortcoming of the technology in its usage environment, and can therefore be minimized, but not entirely eliminated. Proper selection of wear-resistant barcode printing (and proper maintenance of barcode printers, with specific emphasis on the print heads) can help avoid read errors due to degradation. Data can be redundantly encoded in such a fashion that it can still be perfectly read even with the effacement of a large part of the original barcode; in the case of two-dimensional Quick Response (QR) codes, for instance, up to 30% of an individual barcode can be destroyed before content is lost. Positive patient identification technologies that are not dependent on printing at all [*e.g.* radiofrequency identification (RFID) tags] are under active investigation and may provide solutions to the shortcomings of