ASCP STRONGERTOGETHER

Promoting Diagnostic Excellence by Improving the Communication of Urgent and Significant Unexpected Diagnoses in Anatomic Pathology

Resource Guide with Best Practice Recommendations

CONTENTS

Purpose of This Guide

This guide is designed for pathologists and laboratory professionals and outlines best practices to ensure effective and timely communication of urgent and significant unexpected findings in anatomic pathology.

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Background

The exact prevalence of diagnostic errors resulting from missed or delayed notification of urgent or significant unexpected diagnoses is unknown. However, a nationwide survey found that missed, incorrect, and delayed diagnoses were the most common cause of medical errors, accounting for 59% of errors experienced by more than 500 patients. When this concern is considered through the lens of a failure mode and effects analysis (a widely recognized method to identify and avert potential risks), the high potential for severe patient harm combined with low baseline detectability makes mitigation of the risk for missed notifications a high-priority initiative.

Diagnostic excellence requires both an optimal process and an accurate understanding of a patient's condition. While most diagnostic reports generated by pathologists do not require urgent communication beyond a standard electronic health record (EHR) report release, urgent and significant unexpected diagnoses require prompt, intentional communication beyond the standard report release to ensure that treating physicians receive, acknowledge, and use the results to optimize patient care. There is a lack of standardization on how and when pathologists should close the loop and directly notify treating physicians of these findings. Recommendations from Clinical Laboratory Improvement Amendments (CLIA), the College of American Pathologists (CAP), and The Joint Commission (TJC) are nonspecific, directing each institution to develop their own policies for identifying what constitutes a critical and unexpected finding, as well as how and when these findings should be communicated and documented. This has contributed to confusion, significant variation, and suboptimal or delayed notifications from pathologists negatively impacting patient care. Suboptimal clinical communication to and among healthcare teams also further compounds health inequities already faced by minority communities.

Proactively improving the communication of urgent or significant unexpected diagnoses to the relevant clinical care teams and providers increases high-reliability processes by avoiding missed or delayed notifications, rather than taking a typical retrospective approach to identifying mistakes or failures once harm has already reached the patient. By developing best practices for these clinical diagnostic communications, organizations can improve their efficiency and reliability, thus improving diagnostic excellence and enhancing equitable care for patients.

Anticipating Challenges, Opportunities, and Best Practices

By leveraging lessons learned from past quality improvement (QI) projects focused on improving safety and equity for patients, the American Society for Clinical Pathology (ASCP) is poised to facilitate diagnostic excellence among pathologists through education and resources that enhance communication within the multispecialty care team. In 2023-2024, ASCP convened a learning collaborative group of pathologists and laboratory professionals from various practice settings serving diverse patient populations. The group participated in virtual meetings, discussed current practices, and identified variations in practices and barriers to the communication of urgent or significant unexpected diagnoses in pathology practice. From the literature, lessons learned from QI projects, and their practice, the group identified opportunities for improvement and proposed a list of best practice recommendations for effective and timely communication of these diagnoses. These recommendations cover opportunities for addressing communication challenges across 8 broad categories:

- AP Laboratory Policies
- Definitions
- Examples
- Methods of Notification
- Timeframe
- Identification of Ordering Provider
- Documentation
- Quality Assurance

AP Laboratory Policies

CHALLENGE AND OPPORTUNITY

There is an opportunity to ensure that an institutional policy exists for the communication of urgent and significant unexpected diagnoses in anatomic pathology that contains all elements such as definitions, examples, documentation requirements, escalation methods, etc.

BEST PRACTICE RECOMMENDATION

- AP laboratories should have a policy on the communication of urgent and significant unexpected diagnoses.
- The policy should include:
    - Definitions
    - Examples of urgent and significant unexpected diagnoses (provided on page 6)
    - The requirements for the timeframe to communicate these findings (provided on page 7)
    - Documentation requirements for the notification of the results (provided on page 8)
- These policies should be developed in partnership with relevant stakeholders, including clinical colleagues affected by these policies

Definitions

CHALLENGE AND OPPORTUNITY

Many pathologists are unaware of the differences in the definitions of urgent and significant unexpected diagnoses in anatomic pathology. These definitions should be included in the institutional policy for the communication of urgent and unexpected findings in anatomic pathology.

BEST PRACTICE RECOMMENDATION

Document/apply the following definitions:

- **Urgent Diagnosis:** A medical condition that poses an immediate health risk to the individual or requires immediate action by the ordering physician.
- **Significant Unexpected Diagnosis:** A medical condition that is not clinically expected or is unforeseen and is significant enough to potentially alter patient management or follow-up.

Examples

CHALLENGE AND OPPORTUNITY

Many laboratories do not list specific examples of urgent and significant unexpected diagnoses for anatomic pathology in their policies

Lists should include examples of urgent, as well as significant unexpected diagnoses. The list should be included in the institutional policy for the communication of urgent and unexpected findings in anatomic pathology.

BEST PRACTICE RECOMMENDATION

The following list is provided as an illustration of examples that can be included in a laboratory's institutional policy. It is not intended to be comprehensive, and each practice or institution may determine that some of these entities do not belong on their site-specific list.

URGENT DIAGNOSIS

Urgent inflammatory diseases

- Vasculitis/glomerulonephritis
- Temporal arteritis (giant cell arteritis)
- Kidney biopsy with crescents in greater than 50% of glomeruli

Transplant

- Acute graft-versus-host disease in any specimen from a patient who received a transplant
- Acute rejection in transplant biopsies

Other

- Toxic epidermal necrolysis
- Acute/fulminant autoimmune hepatitis

Acute leukemia/Burkitt lymphoma, new diagnosis, especially:

- *Acute promyelocytic leukemia (APL)*
  - Morphologic features on peripheral blood or bone marrow aspirate smears suggestive of or consistent with APL
  - Positive t(15;17) by fluorescence in situ hybridization (FISH)
- *Burkitt lymphoma*
  - Morphology on surgical pathology specimen suggestive of Burkitt lymphoma
  - Positive t(8;14) by fluorescence in situ hybridization (FISH)

SIGNIFICANT UNEXPECTED DIAGNOSIS

Unexpected malignancy, examples given below:

- Malignancy identified in an anatomic pathology specimen assumed to lack neoplasia (e.g. hernia sac, appendix, gallbladder, etc.)
- Suspected benign neoplasm with malignant findings (e.g. struma ovarii with papillary thyroid cancer (PTC)
- Any malignancy detected in a clinical pathology specimen (examples: blood and body fluid) in a patient without a previous diagnosis of malignancy
- Invasive carcinoma or "cannot exclude invasion" in Papanicolaou-stained cervicovaginal smears

Changes in diagnosis:

- Significant disagreement between the rapid on-site evaluation (ROSE) and the final fine needle aspiration (FNA) diagnosis
- Significant disagreement between an intraoperative diagnosis and the final diagnosis
- Any amended (revised) reports with a change in diagnosis (except for administrative revised reports and medical record updates)
- Significant disagreement and/or change in diagnosis between the primary pathologist and another consulting pathologist (at either the original or consulting institution)

URGENT AND SIGNIFICANT UNEXPECTED DIAGNOSIS

Infections:

- Organisms in sterile sites (e.g. CSF, heart valve, bone marrow) not interpreted to be the result of contamination.
- Pathogenic organism such as:
  - Bacteria, e.g. acid-fast bacilli
  - Fungi, e.g. Pneumocystis, Mucor, Aspergillus
  - Virus, e.g. Herpesvirus in Papanicolaou-stained cervicovaginal smears from pregnant patients
- Organisms demonstrating evidence of invasive infection in biopsies/resections where infection was not suspected

Findings indicative of perforation/fistula formation

- Adipose tissue (fat) identified in an endometrial curettage
- Mesothelial cells in a heart biopsy
- Hepatocytes in paracentesis fluid
- Bile in thoracentesis fluid (fistula)

Methods of Notification

CHALLENGE AND OPPORTUNITY

Pathologists utilize different methods for notifying urgent and significant unexpected diagnoses to the treating clinician. There is an opportunity for standardizing an effective mode of communication method.

BEST PRACTICE RECOMMENDATION

Pathologists can/should use one or a mix of methods to communicate urgent and significant unexpected findings to the treating clinician.

- Phone call
- In-person
- Email
- Secure text

If possible, leverage technology to facilitate automated flagging and notification to communicate these findings. We encourage the development of functionality for laboratory information systems to provide seamless transmission for closing the loop between the pathologist and the ordering provider, including

Documentation of the provider's acknowledgement of receipt of the results.

Timeframe

CHALLENGE AND OPPORTUNITY

There is not a recommended standard timeframe for notifying urgent and significant unexpected diagnoses to the treating clinician. There is an opportunity to define best-practice timeframes for communicating these findings to the provider.

BEST PRACTICE RECOMMENDATION

An attempt should be made to communicate both urgent and significant unexpected findings **within 24 hours of the diagnosis, preferably on the same day of the diagnosis**.

Identification of Ordering Provider

CHALLENGE AND OPPORTUNITY

It is possible that the primary ordering provider is not identified on anatomic pathology requisitions. There is an opportunity to ensure that the primary ordering provider's name is correctly stated on the requisition. Also, there is an opportunity to ensure that a secondary provider's name, who could be contacted, is listed on the requisition in case the primary ordering provider is non-reachable.

BEST PRACTICE RECOMMENDATION

Ordering providers' names should be clearly listed on the requisition form. This information should be a required field on the requisition form.

Documentation

CHALLENGE AND OPPORTUNITY

There is no existing standard for what and where the notifying personnel need to document regarding the details of the communication of urgent or significant unexpected findings. There is an opportunity to ensure that appropriate documentation exists, and that it meets the requirements of the checklist by the accrediting organization.

BEST PRACTICE RECOMMENDATION

The communication details should be documented in one of the locations below:

- Pathology final report
- Pathology addendum report
- Laboratory Information System (LIS)
- Secure text

The notification documentation should include:

- Date/time of communication
- Mode of communication (ie, phone call, secure text)
- Full name of person notified
- Name of the person notifying the results (may be electronic signature)
- Findings communicated (only if using modes like email or chat)

Quality Assurance

CHALLENGE AND OPPORTUNITY

Each practice or institution has their own method of tracking, auditing, and performing quality assurance tasks for cases with urgent and significant unexpected findings. There are challenges regarding the best methods to track cases for urgent and significant unexpected findings and the documentation of communication.

BEST PRACTICE RECOMMENDATION

Departments should design methods to track cases for urgent and significant unexpected findings and documentation of communication.

Information technology solutions can assist in tracking such cases.

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