Communicating Critical Test Results

Communicating Critical Test Results:

Safe Practice Recommendations

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Massachusetts hospitals have collaborated in a statewide patient safety initiative aimed at improving our ability to communicate critical test results in a timely and reliable way to the clinician who can take action. This topic was selected in March 2002 by an advisory group of hospital representatives convened by the Massachusetts Coalition for the Prevention of Medical Errors (the Coalition) and the Massachusetts Hospital Association (MHA). There was broad consensus that errors in the process of communication of test results were both frequent and had the potential for serious harm. Solutions to this problem would address enhancing communication, teamwork, and information transfer, all fundamental system factors linked to patient safety.

The Coalition and MHA convened a multi-disciplinary stakeholder group that included representation from the laboratory, cardiology, radiology, and physicians and nurses from inpatient and ambulatory sites. This Consensus Group met monthly from early June 2002 through early February 2003 to identify guidelines, implementation issues, and useful strategies to improve communication processes. The group defined critical test results as any values/interpretations for which delays in reporting can result in serious adverse outcomes for patients. The scope included laboratory, cardiology, radiology, and other diagnostic tests in the inpatient, emergency, and ambulatory settings.

The Consensus Group developed two major products: Safe Practice Recommendations to promote successful

Article-at-a-Glance

Background: Massachusetts hospitals have collaborated in a patient safety initiative conducted by the Massachusetts Coalition for the Prevention of Medical Errors and the Massachusetts Hospital Association which is aimed at improving the ability to communicate critical test results in a timely and reliable way to the clinician who can take action. Solutions to this problem would address enhancing communication, teamwork, and information transfer, all fundamental system factors linked to patient safety.

Developing the Safe Practice Recommendations and the "Starter Set": A Coalition-convened Consensus Group defined critical test results as values/interpretations for which reporting delays can result in serious adverse outcomes for patients. The scope included laboratory, cardiology, radiology, and other diagnostic tests in inpatient, emergency, and ambulatory settings. The Consensus Group developed Safe Practice Recommendations to promote successful communication of results, and a "starter set" of test results sufficiently abnormal to be widely agreed to be considered "critical."

Dissemination: The recommendations and the starter set of test results were disseminated in a statewide collaborative open to all Massachusetts hospitals. Hospitals' team members tested changes and shared successful strategies that improved the reliability of communicating critical test results. An evaluation of the results of this collaborative is underway.

communication of these results, and a "starter set" of test results sufficiently abnormal to be widely agreed to be considered "critical."

The Safe Practice Recommendations address the following:

- Who should receive the results
- Who should receive the results when the ordering provider is not available
- What results require timely and reliable communication
- When the results should be actively reported to the ordering provider with explicit time frames
- How to notify the responsible provider
- How to design, support, and maintain the systems involved

Although all hospitals had thresholds regarding which results to communicate, these nearly always included many results that were not truly critical, thus greatly increasing the number of calls and diluting the sense of urgency with which their communication was received by physicians. On the other hand, some abnormalities that were not emergent—yet could not be lost without serious consequences—were not included. As a result, we developed a starter set for test results/interpretations that organizations could use. This set will certainly require additional refinement and we present it as a place to begin.

The recommendations were disseminated in a statewide collaborative open to all Massachusetts hospitals. Hospitals working on this project met together in four collaborative sessions (May and November 2003 and March and September 2004) in a 16-month period to learn how to implement these recommendations. Using the Institute for Healthcare Improvement's Model for Improvement, team members tested changes, relied on measurement to monitor their progress, and shared successful strategies that improved the reliability of communicating critical test results. An evaluation of the results of this collaborative is currently underway.

The Safe Practice Recommendations can be found in Table 1 (page 70–76). References for the Safe Practice Recommendations follow. The Rationale and Operating Definitions for Communicating Critical Test Results can be found in Appendix 1 (pages 78–79). An excerpt—limited to the laboratory testing areas of chemistry and blood gases from the Consensus Group Recommendations for "Starter Set" Values/Interpretations—can be found in Appendix 2 (page 80). These values and interpretations are not intended to serve as a standard but rather as a starting point for hospitals' own determination of values and interpretations appropriate to the populations served. J

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Table 1. Safe Practice Recommendations for Communicating Critical Test Results*

Safe Practice Recommendation	Implementation Context
1. Identify *who* should receive the results	
■ The primary responsibility for receiving and following up on test results lies with the ordering provider or the responsible provider as appropriate	■ The ordering provider should receive and follow up on the results of all ordered tests ■ The ordering provider has the responsibility to communicate outstanding diagnostic tests and assign responsibility for follow up to a covering provider
■ Test results must be reported directly to a provider who can take action, not an intermediary *For red category values/interpretations, notify the nurse caring for a patient on the inpatient unit simultaneously*	■ Notify the PCP and the ordering physician of all "yellow" category test results to ensure follow-up ■ Institutions can make institution-specific additional recommendations for notification of clinicians who serve as the "end point" for taking clinical action, e.g., nurse-run Coumadin clinics ■ Identify situations when other members of the clinical team should also be notified, e.g., pharmacy
2. Identify *who* should receive the results when the ordering provider is not available	
■ Develop a procedure to link each patient with either a provider or a service at the time of admission *A patient should be linked at all times with a provider (or practice) who is responsible for his/her care*	■ Identify and/or validate a PCP or practice for each patient at the time of admission
■ Create a call schedule/system that works to identify whom the results should go to when the ordering provider is not available *Clinical team members should always be able to easily identify which provider is responsible for each patient at any given point in time* *"Role-based" coverage models have proven more reliable than traditional call systems* *"Role-based" models link each patient with a position/service designated at admission and then have an on-call system tied to that position; traditional call systems create a chain for each doctor rather than work from the patient*	Elements of a successful call system ■ Simple to understand ■ Easily available to all stakeholders ■ The procedures for changes to the call schedule are explicitly clear to all users ■ Supports reporting clinicians in identifying and reaching responsible provider ■ Supports automatic forwarding of calls to the covering provider/service if ordering provider not available Effective implementation strategies *Simplify:* Call systems that use a "role-based" ("coverage list") model are patient focused, i.e., patient is linked to role (position) and the role is linked to various responsible individuals, depending on coverage, shift changes, etc. *Improve Access:* Place call schedule information on the hospital intranet; integrate technology solutions, e.g., auto-paging, auto-forwarding

Table 1. Safe Practice Recommendations for Communicating Critical Test Results, *continued*

Safe Practice Recommendation	Implementation Context
■ Centralize and empower the hospital or practice call (communication) center to serve as the centralized repository of all call schedule and notification operations *A centralized hospital call system under the management of the communication center is a demonstrated strategy to promote reliability* *Practice call centers should be linked to the hospital call center*	Effective Implementation Strategies *Build reliability* ■ The hospital has the responsibility to know who is on call in every service, every day; the call center should serve as the primary source for all services, including reference laboratories; ancillary departments may maintain separate lists in addition ■ Practice call centers should be coordinated for the practice, i.e., who is on call for every physician, every day; practice call systems should be linked to the hospital call center ■ Assign accountability and responsibility for the accuracy and administrative control of call schedules to the call center and the medical staff executive team – Medical staff executive team defines rules to ensure the safety of the patient – Empower only the communications center with the authority to make edits/changes to call schedules – Provide authority to activate the "fail-safe" system if necessary – Maintain a database and ensure the call center has an up-to-date personal notification plan for all providers ■ In a centralized system, call schedules should be – Sent to the call center – Input by the call center only – Typed, legible – Complete, using full names of providers – Coordinated with answering services to validate accuracy *Monitoring effectiveness of systems* ■ Validate that the call center has the most current call schedule list and that users assign coverage 100% of the time – Conduct periodic tests to validate "accepting coverage" process, e.g. beeper/pager check or acknowledgment process ■ Validate the accuracy of provider access information as part of existing hospital systems, e.g., credentialing process ■ Validate accuracy of contact information with physicians' answering services ■ Gather data about delays in notification process
3. Define *what* test results require timely and reliable communication	
■ Maintain a prioritized list of critical test values/interpretations that require accelerated notification systems	Ensure your institution's list ■ Is segmented into categories that correspond to differentiated notification time requirements (Appendix 2)

continued

Table 1. Safe Practice Recommendations for Communicating Critical Test Results, *continued*

Safe Practice Recommendation	Implementation Context
Define a set of "high alert" results that get special precedence; set priorities to focus energies, limited resources on what really matters ■ Limit the number of tests categorized as highest priority (red).	■ Introduces institutionwide standardized terminology for naming each category (e.g., red, orange, yellow categories) ■ Focuses primarily on the Consensus Group set of "starter set" of results identified for the "red" category ■ References existing standards and evidence on criticality ■ Addresses all practice areas: inpatient, outpatient, and ED ■ Addresses all test types: laboratory, cardiology, radiology, etc. ■ Is reviewed and verified at least annually and includes a process for adding/dropping tests from each list
4. Identify *when* test results should be actively reported to the ordering provider and establish explicit time frames for this process	
■ Define appropriate notification time parameters for communicating critical test results according to urgency, e.g. within 1 hour, within the shift (target 6-8 hours), within 3 days *For orange categories, the guiding principles for decision-making are* ■ *Maximize efficiencies of workflow issues* ■ *Avoid unnecessary calls late at night* ■ *Synchronize calls with other existing systems, e.g. change of shifts, etc.*	Example (all categories require acknowledgement) ■ "Red" category—requires stat page, immediate clinical decision required ■ "Orange" category—results should be called; clinical decision required within hours ■ "Yellow" category—results can be sent passively; clinical decision required within days
■ Describe explicit steps in notification system; describe when reporters should initiate and follow up on notifying the ordering provider about critical test results	An example of a sequential notification system for "red" category values/interpretations would include ■ First call to MD #1 (ordering or covering) ■ Coincident call to RN (inpatient), pharmacy, and/or PCP under specific circumstances ■ If no response after 15 minutes, call MD #1 again ■ After 30 minutes, escalate to MD #2; identified by call center ■ After 45 minutes, call MD #2 again ■ After 60 minutes, activate "fail-safe" plan; notification of "fail-safe" clinical provider, examples below *Note:* An example of a more accelerated follow-up would be 3 calls within first 10 minutes. ■ Implement a reporting strategy that is clinically useful to the physician but does not overburden the laboratory; aim to reduce the number of alerts to clinicians about conditions of which they are aware – To determine whether a particular test result deserves urgent communication consider: the degree of change from historical results; the time span in which the change occurred; the direction of change (worsening vs improving); and the patient's medical history – The reporting strategy, in order of preference, follows: ● Identify a trend and report critical values if trend criteria are met

Table 1. Safe Practice Recommendations for Communicating Critical Test Results, *continued*

Safe Practice Recommendation	Implementation Context
	● Calculate delta changes and report only when criteria met ● If report absolute values only, strongly consider use of "first instance of" (as described in operating definitions) If unable to easily implement manual or programmed logic into laboratory systems, continue to call all "orange" values as "red"
■ Develop a fail-safe plan for communicating critical test results when the ordering or covering provider cannot be contacted within the designated time frame *Hospitals should have fail-safe plans in place for reporting critical findings and to ensure that the patient will receive timely clinical attention*	■ Key elements of a "fail-safe" plan include – Utilized when clinical decision is required ("red" category) – Provides a schedule to identify a clinical provider who: ● Is able to assume responsibility for patient ● Can take clinical action ● Available 24/7/365 ● Has access to the medical record ■ Examples of "fail-safe" provider would be Inpatient areas – ED physician – Senior medical resident – Medical officer of the month/day – A member of the medical emergency team – A member of a mini-code team – Lab director Outpatient areas – PCP or covering physician, lab directors, or clinic directors who could call the EMTs or direct the patient to the ED
5. Identify *how* to notify the responsible provider(s)	
■ Identify and utilize the communication techniques that are most appropriate for the particular clinical situation, e.g. active "push" system for results requiring a prompt clinical response	■ "Red" category results should be called to the responsible provider; provider response to a page necessary ■ Results should not be left with secretary or answering machine
■ Ensure acknowledgement of receipt of test results by a provider who can take action for all categories (red, yellow, orange) of critical test values/interpretations *Although the time frames for notification in the orange and yellow categories are extended, systems should reliably ensure the handoff to the responsible clinician is complete, i.e. systems should verify that a responsible provider is aware of the communication and has accepted the handoff. The responsibility for follow-up should be clear to all parties.*	■ When communicating test results, senders should document – Name and credentials of sender – Name and credentials of receiver – Test name – Test value/interpretation – Date and time ■ Guidelines for acceptable acknowledgment systems – Sender must receive confirmation from the receiving provider that they have accepted the responsibility for follow-up, e.g., phone call, confirmation of receipt of list, change of shift report, call back from page

continued

Table 1. Safe Practice Recommendations for Communicating Critical Test Results, *continued*

Safe Practice Recommendation	Implementation Context
	– Acknowledgment must occur within time frames for each category of test – Communication of these test results/interpretations must occur between responsible providers, not an intermediary ■ Examples of unacceptable acknowledgement systems include answering machines, all e-mails including those with read-receipt
6. Establish a shared policy for uniform communication of all types of test results (laboratory, cardiology, radiology, and other diagnostic tests) to all recipients	
■ Make the notification system explicitly clear to all stakeholders	■ Develop a consistent standardized communication technique for the sender to identify (flag) "red" category values/interpretations to alert the receiver that this is a "red" category finding ■ All stakeholders should share the same understanding of the clinical urgency categories and the steps to take when escalation is necessary ■ Use "read back" techniques in the process of acknowledging receipt of results ■ Develop a shared policy with the key elements of – Definitions of all categories of values – Lists of all values from each diagnostic area as appendices – Time parameters and procedures for notification for all categories – A description of the "fail-safe" plan – Description of the responsibilities of all team members – Documentation requirements – Quality improvement monitoring plan – Plan for annual review and validation – References
■ Encourage and foster shared accountability and teamwork across and between clinical disciplines	■ Implement face-to-face interdisciplinary change-of-shift debriefings for the handoff of laboratory, cardiology, radiology, and other relevant clinical information, e.g., problem lists, allergies, medications, a "to do" list ■ Describe relative responsibilities of the laboratory, cardiology, radiology, the ordering provider, covering provider, and the nurse ■ Address the importance of shared responsibility and partnering when facing a "red" category finding ■ Develop action plans/protocols for the RN jointly by medicine and nursing and other related disciplines; clearly describe criteria for use, e.g. insulin, heparin, solution changes, glucose for hypoglycemia, monitoring expectations ■ The clinical team should provide sufficient information to the responsible or back up provider to support action:

Table 1. Safe Practice Recommendations for Communicating Critical Test Results, *continued*

Safe Practice Recommendation	Implementation Context
■ Decide what information should be included as a minimal data set to be communicated to the responsible person	– In many situations the RN will be central in providing access to this information – The laboratory will provide results information and recent previous results when available ■ Examples of a minimal data set should include – This is a "red" (orange) category finding – Significant comorbidities – Prior test results, if available – Related medication (s) – Other relevant clinical information
7. Design reliability into the system	
■ Utilize forcing functions at the point of test ordering to identify the ordering provider with complete contact information with pager or beeper number ■ Utilize forcing functions at the point of test ordering to include a minimal data set of clinical information to support the interpretation of diagnostic tests	■ Use manual or computer systems ■ Expand information at point of test ordering regarding call-back instructions, e.g. alternative contact providers, identify PCP, patient contact information, location ■ Expand information at point of test ordering (for cardiology, radiology, and other diagnostic tests) to include – Diagnosis – Reason for requesting this test – What the clinician wants to assess or rule out
■ Create tracking systems to assure timely and reliable communication of test results	■ Develop special procedures for situations where delays typically occur: – After discharge – Ambulatory (cross border) – Late arriving – Other predictable relevant situations (shift changes, after-hours, surgeon in OR, etc.) ■ The responsibility for tracking and follow-up on positive findings lies with the individual physician practice ■ Develop or utilize existing tracking systems in ambulatory areas to prevent test results from falling through the cracks, e.g. automated or manual tickler systems ■ Design reliable follow-up systems for high-risk situations, e.g. certified letters with return receipt requested ■ Explore possibility that laboratory, cardiology, and radiology would monitor the receipt (acknowledgement) and document handoff of findings
8. Support and maintain systems	
■ Partner with patients in the communication about test results	■ "Nothing about me, without me"

continued

Table 1. Safe Practice Recommendations for Communicating Critical Test Results, *continued*

Safe Practice Recommendation	Implementation Context
Include family as appropriate, given consideration to confidentiality and regulatory compliance	■ Provide patients access to their test results (whenever medically reasonable) ■ Develop strategies to assist clinicians in assessing when and how to notify patients, especially in cases when patient is no longer at the hospital ■ Develop strategies to educate patients/families to participate in monitoring prompt turnaround of critical test results, e.g., Joint Commission Speak Up program
■ Provide orientation and ongoing education on procedures for communicating critical test results to all health care providers	Provide orientation and continuing education on ■ How to communicate critical test results ■ How to respond to critical test results in the "red" category ■ Principles of communication and teamwork for clinical emergencies ■ Core curriculum on patient safety
■ Provide ongoing monitoring of the effectiveness of systems, e.g., weekly failure rates, tests of call systems, response times	■ Monitor effectiveness of – Call schedule – Existing notification system – Feedback loops/tracking systems
9. Support infrastructure development	
■ Adopt advanced communication technologies	Upgrade call enter/communication capabilities ■ Intranet access ■ Automatic page forwarding and other automated notification systems ■ E-mail to patients with attention to confidentiality issues
■ Improve laboratory and other test system capabilities	■ Plan for integrated medical record solutions to link clinical information with laboratory results, as in the following: – Drug-drug interactions – Previous test results – Enable reporting of complex threshold criteria such as renal and pediatric dosing – Track trends in patient conditions – Link to medical record to identify first diagnosis of cancer or diabetes ■ Distribute tracking system reports to responsible clinicians ■ Link documentation of acknowledgement fields to tracking reports to monitor feedback loop ■ Evaluate the use of POC testing in critical and ambulatory areas carefully with consideration of emerging evidence-based studies; integrate POC test results with other test results and make them available to other providers

* Rationale and Operating Definitions for Communicating Critical Test Results (Appendix 1 [pages 79–80]), Consensus Group Recommendations for "Starter Set" Values/Interpretations (as excerpted in Appendix 2 [page 80]), and the references (page 77) can be found on the Coalition Web site: http://www.macoalition.org/initiatives.shtml (last accessed Dec. 6, 2004). PCP, primary care provider; ED, emergency department; MD, physician; RN, registered nurse; EMT, emergency medical technician; OR, operating room; Joint Commission, Joint Commission on Accreditation of Healthcare Organizations; POC, point of care.

References

1. Anonymous: Clinical laboratory review. *Medical Laboratory Observer* 2001; 12–15.
2. Bates D.W., et al.: Potential identifiability and preventability of adverse events using information systems. *J Am Med Inform Assoc* 11:404–411, Sep.–Oct. 1994.
3. Block C., et al.: Limitations of paperless on-line reporting of diagnostic bacteriology culture results. *J Clin Pathol* 49:759–761, Sep. 1996.
4. Boohaker E.A., et al.: Patient notification and follow-up of abnormal test results: A physician survey. *Arch Intern Med* 156:327–331, Feb. 1996.
5. Catrou P.G.: Editorial: How critical are critical values? *Am J Clin Pathol* 108:245–246, Sep. 1997
6. Couchman G.R., et al.: E-mail communications in family practice: What do patients expect? *J Fam Pract* 50:414–418, May 2001.
7. Edelman D.: Outpatient diagnostic errors: Unrecognized hyperglycemia. *Eff Clin Pract* 5:11–16, Jan.–Feb. 2002.
8. Emancipator K.: Critical values: ASCP practice parameter. *Am J Clin Pathol* 108:247–253, Sep. 1997.
9. Fine R.H.: Laboratory critical limits [letter to the editor]. *JAMA* 264:334–335.
10. Greenes D.S., Fleisher G.R., Kohane, I.: Potential impact of a computerized system to report late arriving laboratory results in the emergency department. *Pediatr Emerg Care* 16:313–315, Oct. 2000.
11. Hiltz F.L., Teich J.M.: Coverage list: A provider-patient database supporting advanced hospital information services. In Ozbolt J. (ed.): *Proc Annu Symp Comput Appl Med Care* 809–813, 1994.
12. Hobbs G.A., Jortani S.A., Valdes R.: Implementation of a successful on-call system in clinical chemistry. *Am J Clin Pathol* 10:556–563, Nov. 1997.
13. Hortin G.L., Csako G.: Critical values, panic values, or alert values? *Am J Clin Pathol* 109:496–498, Apr. 1998.
14. Howanitz P.J., Steindel S.J., Heard N.V.: Laboratory critical values policies and procedures: A college of American Pathologists Q-Probes Study in 623 institutions. *Arch Pathol Lab Med* 126:663–669, Jun. 2002.
15. Iordache S.D., Orso D., Zelingher J.: A comprehensive computerized critical laboratory results alerting system for ambulatory and hospitalized patients. In Patel V., et al. (eds.): *Medinfo* 10 (Pt 1):469–473, 2001.
16. Kost G.J.: Critical limits for urgent clinician notification at US medical centers. *JAMA* 263:704–707, Feb. 2, 1990.
17. Kost G.U.: Critical limits for emergency clinician notification at US children's hospitals. *Pediatrics* 88:597–603, Sep. 1991.
18. Kuperman G.J., et al.: Detecting alerts, notifying the physician, and offering action items: A comprehensive alerting system. *Proc AMIA Annu Fall Symp* 704–708, 1996.
19. Kuperman G.J., et al.: How promptly are inpatients treated for critical laboratory results? *J Am Med Inform Assoc* 5:112–119, Jan.–Feb. 1998.
20. Kuperman G.J., et al.: Improving response to critical laboratory results with automation: Results of a randomized controlled trial. *J Am Med Inform Assoc* 6:512–522, Nov.–Dec. 1999.
21. Kuperman G.J., et al.: A clinical information systems strategy for a large integrated delivery network. *Proc AMIA Symp:* 438–442, 2000.
22. Leape L.L., et al.: The nature of adverse events in hospitalized patients: Results of the Harvard Medical Practice Study II. *N Engl J Med* 324:377–384, Feb. 7, 1991.
23. Leape L.: Error in medicine. JAMA 272:1851–1857, Dec. 21, 1994.
24. Lundberg G.D.: When to panic over abnormal values. *Medical Laboratory Observer* 4(2):47–51, 1972.
25. Lundberg G.D.: Acting on significant laboratory results. *JAMA* 245:1762–173, May 1, 1981.
26. Lundberg G.D.: Critical limits for urgent clinician notification at US medical centers. *JAMA* 263:704–707.
27. Lundberg G.D: Critical (panic) value notification: An established laboratory practice policy (parameter). *JAMA* 263:709, Feb. 2, 1990.
28. Manor P.G.: Turnaround times in the laboratory: A review of the literature. *Clin Lab Sci* 12:85–89, Mar.–Apr. 1999.
29. Mallon R.P., Griffin B.T.: Information management, analysis and communication by a national reference laboratory organization. In *Proceedings from the 14th Annual Symposium on Automated Information Management in the Clinical Laboratory (AIMCL)*. Ann Arbor, MI: University of Michigan Medical School, 1996.
30. Murff H.J., Bates D.W.: Notifying patients of abnormal results. In Shojania K.G., et al.: *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*. Evidence Report/Technology Assessment No. 43 from the Agency for Healthcare Research and Quality: AHRQ Publication No. 01-E058. Rockville, MD, 2001. http://www.ahrq.gov/clinic/ptsafety/ (last accessed Dec. 1, 2004).
31. Oppenheim J.I., et al.: Design of a clinical alert system to facilitate development, testing, maintenance and user-specific notification. *Proceedings AMIA Annual Symposium* 2000, 630–634.
32. Poon E.G., et al.: Real-time notification of laboratory data requested by users through alphanumeric pagers. *J Am Med Inform Assoc* 9:217–222, May–Jun., 2002.
33. Rind D.M., et al.: Effect of computer-based alerts on the treatment and outcomes of hospitalized patients. *Arch Intern Med* 154:1511–1517, Jul. 11, 1994.
34. Shea S., et al.: A metanalysis of 16 randomized controlled trials to evaluate computer-based clinical reminder systems for preventive care in the ambulatory settings. *J Am Med Inform Assoc* 3:399–409, Nov.–Dec. 1996;.
35. Silvestri A., McDaniel-Yakscoe N.: A pediatric emergency department follow-up system: Completing the cycle of care. *Pediatr Emerg Care* 17:392–395, Oct. 2001.
36. Tate K.E., et al.: A computerized laboratory alerting system. *MD Comput* 7:296–301, Sep.–Oct. 1990.
37. Tate K.E., Gardner R.M.: Computer, quality, and the clinical laboratory: A look at critical value reporting. *Proc Annu Symp Comput Appl Med Care* 193–197, 1993.
38. Tate K.E., Gardner R.M., Scherting K.: Nurses, pagers, and patient-specific criteria: Three keys to improved critical value reporting. *Proc Annu Symp Comput Appl Med Care* 164–168, 1995.
39. Winkelman J.W., et al.: How fast is fast enough for clinical laboratory turnaround? Measurement of the interval between result entry and inquiries for reports. *Am J Clin Pathol* 108:400–405, Oct. 1997.

Appendix 1. Rationale and Operating Definitions for Communicating Critical Test Results*

Scope

The scope of the project is being defined broadly to include all test values where delays would result in serious adverse consequences for patients. The recommendations will address the communication of findings from laboratory, cardiology, radiology, and other diagnostic areas to inpatient, emergency, and ambulatory areas.

Rationale for Three Categories of Test Values/Interpretations

Wide variations exist in the terminology, definitions, test types, and communication practices for critical test values/interpretations. Typically, critical value lists are too long and not consistent across institutions. There is no uniform standard or framework for detection and notification of laboratory results on a local or national level. Diagnostic test centers such as laboratory, radiology, and cardiology differ in their communication practices to the responsible provider. Significant delays do occur in the communication process from the identification of critical values/interpretations to action to resolve the clinical condition.

The Consensus Group made several strategic decisions to guide their work:

1. Agreed that recommendations must do the following:
   a. Be simple to understand
   b. Be flexible across practice settings
   c. Be dynamic in nature
   d. Respect limited resources
   e. Respect team work
   f. Reflect the patient's best interests
2. Adopted a conceptual framework to enhance communication within and between groups with a common language understood and accepted by all.
3. Agreed that the scope of the project would include all tests/interpretations where there is a high value on follow-up.
4. Accepted three discrete categories of values/interpretations differentiated primarily by the maximum amount of time that should elapse between identification of a test value/interpretation and clinical action for the patient; the results included in the lists likely represent conditions that, if left untreated, could result in significant harm to the patient. Most of these conditions will require a change in the patient's therapy.
5. Used the same categories for all diagnostic areas (e.g. laboratory, cardiology, and radiology) to enhance communication across systems.
6. Provided examples of values/interpretations for each category to serve as a "starter set" for hospitals.
7. Recommended 100% acknowledgement for every test on the list (in all categories); the lists include only those tests where there is especially high value for follow-up.
8. Agreed that notification of all other tests results were not within the scope of our work although some of the practice recommendations might improve communication of all test values.

Red Zone Values/Interpretations

Those values/interpretations that indicate the patient is in imminent danger of death, significant morbidity, or serious adverse consequences unless treatment is initiated *immediately.* These values/interpretations require immediate (within 1 hour) interruptive notification of the responsible (ordering or covering) physician who can initiate the appropriate clinical action for the patient.

Orange Zone Values/Interpretations

Those test values/interpretations that indicate significant abnormalities that warrant rapid, but not immediate, attention by the responsible clinician. These values do not represent a clinical emergency and do not warrant a stat page to the physician. These values however require prompt clinical attention for the patient or for the patient's contacts to avoid serious adverse outcomes. Physicians should be notified of these values/interpretations within the shift (target 6–8 hours) and acknowledgement is required.

Yellow Zone Values/Interpretations:

Those test values/interpretations that indicate a significant abnormality that may threaten life or, cause significant morbidity, complications, or serious adverse consequences unless diagnosis and treatment is initiated in a *timely and reliable* manner. There is no immediate threat to life. These test values/interpretations are targeted at diseases that merit timely detection and evaluation and for which a corrective action can be taken. Physician notification and acknowledgement should occur within three days.

Appendix 1. Rationale and Operating Definitions for Communicating Critical Test Results,* *continued*

Acknowledgment

Acknowledgement implies that the sender (clinician reporting the results of a diagnostic test value/interpretation) has received confirmation from the recipient (responsible provider or their covering provider) that he/she has received the results of a diagnostic test and has accepted the responsibility for follow-up. The sender is responsible for documenting details of the handoff process (i.e. name and role of the person receiving the information, date and time, type of test and test value/interpretation and his/her name and role).

Backup System

The usual coverage system in a hospital. The on-call schedule is designed to ensure that there is always a clinician available to accept responsibility for a patient. In an academic medical center, the coverage system usually involves house officers (interns), seniors, fellows, and attendings, each with rotating call schedules. In other hospital types, the coverage system is shared within group practices or between group practices.

Fail-Safe System

This is the plan a hospital develops to respond to a clinical crisis when the usual back-up system has not been effective in reaching a clinician who can take action within a specified period of time. A fail-safe system implies the clinician who can take action will be on site for clinical emergencies.

First Instance of

The first time the laboratory or other diagnostic test center determines a test value/interpretation defined as a critical value; for laboratory systems, if the patient has been in the hospital before, the "first instance of" means no critical values in the same result range (high vs low) in the past 5 days; for cardiology tests, "first instance of" means no critical result of the same kind in the past 24 hours. Each institution should determine appropriate time parameters based on its population and clinical processes.

Provider

Any licensed independent provider who would be responsible for ordering and/or acting on the results of diagnostic testing in either the inpatient or ambulatory setting. Providers are those individuals who have clinical privileges and are required to be credentialed within a hospital, HMO, or private practice. These individuals are typically MDs, DOs, nurse practitioners, and physician's assistants.

* HMO, health maintenance organization; MD, physician; DO, doctor of osteopathy.

Source: Massachusetts Coalition for the Prevention of Medical Errors: *Communicating Critical Test Results.* http://www.macoalition.org/initiatives.shtml.

Appendix 2. Excerpt from Consensus Group Recommendations for "Starter Set" Values/Interpretations for the Red, Orange, and Yellow Categories from Laboratory, Cardiology, and Radiology*

Testing Area	Alerting Category	Test	Red Category Conditions Complete Alert within 1 hour	Orange Category Conditions Complete Alert within 8 hours May be acceptable to defer alert between 11pm and 6am	Yellow Category Conditions Complete Alert within 3 days
Chemistry	Always Red (Always potentially life-threatening to patient, even if patient is actively being treated)	Glucose (adult)	HIGH (e.g. > 400) LOW (e.g. < 50)		
		Potassium	HIGH (e.g. > 6) LOW (e.g. < 2.8)		
		Phosphorus	LOW (e.g. < 1.0)		
		Sodium†	HIGH (e.g > 160) LOW (e.g. < 120)		
		Bicarbonate‡	LOW (e.g. < 10)		
	Red on first instance, orange thereafter (Most dangerous when first detected, but providers should know about these results as the condition is being treated)	Bicarbonate‡	LOW (e.g. 10–15), first instance only§)	LOW (e.g. 10–15), not first instance§)	
		Magnesium	HIGH (e.g. > 5), first instance only§. May tolerate higher level for L&D patients LOW (e.g < 1), first instance only§	HIGH (e.g. > 5), not first instance§. May tolerate higher level for L&D patients LOW (e.g < 1), not first instance§	
		Calcium (total or ionized)	HIGH (e.g. >13 total, >6 ionized), first instance only§ LOW (e.g. < 7, < 3.5 ionized total), first instance only§	HIGH (e.g. > 13 total, > 6 ionized), not first instance§ LOW (e.g. < 7 total, < 3.5 ionized), not first instance§	
		CK/MB	HIGH, indicative of acute MI, first instance only§		
		Troponin	HIGH, indicative of acute MI, first instance only§		
		Lactic Acid	HIGH (e.g. > 5), first instance only§	HIGH (e.g. > 5), not first instance§	
	Orange on first instance, routine thereafter (Only worth alerting once so that providers can initiate treatment program within the next few hours)	SGOT		HIGH (e.g. > 500), first instance only§	
		SGPT		HIGH (e.g. > 500), first instance only§	
		BUN		HIGH (e.g. > 100), first instance only§	
		Creatinine		HIGH (e.g. > 4), first instance only§	
		Amylase		HIGH (e.g. > 500), first instance only§	
		Lipase		HIGH (e.g. > 200), first insance only§	
	Yellow only (Rarely an emergency, but needs follow-up within days)	TSH			HIGH (e.g > 50) LOW (e.g. < 0.1)
		Lead			HIGH (e.g. > 25)
Blood Gases‖	Always Red	pH	HIGH (e.g. > 7.6) LOW (e.g. < 7.2)		
		pO_2	LOW (e.g. < 60)		

* Critical test results are listed here by degree of urgency to facilitate discussion at each institution. In practice, critical test results can be listed alphabetically to facilitate lookup by technicians in the laboratory. This excerpt shows values and interpretations for laboratory: chemistry and blood gases. Values/interpretations for other laboratory results (hematology, microbiology, and toxicology) and results for cardiology and radiology are shown in the full document. L&D, labor and delivery; MI, myocardial infarction; SGOT, serum glutamate oxaloacetate transaminase; SGPT, serum glutamate pyruvate transaminase; BUN, blood urea nitrogen; TSH, thyroid stimulating immunoglobulin.

† Serum sodium is a good example in which it would be helpful to use the direction of change to determine whether a particular result should be treated as 'red'. For example, if the serum sodium level is improving compared to a sample within the past 24 hours, it can be considered an 'orange' result.

‡ Serum bicarbonate is an good example in which it would be helpful to use delta checks to determine whether a test result deserves urgent notification. For example, significant drops of > 8 might be considered a 'red' result.

§ First instance = No critical value in the same result range (high versus low) in the past 5 days.

‖ Alerts not necessary if blood gases are routinely called up to the responsible clinician. However, the Consensus Group is neither endorsing not discouraging that practice.

Source: Massachusetts Coalition for the Prevention of Medical Errors: *Communicating Critical Test Results.* http://www.macoalition.org/initiatives.shtml