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

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• ***Context.*—Recognizing the difficulty in applying the concept of critical values to anatomic pathology diagnoses, the College of American Pathologists and the Association of Directors of Anatomic and Surgical Pathology have chosen to reevaluate the concept of *critical diagnoses*.**

***Objective.*—To promote effective communication of urgent and significant, unexpected diagnoses in surgical pathology and cytology.**

***Design.*—A comprehensive literature search was conducted and reviewed by an expert panel.**

***Results.*—A policy of effective communication of important results in surgical pathology and cytology is desirable to enhance patient safety and to address multiple regulatory requirements.**

***Conclusions.*—Each institution should create its own policy regarding urgent diagnoses and significant, unexpected diagnoses in anatomic pathology. This policy should be separate from critical results or panic-value policies in clinical pathology, with the expectation of a different time frame for communication. *Urgent diagnosis* is defined as a medical condition that, in most cases, should be addressed as soon as possible. *Significant, unexpected diagnosis* is defined as a medical condition that is clinically unusual or unforeseen and should be addressed at some point in the patient's course. Further details of this statement are provided.**

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To comply with regulatory and accreditation requirements, most institutions have adopted policies for communicating critical test results from clinical pathology laboratories, radiology departments, and other testing areas, such as the departments of cardiology and respiratory therapy (Appendix).[1–3] The importance of effectively communicating pathology results is further highlighted by inclusion in the 2011 National Quality Forum's list of Serious Reportable Events of the following item ''Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.''[4(p2)]

In 2006, the Association of Directors of Anatomic and Surgical Pathology (ADASP) published recommendations for *critical diagnoses* in anatomic pathology.[5] These recommendations included many sound elements, but the term *critical* signifies a need for communication within a short time frame (usually less than an hour).[5] The original Lundberg[6] definition of *critical* in clinical pathology implies an imminently life-threatening condition that requires immediate notification of the result. Surgical pathology and cytopathology testing by their nature take at least several hours to a day to complete before materials are ready for examination (aside from frozen sections).[7] Although many surgical pathology and cytology diagnoses are actionable and in need of effective communication,

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few need to be communicated urgently, and they could be termed *actionable*, *noncritical* results.[8] Furthermore, surveys among clinicians and pathologists also find poor agreement as to what constitutes a critical diagnosis in anatomic pathology.[9–14]

Recognizing the difficulty in applying the concept of critical values to anatomic pathology diagnoses, the College of American Pathologists (CAP) and ADASP have chosen to reevaluate the concept of *critical diagnoses* in an effort to promote effective communication of urgent and significant, unexpected diagnoses in surgical pathology and cytology.

THE CAP PATHOLOGY AND LABORATORY QUALITY CENTER

The CAP developed the Pathology and Laboratory Quality Center (the CAP Center) as a forum to write and maintain evidence-based guidelines and consensus statements. Focused on optimizing patient safety and outcomes, most CAP Center topics originate with practicing pathologists who describe variance in approaches to care, test selection, and diagnosis. The CAP Center aims to develop guidelines that reduce risks for patients, while facilitating the efficient use of resources for timely and accurate diagnosis.

PRACTICE GUIDELINES AND CONSENSUS STATEMENTS

Practice guidelines and consensus statements reflect the best available evidence and majority expert agreement supported in practice. They are intended to assist physicians and patients in clinical decision making and to identify questions and settings for further research. With the rapid flow of scientific information throughout medicine and especially in pathology and laboratory medicine, new evidence may emerge between the time an updated guideline was submitted for publication and when it is read or appears in print or online. These documents are reviewed periodically as well as after the publication of substantive and high-quality medical evidence that could potentially alter the original guideline recommendations. This manuscript and its recommendations are meant only to address the topics within the scope of the guideline or consensus statement. They are not applicable to interventions, diseases, or stages of diseases not specifically identified.

Furthermore, guidelines and consensus statements cannot account for individual variation among patients and cannot be considered inclusive of all proper methods of care or exclusive of other treatments. It is the responsibility of the treating physician or other health care provider, relying on independent experience and knowledge of the patient, to determine the best course of treatment for the patient. Accordingly, adherence to any guideline or consensus statement is voluntary, with the ultimate determination regarding its application to be made by the physician in light of each patient's individual circumstances and preferences. The CAP/ADASP guidelines and consensus statements describe the use of communications of findings, procedures, and therapies in clinical practice and cannot be assumed to apply to the use of interventions in the context of other settings. The CAP and ADASP assume no responsibility for any injury or damage to persons or property arising out of or related to any use of the CAP/ADASP guidelines or consensus statements or for any errors or omissions.

MATERIALS AND METHODS

The ''Supplemental Material,'' including methods and detailed analysis of the strength of evidence, are available (see ''Supplemental Material'' file at www.archivesofpathology.org in the February 2012 table of contents).

Panel Composition and Process

The CAP Center and ADASP convened a work group (WG) of experts in anatomic pathology to address what constitutes a *critical value* in anatomic pathology and how best to ensure proper and timely communication of those results. Both organizations used their respective organization's approval processes in formal review and appointment of the project, chair, and WG members.

All members of the WG complied with the CAP conflicts of interest policy dated April 2010, which requires disclosure of financial or other interests that may have an actual, potential, or apparent conflict. All WG members were required to disclose any new conflicts continuously, and no conflicts were disclosed throughout the project.

The WG met in September 2010; additional work on the project was completed through teleconference Webinars, collaboration site access (Oracle WebCenter Spaces v11.1.1.2.0, Oracle Corporation, Redwood Shores, California), and electronic mail by all members of the WG. The method used to create the recommendations was expert consensus. Resolution of discordant ideas was obtained by majority consensus of the WG members. Feedback of the draft recommendations was solicited from ADASP members, CAP scientific resource committees, CAP members, other pathology societies, and external reviewers via public comment hosted on the CAP Web site (http://www.cap.org/center) from March 11, 2011, through April 10, 2011 (last accessed April 10, 2011). The CAP Center Subcommittee and the ADASP Council provided final review and approval.

Literature Search

We conducted a computerized search during May 2010 to February 2011 of the following electronic databases: Ovid MEDLINE (Ovid, New York, New York), CSA Illumina Conference Papers Index (ProQuest, Ann Arbor, Michigan), and Google Scholar (Google, Mountain View, California), for English language only articles from 1990 through February 2011. All study designs and publication types were included. In addition, the WG requested the George D. Lundberg 1972 article ''When to Panic Over Abnormal Values.''[6] The search used the following terms:

- (Anatomic pathology OR surgical pathology OR cytopathology OR radiology OR cardiology) AND
- ((Critical OR significant OR unexpected) AND (values OR diagnosis OR results))

Reference lists from identified articles were scrutinized for articles not identified in the above search. A search of the LexisNexis database (Reed Elsevier Inc, New York, New York) was also conducted to evaluate and understand claims, judgments, and settlements against pathologists in which communication failure was the primary reason.

Studies were selected for full-text review based on the following criteria: (1) the abstract referred to pathology (except autopsy or forensic), cardiology, or radiology; (2) the abstract included or implied one or more of the terms *critical*, *panic values*, *urgent*, *significant*, or *unexpected*; and (3) the abstract addressed communication or reporting. The 128 studies that met the search term requirements underwent an inclusion-exclusion, dual independent review conducted by the chair and a member, with a third member referee for nonconsensus abstracts. Sixty-four articles (50%) made it through full review, and 19 articles (15%)

Table 1. Criteria for Evaluation of the Full-Text Articles and Points Assigned to Stratify Papers by Relevance

Does this article pertain to our scope as defined here?
- To devise sound communication strategies for urgent or significant unexpected findings in anatomic pathology
- To review other communication efforts of ''critical'' values in comparable clinical settings, such as clinical pathology, cardiology, or radiology
  - Directly (3 points)
  - Partially (2 point)
  - No relevance (0 points)

Does this article:
- Provide *consensus recommendations* by an authoritative organization? (3 points)
- Represent *results* of a single institutional review of experience? (2 points)
- Represent *editorial* or *opinion* of a single group? (1 point)

Composite scoring was done for each article to determine which articles were most relevant to the recommendations and then forwarded for review by a contracted methodologist.

were determined to have the most relevance. Table 1 includes the criteria for evaluation.

The 19 articles determined to have most relevance were analyzed to determine the strength of evidence for the recommendations. Of the 19, 10 (53%) were eliminated: 8 for study design not of interest and 2 for duplicate data. Of the remaining 9 studies, 6 (67%) represented surveys, 2 (22%) were time series, and 1 (11%) was a randomized, controlled study. These 9 studies underwent data extraction to capture evidence in support of the recommendations. Each study was assessed for strength of evidence, which consists of level of evidence, quantity, size of the effect, statistical precision, and quality assessment (risk of bias), of included studies. Also taken into account were the study components of consistency, clinical impact, generalizability, and applicability to anatomic pathology when determining the strength of evidence score for individual studies. The studies' individual component scores derived from predetermined criteria, generated the overall grade for the strength of evidence. The scientific quality of the randomized, controlled trial was assessed using the SIGN 50 instrument (Scottish Intercollegiate Guidelines Network, Edinburgh, Scotland), and its quality was poor.[15] The scientific quality of the time series was determined using the Ramsay et al[16] instrument, and the quality of both studies was good. However, both studies lacked comparative control groups.

Draft recommendations were subjected to a public comment period (March 11, 2011, to April 10, 2011). Comments were used to further refine the recommendations.

RESULTS

Most of the literature concerning anatomic pathology ''critical diagnoses'' was composed of editorials and case reports (n = 20) with calls for effective communication of significant diagnoses. Several recent reports[9–14] documented what pathologists and clinicians consider as *critical diagnoses* in anatomic pathology. There were 9 reports of various types of surveys of practice in clinical pathology.[17–25] Five articles described attempts to improve communication of critical values in the clinical laboratory.[26–30] There were 3 reports of general recommendations regarding implementation of a critical value policy.[21,28,31] The remaining relevant publications consisted of abstracts, presentations, letters to the editor, and trade journal discussions. There were no reports of systematic documentation of failed communications in anatomic pathology with evaluation of the consequences of those failures. Based on the data extraction of 9 studies (Table 2) and relevance to the recommendations, the overall strength of evidence was poor. For a detailed analysis on the evaluation of the strength of evidence, please refer to the ''Supplemental Material'' file at www.archivesofpathology.org in the February 2012 table of contents.

During the public comment period on the draft recommendations, there were 599 visits to the Web site,

Table 2. Nine Studies Deemed to be Most Relevant to Effective Communication in Anatomic Pathology

Source, y	Study Type	Focus	No. of Physicians or Reports Surveyed
Huang et al,[13] 2009	Single-institution time trial	Monitoring of surgical pathology critical diagnoses	1894 reports with physician notification were reviewed during two, 6-mo periods
Pereira et al,[10] 2006	2-institution survey	Cytology critical values	2000 reports reviewed with 52 ''critical diagnoses'' identified; 22 cytopathologists and 13 clinicians surveyed
Pereira et al,[9] 2004	Single-institution survey	Surgical pathology critical diagnoses	2659 reports reviewed with 13 ''critical diagnoses'' identified; 11 pathologists and 5 clinicians surveyed
Pereira et al,[12] 2008	Multi-institution survey	Surgical pathology and cytology critical diagnoses	73 pathologists surveyed
Coffin et al,[11] 2007	Single-institution survey	Pediatric pathology critical diagnoses	91, 23, and 413 reports of ''critical diagnoses'' were reviewed; 8 pediatric pathologists and 18 clinicians surveyed
Nakhleh et al,[14] 2009	Multi-institution survey	Surgical pathology critical diagnoses	1130 pathologists surveyed
Kuperman et al,[29] 1999	Single-institution, randomized, controlled trial	Clinical laboratory critical values	192 alerting situations (94 automated, 98 controls)
Wagar et al,[25] 2007	Multi-institution time trial	Clinical laboratory critical values	Longitudinal study evaluation of clinical practice patterns in 180 institutions
Wagar et al,[24] 2007	Multi-institution survey	Clinical laboratory critical values	163 laboratories surveyed for critical value ranges

Table 3. Definitions and Consensus Statements

Definitions

Urgent Diagnosis: A medical condition that, in most cases, should be addressed as soon as possible.

Significant, Unexpected Diagnosis: A medical condition that is clinically unusual or unforeseen and should be addressed at some point in the patient's course.

Consensus Statements

1. Each institution should create its own policy regarding *Urgent Diagnoses* and *Significant, Unexpected Diagnoses* in *Anatomic Pathology*. This policy should be separate from critical result or panic value policies in clinical pathology with the expectation of a different time frame for communication.
2. Pathology departments should determine specific urgent diagnoses in collaboration with the clinical staff. These diagnoses should include situations in which urgently conveying the information may directly affect patient care. An example of an urgent diagnosis is an unknown life-threatening infection in an immune-compromised patient. Pathologists, however, should use their experience and judgment to communicate any diagnoses, even if not included in the policy. In hospital practice, approval by the appropriate institutional governing body is recommended.
3. Determination of a significant, unexpected diagnosis is heavily dependent on the pathologist's judgment as a physician. By their nature, significant, unexpected diagnoses cannot always be anticipated. Examples such as a frozen section–permanent section discordance that affects patient care or a clinically unsuspected malignancy may be listed in the policy.
4. Pathologists should communicate urgent diagnoses as soon as possible because it may directly affect patient care, but each institution should establish a reasonable time frame. We recommend no longer than the same day on which the diagnosis is made. Communication of significant, unexpected diagnoses should occur as soon as practical; pathologists may exercise their judgment as to the appropriate timing of communication.
5. Pathologists should communicate verbally and directly with physicians, but other satisfactory methods of communication may be established and validated by each institution. Backup communication plans should be developed for those circumstances in which a physician is not available.
6. Pathologists should document the communication. This can be done in the original pathology report, as an addendum, in the electronic medical record, or by another mechanism. Documentation should include the person with whom the case was discussed, the time and date, and when appropriate, the means of communication.

with 441 comments (74% left comments). These comments were used to modify the draft recommendations. Table 3 lists the WG definitions and final consensus statements for effective communication in surgical pathology and cytology.

COMMENT

Critical result policies are mandated to enhance communication among caregivers and to decrease the chance of patient harm (Appendix). Most institutions have established critical result policies that impose a specific time frame (eg, 30 minutes, 60 minutes) for communication of the result to the responsible caregiver.[17,18,20,22,23] Most clinical laboratories comply with those mandates and communicate a high proportion of their designated critical results within 30 minutes.[17,18,20–25]

Surgical pathology and cytology stand apart for several reasons. First and foremost, routine specimen processing (including adequate fixation) requires up to 24 hours, rendering meaningless a 30 or 60 minute window to report the results. Second, the term *critical* implies an imminently life-threatening condition. Most diagnoses recommended as critical for surgical pathology and cytology are serious conditions that require attention but are not imminently life threatening. Third, surveys have shown little agreement on what constitutes a *critical* diagnosis. Fourth, wide use of the term *critical* has diluted its effectiveness for surgical pathology and cytology. Fifth, most reported cases where patient harm is reported have occurred because of lack of communication or missed communication, rather than from a brief delay in reporting the diagnosis. Sixth and finally, communication in surgical pathology and cytology is usually done to ensure that the written report is not overlooked. Given these considerations, it may be better for policies in anatomic pathology departments to emphasize that *effective and timely* communication occurs, instead of insisting that communication occurs within 30 minutes or 1 hour. Intraoperative consultation was excluded from this matter because it has well-established expectations for communication and turnaround.

Although we recognize that there are conditions in anatomic pathology that demand immediate communication as soon as the diagnosis is known, we propose using the term *urgent diagnosis* instead of *critical diagnosis* because the tissue may have been obtained hours or even days before the diagnosis is rendered. We also believe that pathologists should distinguish *urgent diagnoses* from *significant, unexpected diagnoses* that need not be communicated with the same level of urgency. As such, we propose that both the terms *urgent diagnosis* and *significant, unexpected diagnosis* be used in surgical pathology and cytopathology. We advocate that each department develop policies and procedures for effective communication of urgent diagnoses and significant, unexpected diagnoses in surgical pathology and cytology that are separate from institutional policies and procedures for critical results.

Given the variability in local practices and expectations and the lack of consensus among pathologists and clinicians on which diagnosis must be included in this policy, each institution should determine its own list of urgent diagnoses. However, pathologists also must use their medical judgment in urgently communicating individual diagnoses any time that safe patient care may be at risk, even if it is a situation not listed in the policy.

Significant, unexpected diagnoses by their nature may not be entirely anticipated, so departments may list examples of significant, unexpected diagnoses to demonstrate such cases. Pathologists should communicate significant, unexpected diagnoses as soon as is practical but may use their judgment to determine the appropriate timing for that communication.

On the other hand, institutions may also choose to have a communication policy regarding specimens or diagnoses other than urgent and significant, unexpected diag-

noses on the basis of clinician considerations and preferences. Pathologists and their clinical counterparts may work together to find the most suitable means of ensuring proper communication of such diagnoses. Although this represents good patient care, these types of cases may be designated using other terms (eg, *call list*) but should NOT be designated as *urgent diagnoses* or *significant, unexpected diagnoses*.

In addition, each institution or health care system should develop policies regarding the most appropriate recipient of the information and a process for escalating the results to others should the designated recipient be unavailable or fail to respond.[21,28,32] These policies affect providers well beyond the purview of individual pathology departments and must reside with the institutional body charged with quality and safe patient care. In many practice environments, inpatient and outpatient results will require distinct policies and procedures. Policies for effectively relaying urgent diagnoses and significant, unexpected diagnoses should also account for off-hours, including weekends.

Critical clinical laboratory results are typically called to the physician or nurse by a laboratory technician. In surgical pathology and cytology, physicians ordinarily make the call because the diagnoses tend to be interpretive and consultative. Most feel that there is inherent value in direct physician-to-physician communication of urgent diagnoses or significant, unexpected diagnoses. Indeed, there is evidence that direct verbal communication is likely to be more effective than other forms of communication.[33] There have been experiences with automated methods of communication for critical values in the clinical laboratory using automated paging systems. These methods appear to be effective in reducing the time it takes to relay critical value to the physician and the time for therapy to be started.[21,27,29] However, these methods are untested in anatomic pathology and are based on discrete laboratory values for specific tests, a circumstance that is usually not applicable to anatomic pathology. Nevertheless, communication methods other than direct physician-to-physician dialogue may develop. Any alternative to direct physician-to-physician communication should be validated and audited to ensure ongoing effectiveness.

Written documentation of verbal or other communication is recommended because it provides evidence that direct communication occurred. If the treating clinician cannot be reached in a timely manner, documentation of the communication may be done as an addendum or in a separate (electronic or paper) log. This form of documentation can be the basis of any audit of effective communication practices.

Audits or quality-assurance monitoring of this practice are currently difficult to conduct. The difficulty lies in determining the group of cases to be audited. It is easy to retrieve and demonstrate cases that were documented as urgent diagnoses or significant, unexpected diagnoses. It is much more difficult to audit cases that may have been missed. One approach could be that selected diagnoses listed as urgent diagnoses be retrieved and evaluated for documentation of communication. For example, in a transplant center, severe rejection may be listed as an urgent diagnosis. Retrieving all cases of severe rejection and checking to see whether they were urgently communicated would be an appropriate audit. It is a much more difficult task to survey for significant, unexpected diagnoses because they do not represent a list of specific diagnoses. Different approaches in conducting the audit are in the literature. Huang et al[13] retrospectively reviewed all reports for two 6-month periods in 2006 and 2007; more than 3% of cases in those years met the criteria as per their policy, and communication was documented for most cases. Lusky[34] describes an ongoing process of case review used by Myers and Visscher at the University of Michigan Hospitals (Ann Arbor) that helps ensure that cases are not missed. Their process involves daily review of cases, examining diagnoses that possibly meet the criteria for inclusion as an urgent diagnosis or a significant, unexpected diagnosis and checking whether communication occurred in those instances.

Cautionary Notes

In our review of cases, we found that there are situations that may be problematic but are not easily addressed by policy; among them, are the following:

1. A physician performs a biopsy or other procedure but does not participate in the patient's care beyond that point. Sending the surgical pathology report only to the person performing the procedure may result in a delay in follow-up. The laboratory should try to address these situations by having an understanding that all of the patient's relevant providers are included in the requisition, so that reports are sent accordingly. Direct patient access to pathology results may ultimately prove the most effective method for closing the loop on urgent diagnoses and significant, unexpected diagnoses in this sort of scenario.
2. Changed frozen section or cytology preliminary diagnoses are likely covered by this policy, but pathologists should be particularly alert to situations in which a subsequent procedure may have been tentatively scheduled based on the preliminary result. Communicating an unanticipated change in diagnosis as soon as it is known is essential.
3. A patient has a procedure and subsequently moves to a different location and is lost to follow-up.
4. An urgent diagnosis or a significant, unexpected diagnosis is communicated to a member of the health care team who fails to broadcast the message to other providers who may be directly responsible for diagnostic or therapeutic decision making. This occurs, for example, if an unexpected result for a transplant biopsy is communicated to a member of the health care team who rotates off service shortly after receiving the message and fails to document or hand off the message.
5. A diagnosis is made in the evening or on the weekend and is deemed urgent by the pathologist; he or she calls the hospital operator to page the on-call physician for that service and is informed that there is no on-call person for that service. This emphasizes the need to have alternative methods of communication, as well as a primary treating clinician contact for all direct time-sensitive communications.

References

1. Joint Commission. 2011 Laboratory Services: 2011 national patient safety goals. http://www.jointcommission.org/lab_2011_npsgs. Accessed May 3, 2011.
2. College of American Pathologists. CAP Laboratory accreditation checklists. http://www.cap.org/apps/cap.portal. Accessed July 12, 2011.
3. Department of Health and Human Services. Clinical laboratory improvement amendments of 1988: final rule. *Fed Regist*. 1992;57(40):7001–7186. Codified at 42 CFR 1405–494.
4. National Quality Forum. NQF releases updated serious reportable events: latest update includes four new events [press release]. http://www.qualityforum.

org/News_And_Resources/Press_Releases/2011/NQF_Releases_Updated_Serious_Reportable_Events.aspx. Released June 13, 2011. Accessed July 11, 2011.

5. Silverman JF, Pereira TC. Critical values in anatomic pathology. *Arch Pathol Lab Med*. 2006;130(5):638–640.

6. Lundberg GD. When to panic over abnormal values. *MLO Med Lab Obs*. 1972;4:47–54.

7. Lester SC. *Manual of Surgical Pathology*. 2nd ed. New York, NY: Elsevier Saunders; 2006:611.

8. Roy CL, Poon EG, Karson AS, et al. Patient safety concerns arising from test results that return after hospital discharge. *Ann Intern Med*. 2005;143(2):121–128.

9. Pereira TC, Liu Y, Silverman JF. Critical values in surgical pathology. *Am J Clin Pathol*. 2004;122(2):201–205.

10. Pereira TC, Clayton AC, Tazelaar HD, Liu Y, Leon M, Silverman JF. Critical values in cytology. *Diagn Cytopathol*. 2006;34(6):447–451.

11. Coffin CM, Spilker K, Lowichik A, et al. Critical values in pediatric surgical pathology: definition, implementation, and reporting in a children's hospital. *Am J Clin Pathol*. 2007;128(6):1035–1040.

12. Pereira TC, Silverman JF, LiVolsi V, et al. A multi-institutional survey of critical diagnoses (critical values) in surgical pathology and cytology. *Am J Clin Pathol*. 2008;130(5):731–735.

13. Huang EC, Kuo FC, Fletcher CD, Nose V. Critical diagnoses in surgical pathology: a retrospective single-institution study to monitor guidelines for communication of urgent results. *Am J Surg Pathol*. 2009;33(7):1098–1102.

14. Nakhleh RE, Souers R, Brown RW. Significant and unexpected, and critical diagnoses in surgical pathology: a College of American Pathologists' survey of 1130 laboratories. *Arch Pathol Lab Med*. 2009;133(9):1375–1378.

15. Scottish Intercollegiate Guidelines Network. SIGN 50: a guideline developers' handbook: methodology checklist 2: randomized controlled trials. Edinburgh, Scotland: Scottish Intercollegiate Guidelines Network; 2008. http://www.sign.ac.uk/guidelines/fulltext/50/checklist2.html. Accessed June 16, 2011.

16. Ramsay CR, Matowe L, Grilli R, Grimshaw JM, Thomas RE. Interrupted time series designs in health technology assessment: lessons from two systematic reviews of behavior change strategies. *Int J Technol Assess Health Care*. 2003;19(4):613–623.

17. Dighe AS, Rao A, Coakley AB, Lewandrowski KB. Analysis of laboratory critical value reporting at a large academic medical center. *Am J Clin Pathol*. 2006;125(5):758–764.

18. Howanitz PJ, Steindel SJ, Heard NV. Laboratory critical values policies and procedures: a College of American Pathologists Q-Probes study in 623 institutions. *Arch Pathol Lab Med*. 2002;126(6):663–669.

19. Kost GJ, Hale KN. Global trends in critical values practices and their harmonization. *Clin Chem Lab Med*. 2011;49(2):167–176.

20. Lippi G, Giavarina D, Montagnana M, et al; Society of Clinical Biochemistry and Clinical Molecular Biology, Italian Society of Laboratory Medicine, Italian Committee for Standardization of Laboratory and Hematological Methods, Inter-associative Study Group on Extra-Analytical Variability of Laboratory Tests. National survey on critical values reporting in a cohort of Italian laboratories. *Clin Chem Lab Med*. 2007;45(10):1411–1413.

21. Singh H, Wilson L, Reis B, Sawhney MK, Espadas D, Sittig DF. Ten strategies to improve management of abnormal test result alerts in the electronic health record. *J Patient Saf*. 2010;6(2):121–123.

22. Tillman J, Barth JH; for ACB National Audit Group. A survey of laboratory 'critical (alert) limits' in the UK. *Ann Clin Biochem*. 2003;40(pt 2):181–184.

23. Valenstein PN, Wagar EA, Stankovic AK, Walsh MK, Schneider F. Notification of critical results: a College of American Pathologists Q-Probes study of 121 institutions. *Arch Pathol Lab Med*. 2008;132(12):1862–1867.

24. Wagar EA, Friedberg RC, Souers R, Stankovic AK. Critical values comparison: a College of American Pathologists Q-Probes survey of 163 clinical laboratories. *Arch Pathol Lab Med*. 2007;131(12):1769–1775.

25. Wagar EA, Stankovic AK, Wilkinson DS, Walsh M, Souers RJ. Assessment monitoring of laboratory critical values: a College of American Pathologists Q-Tracks study of 180 institutions. *Arch Pathol Lab Med*. 2007;131(1):44–49.

26. Barenfanger J, Sautter RL, Lang DL, Collins SM, Hacek DM, Peterson LR. Improving patient safety by repeating (read-back) telephone reports of critical information. *Am J Clin Pathol*. 2004;121(6):801–803.

27. Etchells E, Adhikari NK, Cheung C, et al. Real-time clinical alerting: effect of an automated paging system on response time to critical laboratory values—a randomised controlled trial. *Qual Saf Health Care*. 2010;19(2):99–102.

28. Jackson C, Macdonald M, Anderson M, Stevens P, Gordon P, Laxer R. Improving communication of critical test results in a pediatric academic setting: key lessons in achieving and sustaining positive outcomes. *Healthc Q*. 2009;12(suppl):116–122.

29. Kuperman GJ, Teich JM, Tanasijevic MJ, et al. Improving response to critical laboratory results with automation: results of a randomized controlled trial. *J Am Med Inform Assoc*. 1999;6(6):512–522.

30. Piva E, Sciacovelli L, Zaninotto M, Laposata M, Plebani M. Evaluation of effectiveness of a computerized notification system for reporting critical values. *Am J Clin Pathol*. 2009;131(3):432–441.

31. Hanna D, Griswold P, Leape LL, Bates DW. Communicating critical test results: safe practice recommendations. *Jt Comm J Qual Patient Saf*. 2005;31(2):68–80.

32. Joint Commission on Accreditation of Healthcare Organizations. Creating a backup system: ensuring timely reporting of critical test results and values. *Jt Comm Perspect Patient Saf*. 2008;8(6):6–8.

33. Hess DR, Tokarczyk A, O'Malley M, Gavaghan S, Sullivan J, Schmidt U. The value of adding a verbal report to written handoffs on early readmission following prolonged respiratory failure. *Chest*. 2010;138(6):1475–1479.

34. Lusky K. Handing off critical results—well before things turn critical. *CAP Today*. 2007;21(6):1;75–82.

Appendix: Legal and Regulatory Standards as of July 2011	
Agency	**Mandate/Standards**
CAP Laboratory Accreditation Program (LAP)	**ANP.12175** **There is a policy regarding the communication, and documentation thereof, of significant and unexpected surgical pathology findings.** *NOTE: Certain surgical pathology diagnoses may be considered significant and unexpected. Such diagnoses may include malignancy in an uncommon location or specimen type (eg, hernia sac, intervertebral disk material, tonsil) or change of a frozen section diagnosis after review of permanent sections. There should be a reasonable effort to ensure that such diagnoses are received by the clinician, by means of telephone, pager, or other system of notification. There must be documentation of the date of communication of these diagnoses.* *In distinction to the above, the pathology department may designate certain surgical pathology diagnoses for prompt communication to the clinician. Such diagnoses may include, for example, neoplasms causing paralysis or fat in an endometrial curettage. There must be documentation of the date of communication of such results.* *Diagnoses to be defined as ''significant and unexpected,'' and those for prompt communication should be determined by the pathology department, in cooperation with local clinical medical staff.* *Documentation of communication of these diagnoses may be included in the pathology report, or in other laboratory records.* **CYP.06450** **There is a policy regarding the communication, and documentation thereof, of significant and unexpected cytopathology findings.** *NOTE: Certain cytopathology diagnoses may be considered particularly significant and unexpected. For example, such diagnoses may include invasive carcinoma found in a cervicovaginal specimen, malignancy in an effusion with no patient history of neoplasm, etc. There should be a reasonable effort to ensure that such diagnoses are received by the clinician, by means of telephone, pager, or other system of notification. There must be documentation of the date of these diagnoses.* *Diagnoses to be defined as ''significant and unexpected,'' should be determined by the cytopathology department, in cooperation with local clinical medical staff.*
CLIA '88	• Sec. 493.1234 Standard: Communications—The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized individual who orders or receives test results. • Sec. 493.1291 Standard: Test Report (a)—The laboratory must have adequate manual or electronic systems in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. (g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminent life-threatening condition, or panic or alert values. (h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. (k) When errors in the reported patient test results are detected, the laboratory must do the following: (1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.
Joint Commission	• Timely Reporting of Critical Tests and Critical Results (NPSG.02.03.01) • Critical results of tests and diagnostic procedures fall significantly outside the normal range and may indicate a life-threatening situation. The objective is to provide the responsible licensed caregiver these results within an established time frame so that the patient can be promptly treated. • Elements of Performance for NPSG.02.03.01 1. Collaborate with organization leaders to develop written procedures for managing the critical results of tests and diagnostic procedures that address the following: ◦ The definition of critical results of tests and diagnostic procedures ◦ By whom and to whom critical results of tests and diagnostic procedures are reported ◦ The acceptable length of time between the availability and reporting of critical results of tests and diagnostic procedures. 2. Implement the procedures for managing the critical results of tests and diagnostic procedures. 3. Evaluate the timeliness of reporting the critical results of tests and diagnostic procedures.

Abbreviations: CAP, College of American Pathologists; CLIA '88, Clinical Laboratory Improvement Amendments of 1988.

*Inactive guidelines are no longer updated with systematic literature reviews, but the recommendations may still be useful for educational, informational, or historic purposes.