

Laboratory Errors & Patient Safety

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Errors in Anatomic Pathology

An interview with: *Dr. Stephen Raab*
Professor of Pathology
University of Pittsburgh Medical Center

LEPS interviewed Dr. Stephen Raab about errors in anatomic pathology. Dr. Raab is the Director of the Center for Pathology Quality and Healthcare Research. The Center is arguably the most productive and influential group studying anatomic pathology errors. A recent study¹ by Dr. Raab and his colleagues estimated that the average discrepancy frequency between originally reported pathology results and the results of a secondary case review in the case samples they examined is about 6.7%, and 5% of the discrepancies have a modest to significant effect on patient care. Discrepancies rates may be even higher for specific specialty areas of anatomic pathology. For example, in the diagnosis of thyroid diseases by cytology and biopsy, Dr. Raab's group has shown that in the case samples they examined 25.0% of patients had a false negative diagnosis and 9.9% had a false positive diagnosis². The most common root causes of these problems were poor specimen quality, and lack of standardization of diagnostic categories.

LEPS: How much time do you spend on research vs. clinical service?

Dr. Raab: I spend about 50% of my time in research related to medical errors, and 50% in clinical service.

LEPS: How did you become interested in errors in pathology?

Dr. Raab: It was a long process. I originally studied health policy at Stanford. My focus was on variability in medical decision-making and how this variability affects diagnosis and patient outcomes. This work sparked an interest in errors. Like many researchers in medical error, the more recent motivator for my interest, was the Institute of Medicine report

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from 1999, *To Err is Human*³. This report led me to review the errors literature in anatomic pathology, and there was not much there. What was there focused on errors in the interpretation of microscope images rather than on the entire process including the systems for collecting the specimen, processing the specimen, and reporting the results. Since scientific studies of errors in anatomic pathology were limited, a group of us at the University of Pittsburgh, who were interested in the field, decided to submit a grant application to the NIH to fund work in this field, and we received the funding.

LEPS: What did this grant allow you to do?

Dr. Raab: In 2002, the NIH Agency for Healthcare Research and Quality funded us to develop a web-based database to collect anatomic pathology errors from four institutions: the University of Pittsburgh, Western Pennsylvania Hospital, University of Iowa Hospitals, and the Henry Ford Hospital System⁴. These institutions voluntarily report their errors in a de-identified fashion. The database is the foundation of most of our research.

LEPS: How many errors have been reported to date, and is the number of participating institutions growing?

Dr. Raab: There are now more than 25,000 errors in the database, and the number of participating institutions has grown from four to nine.

LEPS: What are some current problems in quality improvement in anatomic pathology?

Dr. Raab: Historically, there has been a tendency to overly focus on errors caused by pathologist misinterpretation of microscope slides, and to neglect

errors in specimen collection, and errors in the cytology or histology laboratory that prepared the slides.

Quality improvement is more effective if there are simultaneous efforts to improve quality in specimen collection, laboratory processing, and pathologist interpretation, rather than just focusing on interpretation.

LEPS: Why has the specimen collection and laboratory component been neglected?

Dr. Raab: One factor is that there has been a false belief that it is too difficult to improve these aspects of anatomic pathology. Consequently, in many anatomic pathology laboratories, the specimens are processed today no differently than they were 30 or 40 years ago, when these laboratories first came into being.

LEPS: Error detection is critical to quality improvement. How are errors usually detected in anatomic pathology?

Dr. Raab: The two most common methods of error detection are cytologic-histologic correlation and secondary review of previously reported cases. Cytologic-histologic correlation refers to cases in which the patient has both a cytology specimen and a histology specimen. The cytology specimen is usually collected first, for example by placing a fine needle into a mass and aspirating it. The histology specimen is often prepared from sampling a biopsy or sampling a mass or other lesion that has been surgically removed. Discrepancies between the cytologic and histologic diagnoses often reveal errors.

Disconnection between pathologists and direct care providers is a significant latent source of errors in pathology.

LEPS: What is secondary case review?

Dr. Raab: Secondary review is the most traditional method of error detection. Secondary review refers to having a different pathologist review all the data from a previously reported case including the anatomic pathology specimens. The cases can be selected at random, for example if one wanted to determine agreement rates between pathologists, or could be selected because a physician questions the accuracy of a pathology report.

LEPS: Are there accreditation requirements regarding how frequently cytologic-histologic correlation or secondary review must be performed?

Dr. Raab: CAP has recommendations and requirements but there is no specific legal requirement regarding the minimal frequency or the exact methods employed. In practice, there is significant variability between institutions.

LEPS: What kind of errors do these methods detect?

Dr. Raab: They detect many different errors including mislabeled specimens, suboptimal specimens -for example a cytology or histology specimen that fails to sample the cancerous area of a mass-, and errors in interpretation by a pathologist. As I mentioned, there is a tendency to put too much emphasis on errors in interpretation.

LEPS: What is your general approach to interventions to decrease errors in anatomic pathology?

Dr. Raab: In general, I like Lean as an approach to enhance quality. One aspect of lean I particularly focus on is enhanced communication. Specifically, I favor any intervention that involves more frequent communication between pathologists and other physicians.

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LEPS: Why does frequent communication between pathologists and care providers reduce errors?

Dr. Raab: Disconnection between pathologists and direct care providers is a significant latent source of errors in pathology. When pathologists communicate more frequently with care providers, the quality of the pathologist's work improves because both the clinician and the pathologist are better informed about the patients.

LEPS: What are some examples of enhanced communication between pathologists and care providers?

Dr. Raab: Here are three:

- Pathologists calling their diagnosis directly to the physician caring for the patient,
- Increasing the number of conferences at the multiple-headed scope with both pathologists and care providers present,
- Having the pathologist physically present when a different physician collects a fine needle aspirate.

LEPS: Can you tell us about your work regarding improving service related to fine needle aspirates (FNAs)?

Dr. Raab: We introduced immediate interpretation for FNAs to improve the quality of specimen collection and interpretation. The project was guided by lean principles. Our underlying assumption in the project was that delay in interpreting fine needle aspirates is a wasteful practice that adds no value to the FNA. To improve workflow and communication, we adapted single piece flow for the specimen collection, processing, and interpretation. That means that each specimen moved through the process without becoming part of a batch.

LEPS: How does this intervention illustrate enhanced communication?

Dr. Raab: The specimen collector, who is often a direct care provider or radiologist, receives immediate feedback from the pathologist regarding the adequacy of the specimen. In addition, the pathologist talks to the patient's physician regarding the diagnosis. The overall picture is one of faster, higher quality service, with more communication between providers. The new system promotes teamwork and enhances learning.

LEPS: What about some specific interventions you like in the cytology or histology laboratory?

Dr. Raab: I would like to see lean used to improve the workflow and physical layout of gross pathology processing areas, cytology laboratories and histology laboratories⁵.

LEPS: We know you have done a fair amount of work related to Pap smears. Can you tell us a specific lean success story in this area?

Dr. Raab: We recently published results from a study where we applied lean principles to decrease errors and turnaround time related to Pap testing⁶. Our interventions included:

- Using a checklist in the gynecologist office to maximize the likelihood of an adequate specimen.
- Changing from batch flow to one-piece flow in the cytology laboratory.
- Assigning a unique cytotechnologist and pathologist to the gynecologist and having the technologist and pathologist call abnormal results and inadequate specimens directly to the gynecologists.

Overall, we improved speed, communication, and quality without increasing costs. The new system, with its enhanced interaction between the gynecologist and specific pathology staff, has a higher level of accountability than the previous system.

LEPS: There is a morbid joke circulating in the laboratory industry that when staff hear that lean is being implemented, it means that less employees are needed. This has caused some leaders to adopt lean principles without using the term "lean". What is your approach?

Dr. Raab: I use the term. Technical people like it, as do CEOs.

LEPS: Besides increased communication, what other interventions do you favor regarding decreasing errors in pathologist interpretation?

Dr. Raab: The key to decreasing errors in pathologist interpretation of an adequate specimen is standardization. Standardization is basically an agreement that work is going to be done a certain way. It requires that standards be developed at a national or international level, then adhered to by each pathology practice.

LEPS: How can each pathology practice adhere to a given diagnostic standard?

Dr. Raab: To achieve standardization, the pathologists in the practice must work together as a group and apply methods such as:

- Reviewing a sampling of each other's cases
- Meeting frequently around the multiple-headed scope to decide cases by a consensus-building process.
- Double (redundant) viewing of some specimens before resulting⁷

LEPS: If the specimen is double read, and there is a discrepancy, how do you know which pathologist is correct?

Dr. Raab: You do not know the correct diagnosis at first. But the discrepancy allows the pathologists to take a deeper look at the case and come to a consensus regarding the

diagnosis. Double viewing of slides is also helpful because pathologists do a better job knowing that a colleague is reviewing some of their cases.

LEPS: What is the role of culture in accepting standardization as a strong intervention for decreasing interpretation errors?

Dr. Raab: Clearly, the success of these interventions will depend on the culture of the practice. A pathology practice that has a culture of encouraging debate, admitting error, working as a team, and accepting constructive criticism will be able to adapt these interventions and achieve a high level of standardization. Practices dominated by individualists or egotists tend to resist change and have trouble standardizing. Unfortunately, many practicing pathologists strongly resist standardization.

The key to decreasing errors in pathologist interpretation of an adequate specimen is standardization. Many practicing pathologists strongly resist standardization.

LEPS: This leads us to ask about a new term your group introduced recently. What is the "Big Dog" effect?

Dr. Raab: At many institutions, there is a dominant senior pathologist, the Big Dog, who becomes the gold standard of anatomic pathology. The other pathologists follow the diagnostic beliefs of the Big Dog, and defer to the Big Dog on difficult cases and in the analysis of the cause of an error.

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LEPS: What are the problems caused by Big Dogs?

Dr. Raab: There is a poor agreement between Big Dogs from different institutions in their interpretation of a particular case. This makes it hard to achieve standardization regarding a diagnosis. In addition, Big Dogs agree poorly regarding their assessment of the causes of an error. This hinders quality improvement, since judgments regarding root causes of an error provide a guide for the choice of interventions.

LEPS: If you get the Big Dogs together can they come to a consensus on how to diagnose certain cases?

Dr. Raab: You can get them to agree when they get together, and then when they return to their home institutions they revert to their usual beliefs and practices.



LEPS: Are Big Dogs the source of latent errors in anatomic pathology?

Dr. Raab: They can be. For example, Big Dogs make rules regarding case interpretation that the more junior pathologists follow. When the rules are erroneous, they are systematically embedded in the practice and are the source of systematic interpretation errors.

Big Dogs make it hard to achieve standardization between institutions.

LEPS: Is the Big Dog hypothesis related to the problem of medical narcissism written about by Dr. John Banja⁹.

Dr. Raab: Yes. Unfortunately, many Big Dogs do not see the problem of medical narcissism as applying to them. They have trouble accepting that they sometimes block standardization and quality improvement.

LEPS: Is there an accomplishment that you are most particularly proud of?

Dr. Raab: To date, I think our biggest accomplishment is to get a large number of institutions to participate in the database and share their anatomic pathology errors, all without any financial reimbursement for participating. This gives me hope that institutions are becoming interested in the quality of anatomic pathology.

LEPS: How about an accomplishment regarding interventions?

Dr. Raab: There is no particular intervention that I am particularly proud of. Even when we have attempted an intervention and failed, many times it was not that the intervention was bad, but that the culture was unable to accept it.

LEPS: Since the discrepancy rate for anatomic pathology diagnoses is fairly high¹ should patients always seek a second opinion regarding interpreting their pathology slides?

Dr. Raab: This is a tough question. In the long run, I would like to see pathology practices implement the methods of standardization that I previously discussed. This would result in sufficiently low discrepancy rates such that second opinions would usually be unnecessary. Therefore, I would be hurting my long term goal by suggesting that patients always seek a second viewing of their slides. For now, I think a reasonable compromise is that patients seek a second opinion when their physician lets them know that their results are unexpected. However, if the anatomic pathology results fit together nicely with the rest of the clinical data, there is no need for a second opinion.

LEPS: To conclude, what is the view from 40,000 feet regarding the problem of errors in anatomic pathology?

Dr. Raab: Well, one way of looking at it, which has been adopted by those who resist major changes, is that is we achieve amazingly good results in anatomic pathology given the lack of standardization, and the lack of stringent government regulations.

LEPS: Is that the way you view it?

Dr. Raab: No. My view is that serious errors in anatomic pathology are not that common, but they are common enough that we should be highly motivated to decrease them. In addition, there is a large number of smaller errors which do not dramatically effect patient outcomes but which bring high costs to the healthcare system in terms of retesting and other wasted work. Many of our practices in anatomic pathology are archaic. If we want to significantly increase quality, we have to

get beyond the mentality that the practice of anatomic pathology is good enough.

LEPS: Do you like being the carrier of this message?

Dr. Raab: Not particularly. Some pathologists are resistant to it, and a little bit angry, but I believe it is the right message to be carrying forward.

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The Importance of Nurses as Collaborators in Care: The Work of Linda Aiken, Ph.D., RN

By Kerstin Edlefsen, M.D.

"Nurses constitute the surveillance system for early detection of complications and problems in care, and they are in the best position to initiate actions that minimize negative outcomes for patients. That the exercise of clinical judgment by nurses, as well as staffing adequacy, is key to effective surveillance may explain the link between higher nursing skill mix (i.e., a higher proportion of RNs among the nursing personnel of a hospital) and better patient outcomes."¹

"Moreover, given the approximately 35 million hospital admissions a year, well over 50,000 lives a year could potentially be saved through investments in nursing. Thus, the evidence suggests that improved nurse staffing, investments in enhancing nurses' education, and improvements in the nurse practice environment have the potential to yield benefits to patients as great or greater than other initiatives that have garnered top billing to date in the national effort to make medical care safer."²

Source:

Linda H Aiken, PhD, RN, University of Pennsylvania, Director of the Center for Health Outcomes and Policy Research and the Claire M Fagin Leadership Professor of Nursing and Professor of Sociology.

Specific References:

1. Aiken LH, et al. Educational levels of hospital nurses and surgical patient mortality. *JAMA*, 2003; 290(12):1617-1623.
2. Aiken, Linda H. Perspective: The unfinished patient safety agenda. *AHRQ Web M&M* 2005. www.webmm.ahrq.gov, accessed March 15, 2006.

Relevance of these quotes to laboratories:

Although laboratorians generally think of our primary clients as patients and their physicians, nurses often represent our main point of contact with the clinical team. In many institutions, technologists are on the phone throughout the day with nurses, giving results, reporting critical values, and resolving problems. As such, we are very aware of the vital role that nurses play at the front-line of medical care, serving as the intermediaries between doctors, patients, and the rest of the health care system. It should therefore come as no surprise that improvements in the nursing practice environment, including increasing nurse staffing and enhancing nurse education, could yield substantial improvements in patient safety.

Dr Linda Aiken of the University of Pennsylvania has repeatedly demonstrated that there are significant oppor-




tunities to save lives and improve patient outcomes by improving nurse staffing, education, and practice through her studies on surgical patient mortality in 168 Pennsylvania hospitals. As she says in her own words above, she estimates that over 50,000 lives per year could be saved through nursing improvements. Despite the solid evidence that supports directing patient safety resources towards nurse staffing and education, no major patient safety advocacy group has yet directly addressed this issue or made it a high national priority. Why is this? One explanation is that this may relate to perceptions that nursing problems, such as the national nursing shortage, are impossible to fix, however Dr. Aiken has argued persuasively that there are reasonable targets for intervention and that these should be moved up higher on the national patient safety agenda. Another explanation is that calling for more and better-educated nurses is not as trendy and technological as the high profile patient safety interventions such as rapid response teams, and electronic medical records with computerized physician order entry. This is a shame because there is arguably more evidence supporting the effectiveness of nursing interventions than there is supporting some of the trendier interventions.

In contrast to nursing, clinical laboratories have been attractive early targets for quality improvement interventions. This is partly because the laboratory is central to so many aspects of patient care. It is also because laboratory processes are relatively quantifiable and easily tracked, making them attractive

There is arguably more evidence supporting the effectiveness of nursing interventions than there is supporting some of the trendier interventions.

targets for intervention. As LEPS readers know, however, the majority of "laboratory" errors occur in the pre-analytical and post-analytical phases of testing, and the solutions to these problems generally require system-wide improvements that reach far beyond the laboratory. For example, common and significant pre-analytical problems include the mislabeling of specimens and blood draws contaminated by intravenous fluid. Common post-analytic problems include difficulty reaching an appropriate provider with a critical value or failure by a provider to act on a critical value in an appropriate manner. It is easy to imagine how improvements in nurse staffing, training, and support could lead to improvements in all of these arenas, to a degree far outweighing many changes that could be made within the laboratory itself. As the patient safety movement matures, we are likely to see more of an emphasis placed on interventions that cross disciplines and hospital arenas, and hopefully more opportunities to collaborate with our colleagues in nursing, such as Dr. Aiken, to make medical care safer for all patients.



LABORATORIES

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Overheard: Business Jargon

Senior consultant (25 years of experience as laboratory director, 5 years of consulting experience):

Well we have extensively toured their laboratory, interviewed their staff, and reviewed their performance statistics. What do you think the main problems are in the laboratory, and how can we help them?

Junior consultant (just out of college):

It's all about leveraging their core competencies. It's all about lean and six-sigma, and synergies that enhance the value chain. It's all about right-sizing starting with the middle management. Its all about benchmarking against our proprietary data



“Paradigm shifts, joint management relationships, and value propositions. I look good and I have no idea what I am talking about.”

set. Its all about implementation of leading edge information technology solutions that can provide seamless multisite user access to a continuous longitudinal patient knowledge base. Its all about the highest quality having the lowest cost. I am so happy I bought this \$2000 Valentino suit.

Senior consultant:

This laboratory organization has drifted to below average performance in a couple of specific areas in the laboratory, but overall they are in pretty good shape. Somehow they have been convinced that they are a diminished organization in need of outside consultants, and special tools. We just need to encourage them a bit, and help them better use their existing resources. We should share with them what we have learned from watching the operations at similar facilities that have achieved high quality and high morale. Ironically, this laboratory has entire divisions of the laboratory that are functioning well, so they can actually use their own people to spread what they already know. The truth is that they do not even need you and me. Do you agree with me?

Junior consultant:

It is all about paradigm shifts, flattening the organization, and thinking outside the box, who moved my cheese, and everybody getting black belts. Specifically, its all about decentralizing of the specimen procurement function if it is centralized, and centralizing it if it is decentralized. Where is my Jack Welch biography? Boy does this suit look good on me. I need a pair of Gucci shoes and a shirt with a higher thread count.

Senior consultant:

They have some attendance problems in phlebotomy and specimen processing. It is probably best to work on getting these people

Advice for Patients

Expert: *Michael Astion, M.D., Ph.D.,
Editor-in-Chief, Laboratory Errors and Patient Safety
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to come to work before leaning their workplace. Senior management will need to acknowledge that a small number of their more junior supervisors are weak on personnel issues, and these junior supervisors could be helped by some mentoring from their senior colleagues, who take a tougher stance on attendance.

Junior consultant:

It's all about dialoguing between upper management and feet-on-the-floor supervisors to incentivize staff to leverage their core competencies. Its all about focusing on deliverables. Its all about scalability and understanding their value chain. Its all about getting to the next level¹. Darn it, I told the barber to use a #1 razor on the sides, and a #2 on the sides. I'm going to get a shine.

Senior consultant:

Why don't you do that while I talk to their laboratory director and hospital administrator.

References:

1. For more business jargon see: "MBA Jargon Watch". www.johnsmurf.com/jargon.htm.

What advice would you give to a patient regarding laboratory testing in general and laboratory errors specifically?

I would let them know that there is no laboratory errors crisis, and there is a tremendous likelihood that their laboratory testing experience will proceed successfully. Clinical laboratories occasionally make errors, and they try to direct quality improvement efforts at the errors they perceive as most likely to effect patient care. Occasionally, stories appear in the newspaper about a laboratory error that seriously harmed a patient. These stories are exceptions rather than the rule. The media are fear-mongers that emphasize these stories because they are sensational. "Patient harmed by laboratory error" is a better story than "Ten millionth patient diagnosed with myocardial infarction with the help of a common laboratory test".

If you are very sick, laboratory testing is likely to play an important role in your diagnosis and care. Some tests virtually define your disease. You can't have Hepatitis C without a positive test for Hepatitis C. However, if you are in generally good health and develop a common ambulatory complaint such as headache, backache, neck ache, fatigue, temporomandibular joint pain, and many others, laboratory testing may play a minor role, or no role at all. What is the lab test for headache? There is none.

From a patient's perspective, there are only a few laboratory errors worth worrying about. Therefore, my advice to the patient scheduled for laboratory testing is as follows:

- Know what tests are being ordered and why.
- Make sure your name and other identifying information is on the blood tube (or other container), that holds your specimen.
- Make sure that a care provider follows up with you on your result. Do not assume that no news from your care provider is good news. The test may have been forgotten.
- Follow your care providers instructions regarding preparation for the test. If they tell you not to eat for 8 hours, don't eat for 8 hours. A Big Mac is not a clear liquid, even if you let it sit out for awhile and add lots of special sauce.



Not a clear liquid

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