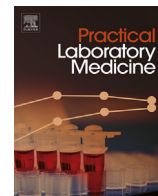


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Crucial role for pathology residents in laboratory self-inspection, a single Institute's experience



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ABSTRACT

Background: Training in patient safety, quality, and management is a key component of Graduate Medical Education (GME) training in all specialties. However, residency programs, especially Pathology programs, often find it challenging to create strong learning opportunities in these areas.

Objectives: Focused quality assurance (QA) projects are one approach to teach and engage trainees in these key areas. Residents have been historically involved in different QA projects in our department but mainly in small secondary roles. Leading a large QA project that can enhance residents' management skills and improve clinical operations in our laboratory was the main objective of our project.

Description: A new process for laboratory self-inspection led by residents was implemented that simulates the exact process of a formal outside College of American Pathologists (CAP) inspection. We aim to prove that resident-led QA activities not only have profound educational benefit but can also result in significant performance and operational improvement.

Results: For this paper, we focus on the Histology laboratory since the ramifications from the self-inspection process during a three year period were profound leading to change in management, workflow changes, and notable improvement in staff morale.

Conclusion: The self-inspection process exposed the residents to operational issues and corrective actions that provided them the opportunity to take a more active role in laboratory management and helped prepare them for post-graduation challenges. It also helped the department identify and rectify many operational issues, confirmed by the enumeration of CAP deficiencies and significant improvement of staff morale.

1. Introduction/background

The practice and concept of Pathology and Laboratory Medicine has evolved significantly during the last few decades, where pathologists were only focused on establishing diagnosis, to the current status of active participation and involvement in patient management and institutional leadership. Management, leadership, and informatics skills are increasingly important for pathologists in academic and private practice. Unfortunately, laboratory management has repeatedly been described in multiple surveys as an

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educational weakness in Pathology residency training programs across the United States in about 65% of the programs [1]. One month of laboratory management rotation in the third or fourth year of Pathology residency, which is in many institutes mostly based on online courses and self-study material, is not sufficient for training future leaders or laboratory directors. Recently graduated Pathology residents rank laboratory management/administration among the top areas in need of improvement due to insufficient residency training [2,3]. A survey of 75 community hospitals' pathologists indicated that skills in management and informatics are considered essential or advantageous for new pathologists they seek to recruit [4]. As such, many employers put an emphasis on laboratory management/administrative knowledge as one of their requirements for hiring medical directors in the different areas of the laboratory.

Publications by the American Pathology Foundation (APF), the American Society of Clinical Pathology (ASCP), the Pathology Residency Training Program Directors (PRODS) section of the Association of Pathology Chairs (APC), and Academy of Clinical Laboratory Physicians and Scientists (ACLPS) have detailed the objectives of a curriculum in laboratory administration [5,6]. However, the challenge is how to incorporate those learning objectives into Pathology residency training programs, where training in many programs is more Anatomic Pathology (AP) biased even if they are combined Anatomic and Clinical Pathology (AP/CP) programs. Web-based learning such as the ASCP Laboratory Management University and the College of American Pathologists (CAP) Virtual Management College have been created to help provide curriculum material for learning laboratory administration, but this cannot replace active mentoring or hands-on experience.

In our program, residents have been historically involved in different Quality Assurance (QA) projects, but mainly in secondary, non-influential roles. Leading and championing a large QA project was a rare occurrence until a decision was made to revamp our laboratory self-inspection process. In this paper, we propose that resident-led QA activities not only have profound educational benefit but can also result in significant performance improvement as determined by conventional measures of laboratory quality such as enumeration of CAP deficiencies.

2. Description of the self-inspection process

As with many CAP-accredited laboratories, an outside peer-based inspection occurs every two years with the requirement of having a self-inspection in the years the outside CAP inspection does not occur. The report of the self-inspection is sent to CAP along with the corrective actions for any identified deficiencies. Our self-inspection process every two years mainly consisted of the division medical director and senior supervisor inspecting their own division and providing our laboratory compliance officer with any identified findings. In 2014, our department leadership elected to revamp such a process in response to concerns raised by our laboratory compliance officer about the lack of actionable or comparative findings to the outside CAP inspection. Moreover, staff complaints and whistle-blowing events were received from different areas of the laboratory, more worrisome from the histology laboratory, which prompted the need for an intervention and a more scrutinized self-inspection process.

The concept of the new process mainly relies on simulating the exact process of a formal outside CAP inspection by having teams cross-inspecting other divisions instead of our historical routine self-inspection. Each team is championed by a Pathology faculty member but led by a senior Pathology resident aided by a junior resident, a supervisor, and a Clinical Laboratory Scientist (CLS). The senior supervisors were generally at the receiving end of the inspection process. A dedicated day was selected for the inspection and all residents were officially relieved from their clinical duties across the different affiliated campuses. At the end of the inspection day, a summation session was scheduled that was attended by staff members, department leadership, including the department Chair, and select hospital leadership. Teams were assigned to each area of the laboratory based on the CAP checklist. The inspectors were instructed to go over each listed item in detail but not to be restricted to just the checklist. In preparation for the inspection, residents and staff had to review the CAP checklists of their inspection area and actively participate in a few pre-inspection meetings to coordinate with other team members and the faculty champion. As an inspection team member, all staff members and residents successfully completed their online training and received their CAP inspection team member certificate. The overall success of the new structure for self-inspection in 2014 prompted the department leadership to adopt that process for all ensuing self-inspections and even prior to the official CAP inspection window as a method of preparation.

In this paper, we will focus on the histology laboratory for the following reasons: it was the laboratory with the most phase 2 deficiencies in the first self-inspection, staff engagement surveys were among the lowest of all divisions, several complaints from the staff were received regarding poor management of the laboratory, and a whistle-blowing event was received pertaining to quality-related issues that could have an effect on patient care. We will review all the inspections of the Histology laboratory during the three year span from 2014 to 2017.

3. Impact of the new self-inspection process

Since 2014, four histology laboratory self-inspections (November 2014, August 2015, November 2016, and October 2017) and two CAP outside inspections (November 2015 and October 2017) have occurred (Table 1). In the first inspection (self-inspection November 2014), a tedious and very detailed inspection took place given the whistle-blowing events received and staff complaints about management of the histology area at the time. The inspection was led by a fourth-year pathology resident and led to the discovery of 11 phase 2 deficiencies. The 11 deficiencies were the most cited in any area of the laboratory during the inspection day.

The ramifications of the histology laboratory self-inspection results were profound. The number of phase II deficiencies, when added to the staff complaints and whistleblowing events, pushed the department leadership to pursue significant changes in AP and histology laboratory personnel, management, procedures, and processes. As such, a new AP manager and new histology supervisor were recruited. The laboratory compliance officer worked closely with the new recruits to rectify most of the processes in the histology laboratory and

Table 1
Histology laboratory deficiencies since 2014.

Deficiency	Phase	Description
CAP self-inspection (November 2014)		
GEN.55900	II	Lack of consistent adherence to semiannual competency training of new employees.
COM.30300	II	Some reagents not labeled.
COM.30450	II	Parallel testing for lot confirmation records are incomplete for special stains.
ANP.8216	II	Formalin and xylene exposure monitoring was not done for new personnel.
ANP.21450	II	No documentation or validation records for some special stains.
ANP.22956	II	No validation records for in situ hybridization testing for kappa and lambda.
ANP.22964	II	No documentation of controls used for EBV testing by in situ hybridization.
ANP.23410	II	No decontamination policy for cryostat in histology lab.
ANP.21850	II	No documentation of utilization of immunofluorescent control.
ANP.22979	II	HER-2 testing is not being repeated on a separate block in cases of histologic discordance.
ANP.22500	II	Missing quality control records for buffers for the months of July and August.
CAP self-inspection (August 2015)		
ANP.08216	II	Formalin and xylene exposure monitoring was not done for rotating residents.
ANP.24300	II	No policy for CJD special tissue handling.
ANP.21050	II	Some blocks with handwritten labels did not have two patient identifiers.
ANP.23410	II	No decontamination policy for cryostat in histology lab.
ANP.22985	I	No procedure for decalcified tissue for predictive marker testing.
CAP formal inspection (November 2015)		
COM.04000	II	One part of quality assurance policy has not been followed. No records reflecting conformance with the program as designed.
CAP self-inspection (November 2016)		
None		
CAP self-inspection (Early October 2017)		
None		
CAP formal inspection (Late October 2017)		
None		

develop a corrective action plan for all the deficiencies cited during the 2014 self-inspection and ensuing inspections. Some of the corrective actions included updating the entire Surgical Pathology QA program, reviewing and updating all histology standard operating procedures (SOPs), validating/revalidating all immunohistochemistry and in situ hybridization probes, acquiring fully-automated slide and paraffin block labelling machines, ensuring formalin and xylene testing for all staff and residents rotating in histology, producing new competency training forms to ensure annual competency training for all employees and semiannual training for new employees, establishing a properly documented policy for immunofluorescence control utilization, establishing a reproducible process for surveying and labelling reagents and buffers, establishing a proper decontamination policy for the cryostats, updating the SOP for proper handling of Creutzfeldt–Jakob disease (CJD) cases, and ensuring proper documentation for every process in the histology laboratory. Once concerns were addressed and all process changes occurred, that led to increased staff morale and engagement, which proved to be the main catalyst for the rapid positive changes observed in the histology laboratory.

The subsequent inspections showed a nice downward trend in terms of the number of deficiencies reflecting the process improvement within the histology laboratory. In 2015, the self-inspection in August prior to the CAP inspection window revealed 4 phase II deficiencies and 1 phase I deficiency. The ensuing CAP inspection in November of the same year showed 1 phase 2 deficiency. Subsequent inspections, including self-inspection November 2016, self-inspection early October 2017, and CAP inspection late October 2017 identified no deficiencies within the histology laboratory (Table 1). Furthermore, staff engagement surveys received during these years show significant upward trend in staff satisfaction and engagement. No staff complaints or whistle-blowing events were received during that time.

4. Discussion

Pathology residency training programs have historically excelled in producing well-trained diagnosticians, especially in Anatomic Pathology, but have not reproduced the same quality in training medical directors with other much needed “non-Pathology” skills or better referred to as “supra-Pathology” skills, which include skills in management, communications, quality assurance, and finances among others. As such, an evident gap has developed between the acquired skills of recently graduating pathologists and the expectations of their new employers. The White Paper produced by CAP and APC emphasized the importance of developing skills in strategic planning, budgeting, operations management, coding and billing, contract negotiations, and the interaction of pathologists with a variety of other constituents in their institutions and communities [3]. Training in patient safety, QA, and management is also a key component of Graduate Medical Education (GME) training in all specialties, including Pathology, where focused management/QA projects are one approach to teach and engage trainees in management.

In the Accreditation Council for Graduate Medical Education (ACGME) Pathology Milestone Project, a framework of parameters was developed to assess the development of residents in different categories of Pathology training including patient care, medical knowledge, systems-based practice, practice-based learning and developments, professionalism, and interpersonal and communication skills [7]. In the systems-based practice category, one of the milestones pertaining to the regulatory and compliance aspects of laboratory management is “participation in an internal or external laboratory inspection” [7]. The decision to involve all of our residents in the

self-inspection process was not only to achieve an ACGME-related milestone but also to address other residency training and departmental needs. Similar to many other institutions, our curriculum for the laboratory management rotation consists mainly of didactic sessions and some online courses with no significant direct involvement of the residents in projects or work flow processes that will teach them effective laboratory management. Involving the residents in divisional quality control, staffing, and administrative meetings, dependent on their respective rotation, was part of the solution on how to better engage the residents and directly involve them in the different aspects of the management process. Leading and operating a focused QA project, such as the self-inspection process, is even more engaging and provides more hands-on experience for the residents. Also, having the senior residents present their findings in the summation meeting, facing the staff and department and hospital leadership, adds to their presentation skills and prepares them for occasions where they face large audiences in their future job opportunities. Some of the residents, equipped with their experience of multiple self-inspections, participated in outside CAP inspections as inspection team members.

From a department prospective, the residents are equipped with basic knowledge of all areas of the laboratory, knowledge of the division work flow intricacies, and knowledge of the daily issues contributing to staff dissatisfaction, which will allow them to achieve the targeted results of a meticulous self-inspection process that would simulate or even exceed the outside CAP inspection. Trying to assign the senior lead residents to areas in the laboratory that they have a special interest in helped make the residents more invested in learning every detail about the operation and achieve positive outcomes. The self-inspection process created rapport between staff, residents, and faculty; the impact of which caused the entire department to become more cohesive and positively engaged with the accreditation process. This team-oriented exercise has equipped residents and staff with crucial learning techniques and awareness of the division work flow intricacies that can help in eradicating daily issues that may cause staff dissatisfaction.

By analyzing the results of the consecutive histology laboratory inspections from 2014 to 2017 (Table 1), a positive downward trend is noted in the number and gravity of deficiencies cited. This correlated with significantly decreased incident reports and staff complaints as well as much improved QA data, performance indicators, and staff engagement surveys during that time period. Granted that other factors contributed significantly to this positive turnaround including significant process changes, new hands-on management, and much improved staff morale and engagement, but the initial self-inspection in 2014 acted as the eye opener for the technical issues we had in the histology laboratory and validated the preceding staff complaints and concerns. Although we can quantitatively measure the overall benefits that this project had on the laboratory clinical operations, limitations of the study include lack of quantitative measurement of the long term longitudinal effects and benefits this project had on the participating residents, especially those who graduated and started their professional careers. However, these self-inspection projects helped the residents meet a portion of their quality-related and educational goals that were established as part of their residency training curriculum. A universal positive feedback pertaining to increased knowledge in laboratory QA management and communication was also received from the participating residents upon completion of each self-inspection process. One relatively consistent request the residents had in the surveys though is to restructure the laboratory management rotation to include more hands-on training similar to that experienced in the self-inspection process. A new revamped curriculum for the laboratory management rotation is currently at the final stages of completion.

5. Conclusion

The self-inspection process exposed the residents to operational issues and corrective actions that provided them the opportunity to take a more active role in laboratory management and helped prepare them for post-graduation challenges that are likely to face them in their future careers. For the department, the self-inspection process led by the residents helped identify and rectify many operational issues, especially in the histology laboratory. While the primary goal of focused laboratory management QA projects is to generally enhance resident training and education, these projects can also lead to operational improvements and positively enhancing patient care, as validated in our project.

Conflict of interests

The authors declare that there is no conflict of interests regarding the publication of this article and there have been no significant financial contributions for this work that could have influenced its outcome.

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