ASCP STRONGERTOGETHER

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

July 16, 2024

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- Presentation slides

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Disclosures

- The following faculty have no relationships with ineligible companies to disclose: Dr. Varsha Manucha and Dr. Sachin Gupta.
- The following faculty have disclosed relationships with ineligible companies: Dr. Govind Bhagat: Blueprint Medicines, Speaker & Advisory Board.
- These relationships have been reviewed and mitigated.

- **This program is funded by the Gordon and Betty Moore Foundation and administered by CMSS (Council of Medical Specialty Societies)**

Learning Objectives

- Define urgent and significant unexpected diagnoses
- Discuss current guidelines and practices
- Discuss high-priority communication barriers
- Discuss best practices and recommendations for effective and timely communication of urgent and significant unexpected diagnoses
- Quality assurance

Promote the role of pathologists and laboratory professionals in advancing diagnostic excellence along the diagnosis-to-treatment trajectory

Diagnostic Excellence - Overview

The Gordon and Betty Moore Foundation created the term **Diagnostic Excellence** to imagine a world in which diagnosis was ideal

- ***Optimal Process and Accurate & Precise diagnosis***
- ***Safe, Effective, Patient-centered, Timely, Efficient and Equitable***

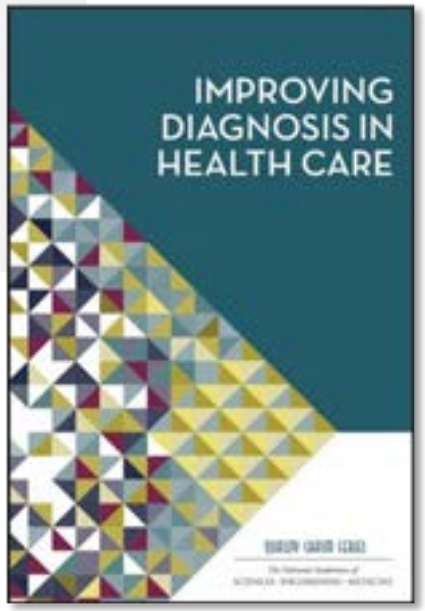
Yang D, Fineberg HV, Cosby K. Diagnostic Excellence. JAMA. 2021 Nov 16;326(19):1905-1906. doi: 10.1001/jama.2021.19493. PMID: 34709367

"Most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences."

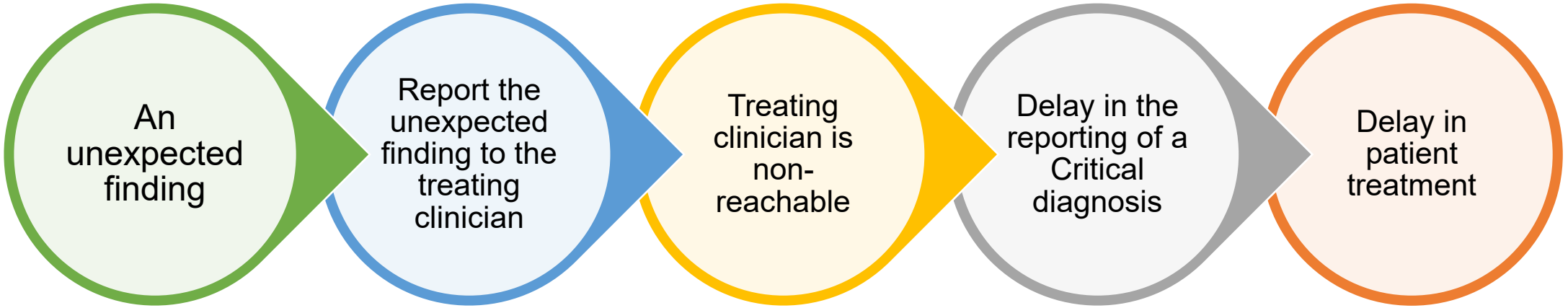
National Academies of Sciences, Engineering, and Medicine. 2015. *Improving Diagnosis in Health Care*. Washington, DC: The National Academies Press.

DIAGNOSTIC ERROR

"the failure to establish a timely and accurate explanation of *the patient's* health problem(s) or communicate that explanation."



Diagnostic Error in Reporting An Unexpected Diagnosis in Anatomic Pathology



Unanswered Questions

- What are urgent and significant unexpected diagnoses in anatomic pathology?
- Are all unexpected diagnoses urgent?
- Why is notification and documentation important?
- How should these findings be communicated in an effective and timely manner?

Learning Collaborative

- A group of pathologists from different practice settings serving diverse patient populations
- Participated in meetings to discuss current practices and barriers to communicate urgent and significant unexpected diagnoses
- Facilitated group discussions and in-meetings polls
- Proposed best practices for effective communication of urgent and significant unexpected diagnoses

Poll - 1

What is your primary healthcare role?

- Pathologist/ Laboratory Medical Director
- Administrator, Technical laboratory Director, Operations Manager/Director etc.
- Other

Poll - 2

Do you currently notify the clinicians of urgent or significant unexpected diagnoses in anatomic pathology?

- Yes
- No

Poll - 3

Do you understand the distinction between urgent and significant unexpected diagnoses in anatomic pathology?

- Yes
- No

Poll - 4

Do you experience any barriers in communicating urgent and significant unexpected diagnoses in anatomic pathology?

- Yes
- No

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Defining “Critical Value”

- **Lundberg in 1972 -** “Laboratory value associated with a life-threatening condition that require immediate attention”
- **The Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) -** “The laboratory must develop and follow written procedure for reporting...”
- **The Joint Commission on Accreditation of Health Organizations (JCAHO) and College of American Pathologists**
- **American Society for Clinical Pathology (ASCP), 1997 -** published guidelines; included generic critical values in clinical pathology

“Improved effectiveness of communication among caregivers”

A Multi-institutional Survey of Critical Diagnoses (Critical Values) in Surgical Pathology and Cytology

Telma C. Pereira, MD,[1] Jan F. Silverman, MD,[1] Virginia LiVolsi, MD,[2] Christopher D.M. Fletcher, MD,[3] William J. Frable, MD,[4] John R. Goldblum, MD,[5] and Paul E. Swanson, MD[6]

- Concept of critical diagnosis
- Degree of urgency for:
  - Completely unexpected malignancy
  - Malignancy in critical sites
  - Organisms in immunocompromised patients

Members of the Association of Directors of Anatomic and Surgical Pathology

Am J Clin Pathol. 2008 Nov;130(5):731-5

Challenges In Implementation of CV in Anatomic Pathology

- Critical value ~ information not numerical
- Actionable - Ultimately fatal but pose no imminent threat to life
- At least 24-hour tissue processing
- Little agreement on what constitutes critical
- Lapse in communication more likely to cause harm rather than a brief delay

Effective & Timely Communication

Is “Critical Value” Correct for Anatomic Pathology?

- Raises inappropriate expectations among clinical teams and regulators
- Needless burden on resources and stress
- May induce the development of unrealistic medical-legal standards of practice

Critical Value

Critical Results

Urgent
Significant
Unexpected

Significant and Unexpected, and Critical Diagnoses in Surgical Pathology

A College of American Pathologists' Survey of 1130 Laboratories

Raouf E. Nakhleh, MD; Rhona Souers, MS; Richard W. Brown, MD

25% of laboratories did not have a policy
30% had a general policy without any specific examples

Table 2. Laboratory Responses to "How Does Your Policy Address Anatomic Pathology Critical Values?" (n = 817)

Question Responses[a]	Frequency	Percent
As a general guideline without specific conditions listed	242	29.6
As a general guideline with a few (≤5) specific examples	272	33.3
As a general guideline with multiple (>5) specific examples	149	18.2
As a strict policy with specifically defined list of diagnoses	154	18.9

Nakhleh et al. Arch Pathol Lab Med. 2009 Sep 133 (9); 1375-8

Consensus Statement on Effective Communication of Urgent Diagnoses and Significant, Unexpected Diagnoses in Surgical Pathology and Cytopathology From the College of American Pathologists and Association of Directors of Anatomic and Surgical Pathology

Raouf E. Nakhleh, MD; Jeffrey L. Myers, MD; Timothy C. Allen, MD, JD; Barry R. DeYoung, MD; Patrick L. Fitzgibbons, MD; William K. Funkhouser, MD; Dina R. Mody, MD; Amy Lynn, MD; Lisa A. Fatheree, BS, SCT(ASCP); Anthony T. Smith, MLS; Avtar Lal, MD, PhD; Jan F. Silverman, MD

Urgent Diagnosis	**Significant Unexpected Diagnosis**
Addressed as soon as possible	Addressed at some point in patients' course

ASCP STRONGERTOGETHER | CMSS grant

Nakhleh et al. Arch Pathol Lab Med. 2012 Feb 136(2); 148-54

Consensus Statements

1. Each institution create its **own policy**
2. Determine list of **“urgent diagnoses” in collaboration with clinical staff**
3. Determination of **“significant unexpected” at pathologists' discretion**
4. Communication of **“urgent” in reasonable time frame** and **“significant unexpected” as soon as practical**
5. **Verbal** communication preferred
6. **Documentation** recommended

Inclusion in CAP AP and Cytology Accreditation Checklists

ANP.12175

CYP.6450

- Significant and unexpected surgical pathology/cytopathology findings that significantly affect patient care should be determined by pathology department in cooperation with local clinical medical staff

- Communication to responsible clinician required with adequate documentation

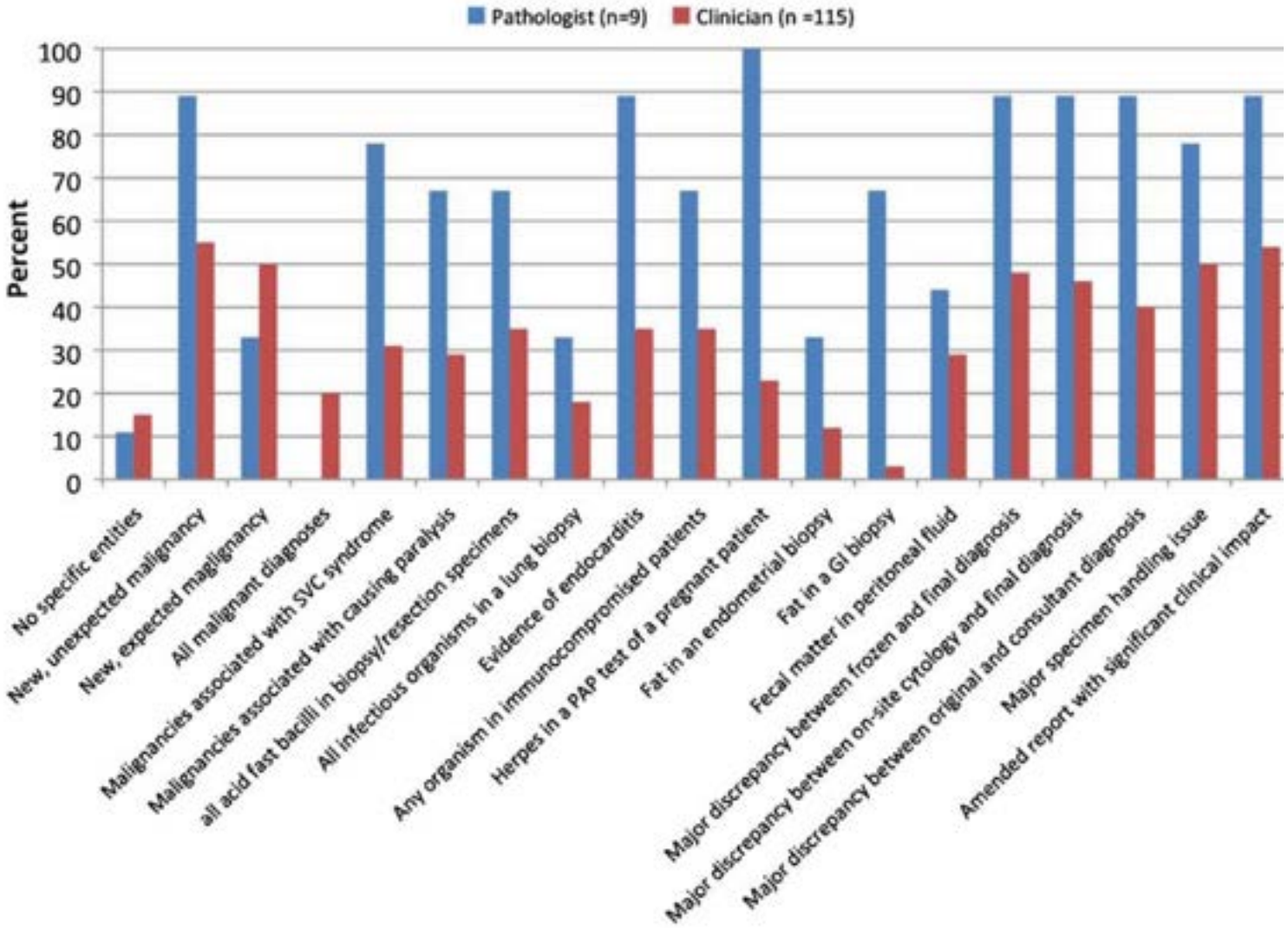
There must be a reasonable effort to ensure that clinicians receive the communications records must include the following:

- *Date of communication*
- *Time of communication (if required by laboratory policy)*
- *Responsible individual communicating the result*
- *Person notified using identifiers traceable to that person (a first name alone is inadequate)*
- *Findings communicated.*

Accreditation Checklists | College of American Pathologists (cap.org). 2023

Commentary

Perspectives and Perceptions of Urgent and Alert Values in Surgical Pathology and Cytopathology: A Survey of Clinical Practitioners and Pathologists



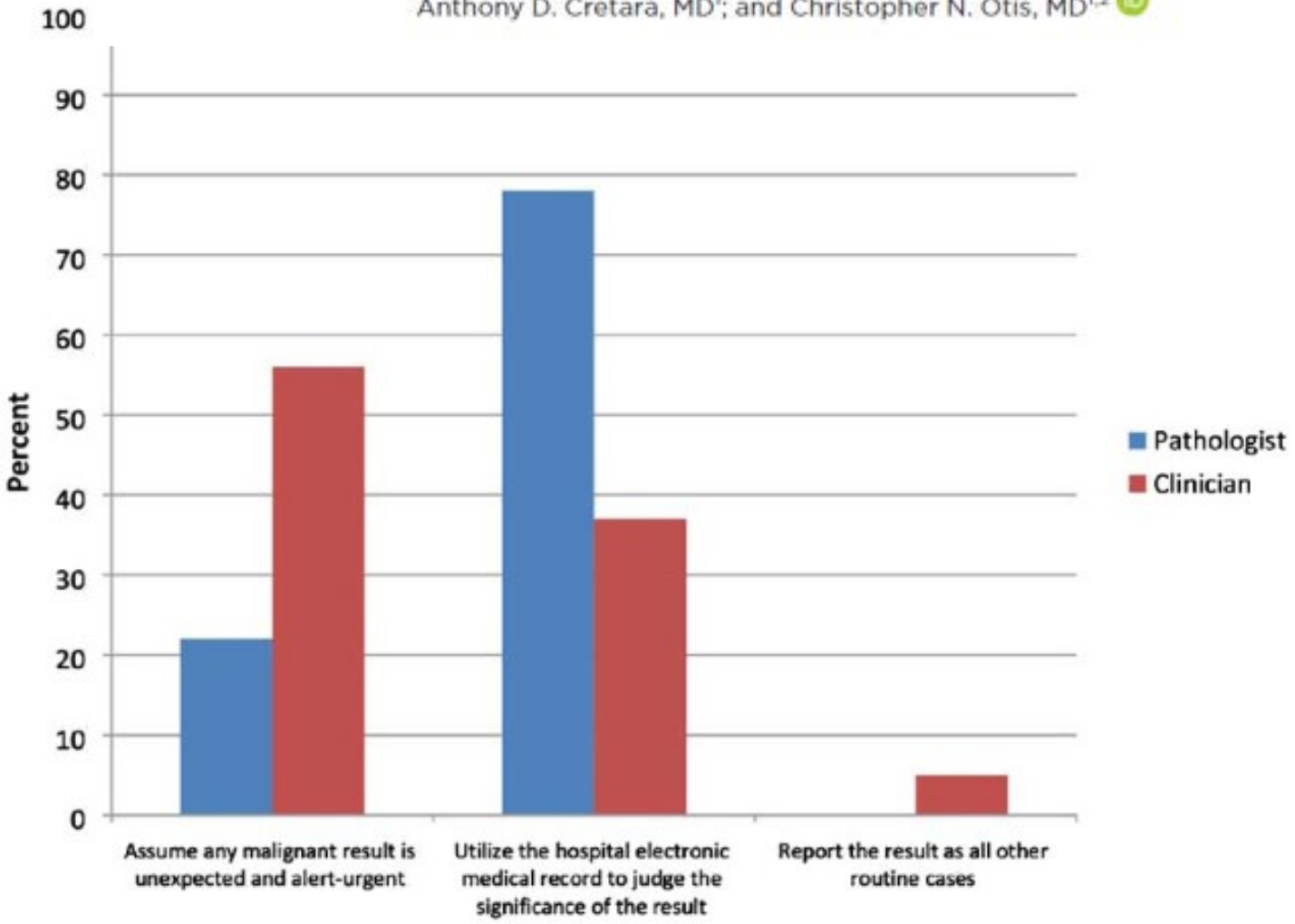
What should be considered alert-urgent diagnoses in anatomic pathology?

Cretara and Otis. Cancer Cytopathol. 2018 Dec;126(12):970-979

Commentary

Perspectives and Perceptions of Urgent and Alert Values in Surgical Pathology and Cytopathology: A Survey of Clinical Practitioners and Pathologists

Anthony D. Cretara, MD[1]; and Christopher N. Otis, MD[1,2]



If clinical history is not provided on the pathology requisition form, how should the pathologist determine if a diagnosis is unexpected?

Cretara and Otis. Cancer Cytopathol. 2018 Dec;126(12):970-979

The Current State of Communication of Urgent and Significant, Unexpected Diagnoses in Anatomic Pathology

Results of an Association of Directors of Anatomic and Surgical Pathology Survey

Paul N. Staats, MD; Vinita Parkash, MBBS, MPH; Christopher N. Otis, MD; Poonam Sharma, MBBS; Olga Ioffe, MD; Erika R. Bracamonte, MD

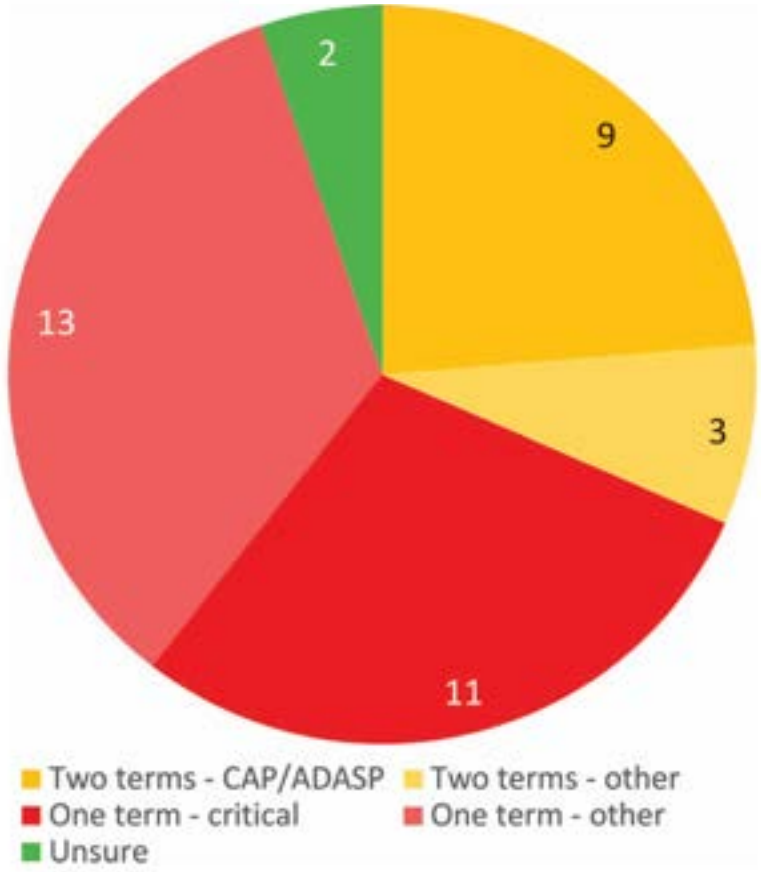


Figure 1. *Responses to:* Do you use the College of American Pathologists/Association of Directors of Anatomic and Surgical Pathology (CAP/ADASP) terminology of "Urgent Diagnoses" and "Significant, Unexpected Diagnoses" in your policy? *Data labels indicate raw numbers; total respondents were 38.*

5% of laboratories did not have a policy

66% indicated that they had read the CAP/ADASP Consensus Statement

Only 24% laboratories used the CAP/ADASP terminology

Staats et al. Arch Pathol Lab Med. 2020 Sep 1;144(9):1067-1074

The Current State of Communication of Urgent and Significant, Unexpected Diagnoses in Anatomic Pathology

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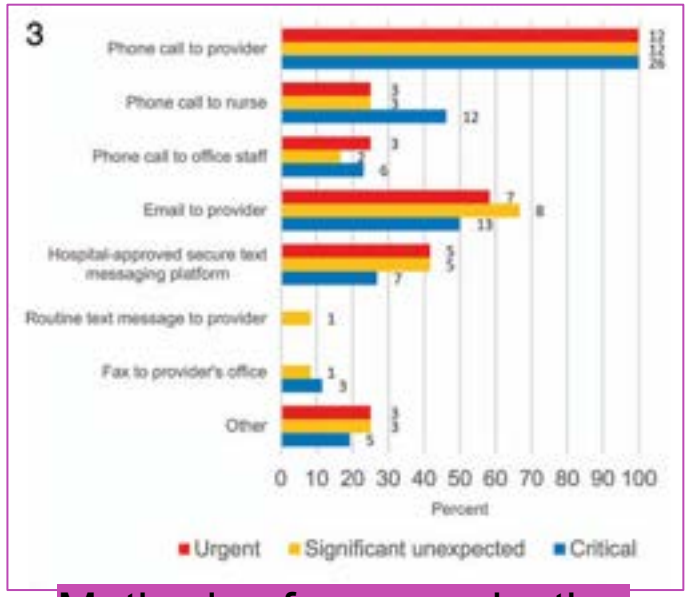
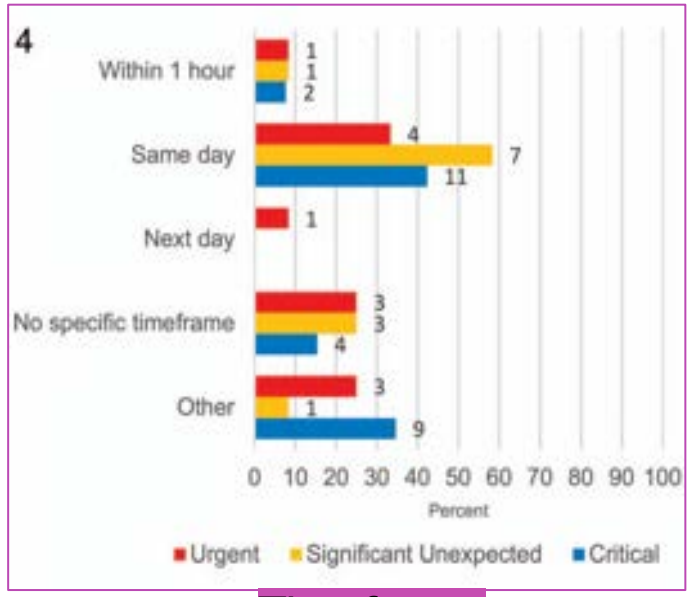
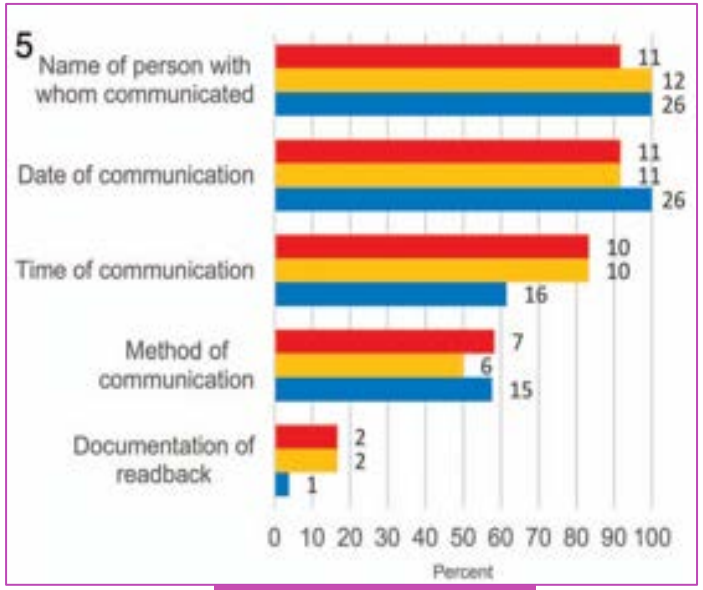
"The division of these categories makes sense in theory, in practice there is no difference in reporting the results"



Methods of communication



Timeframe



Documentation

Staats et al. Arch Pathol Lab Med. 2020 Sep 1;144(9):1067-1074.

Soleimani et al. Diagnostic Pathology (2023) 18:55
https://doi.org/10.1186/s13000-023-01342-8

Diagnostic Pathology

RESEARCH Open Access

Critical value in surgical pathology: evaluating the current status in a multicenter study

Conclusion

Although the concept of critical value in surgical pathology has been recently accepted by most laboratories, there is no standardization for critical items. It might be possible to develop more uniform norms for the determination, reporting, and documentation of these cases by expanding relevant research and recruiting more pathologists and physicians. Additionally, each medical facility is recommended to compile its own unique critical or unexpected diagnosis list and SOP to deal with surgical pathology findings, as these cases vary among medical facilities.

Soleimani et al. Diagn Pathol. 2023 18:55.

Barriers and Variations Among Practices

- Disagreement about urgent and significant unexpected diagnoses amongst pathologists & between pathologist and clinicians
- Variations in the details of policies
- Lack of standardization of time requirements for notification
- Responsible individual – who should communicate and to whom?
- How to track and handle failed communication?

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Opportunities

- Clarification of definitions
- Formulating lists of diagnoses - some examples
- Method(s) of notification
- Considerations for departmental policies
- Timely communication
- Documentation
- Quality assurance

Definitions

Best Practice Recommendation	Urgent diagnosis: • A medical condition that constitutes an immediate health risk to the individual AND/OR may require immediate action on the part of the ordering/treating physician Significant unexpected diagnosis: • A medical condition that is not clinically expected or foreseen and may possibly lead to a change in therapy or follow-up

Nakhleh RE et al. Arch Pathol Lab Med. 2012, 136(2): 148-154

Categories of Urgent and Significant Unexpected Diagnoses

- Infections
- Inflammatory diseases
- Certain hemato-lymphoid malignancies
- Unexpected malignancies
- Change in diagnosis
- Other

Examples of Urgent Diagnoses

Inflammatory/immune diseases

- Vasculitis/glomerulonephritis
  - Temporal arteritis (giant cell arteritis)
  - Leukocytoclastic vasculitis
  - Crescents in >50% of glomeruli in a kidney biopsy
- Transplant
  - Acute graft versus host disease in a specimen from a transplant recipient
  - Acute rejection in transplant biopsies
- Other
  - Toxic epidermal necrolysis
  - Acute/fulminant autoimmune hepatitis

Acute leukemia/Aggressive or high grade lymphoma, new diagnosis

- Acute promyelocytic leukemia (APL)
  - Blood or bone marrow aspirate smear morphology suggestive of APL
  - Positive t(15;17) FISH
- Burkitt lymphoma (BL)
  - Pathology specimen morphology suggestive of BL
  - Positive t(8;14) FISH

Examples of Significant Unexpected Diagnoses

Unexpected malignancies

- Malignancy identified in a surgical specimen not removed for a neoplasm e.g. hernia sac or appendix or gall bladder
- Suspected benign neoplasm with malignant findings e.g. papillary thyroid cancer (PTC) arising in a struma ovarii
- Initial detection of malignancy in a fluid specimen
- Invasive carcinoma or “cannot exclude invasion” in Papanicolaou smears

Change in diagnosis

- Significant disagreement between the immediate readout and the final fine needle aspiration (FNA) diagnosis
- Significant disagreement between the intraoperative diagnosis and final diagnosis
- Any amended (revised) reports that would significantly affect patient care
- Significant disagreement and/or change in diagnosis between the primary pathologist and a consulting pathologist (at original or consulting institution)

Examples of Urgent AND Significant Unexpected Diagnoses

Infections

- Infectious organisms in sterile sites (e.g. CSF, heart valve, bone marrow) OR evidence of tissue invasion when infection was not suspected
- Pathogenic organisms include:
  - Bacteria, e.g. acid-fast bacilli
  - Fungi, e.g. pneumocystis, mucor, aspergillus
  - Virus, e.g. herpes virus in Papanicolaou-stained cervicovaginal smears from pregnant patients

Findings indicative of perforation/fistula formation

- Adipose tissue (fat) identified in endometrial curettage
- Mesothelial cells in endomyocardial biopsy
- Ruptured uterus/bladder/viscus
- Hepatocytes in paracentesis fluid
- Bile in thoracentesis fluid

Methods of Notification

Best Practice Recommendation	• No single preferred universal method
	  • **Phone call**
	  • In-person
	  • Email
	  • Secure text
	• Ordering providers' names should be clearly documented on the requisition form - required field in requisition forms
	• Escalation: Practice or hospital leadership

Harnessing Technology for Efficient and Timely Communication

- Automated flagging in laboratory information systems (LIS) and notification in Electronic Medical Records (EMR)
- Encourage LIS manufacturers/vendors to prioritize the build and facilitate functionality for closing the loop – documenting provider acknowledgement of result receipt
- Use of artificial intelligence (AI) algorithms

Policy Requirements

Best Practice Recommendation	• Institution or practice should have a policy for communicating urgent and significant unexpected diagnoses in anatomic pathology
	
	• Policy should include:
	  • Definitions of urgent and significant unexpected diagnoses
	  • Examples of diagnoses
	  • Timeframes for communicating findings
	  • Documentation requirement for notification of diagnoses
	
	• Policies for subspecialties (in consultation with relevant clinical teams)

Timelines for Notification

Best Practice Recommendation	• Both urgent and significant unexpected diagnoses should be communicated **within 24 hours – preferably on the day of diagnosis**

Documentation of Notification

Best Practice Recommendation	Location of documentation: • Pathology report, including addendum • Laboratory Information System (LIS) • Epic chat (secure text function in EPIC) Notification of documentation should include: • Date/time • Mode of communication • Person notified using traceable identifiers • Name of the person notifying the results (electronic signature) • Finding communicated (only if using modes like email or chat)

Quality Assurance

Best Practice Recommendation	• Departments should design methods to track cases of urgent and significant unexpected diagnoses AND documentation of communication • Information technology solutions can assist in tracking such cases

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- Dalia Ibrahim, MD, MSC, FCAP
- Ali Brown MD, FASCP


Q
A

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