

Critical Values Consensus Statement: Proposed

BC Association of Laboratory Physicians
BC Society of Clinical Chemists

January 2001

Contents

STATEMENT	3
DEFINITION	3
MANAGING POLICY	3
VALIDATION.....	3
NOTIFICATION PROCESS	3
DOCUMENTATION.....	4
CRITICAL VALUES LIST	4
APPENDIX	6
COLLEGE OF PHYSICIANS & SURGEONS OF BRITISH COLUMBIA	6
<i>Opinion from Deputy Registrar.....</i>	6
<i>RE: Notification of physicians and patients when critical lab values are identified</i>	6
CANADIAN MEDICAL PROTECTIVE ASSOCIATION	6
<i>Opinion from Legal Counsel</i>	6
<i>Re: Duty of Laboratory Physician-Pathologist relating to notification of critical lab results.....</i>	6
Shared Responsibility	6
Extent of the Obligation.....	7
Reasonable Notification System	7
DIAGNOSTIC ACCREDITATION PROGRAM OF BRITISH COLUMBIA	8
<i>Clinical Pathology Division.....</i>	8
<i>Guidelines for reporting of results by telephone</i>	8
REFERENCES.....	8

Acknowledgement: We thank Beckman Coulter Canada Inc. and Ortho-Clinical Diagnostics for their financial support for the development of this statement.

Statement

Definition

A critical value is a laboratory result that suggests the presence of physiological state that is life threatening. Critical results are a discrete subset of abnormal test results that require immediate action by the laboratory and the clinician.

Managing policy

The BCALP/CSCC consensus statement should serve as the reference document for an institutional policy. The BCALP will review this document no less frequently than every three years. Reasons for customizing the generic policy adopted by the profession should be explicit. This principle applies but is not limited to the waiver of notification for repeat critical values or for special patient populations. Wherever an institution determines that repeat values do not require notification, the procedure should include confirmation that there was successful notification of the initial critical value.

Validation

Result verification by repeat analysis is neither necessary nor sufficient. Routine inspection of the sample is far more likely to reveal problems than repeat analysis, e.g., incorrect sample tube or hemolysis. As false positive critical values are frequently due to pre-analytic error, prompt reporting of the critical result is preferable to repeat analysis. While reporting the result, the laboratory can suggest repeat specimen collection. Under some circumstances, a laboratory may decide that repeat analysis for a specific test or instrument is necessary. However, this should be the exception not the rule.

Notification Process

After the technologist releases a critical result, an appropriately qualified person should communicate the result verbally to the ordering physician (or an approved surrogate) immediately. The message for the physician should distinguish between a critical result and all other telephoned test results. The laboratory policy should specify the maximum time that laboratory staff should spend on an unsuccessful critical values notification before advising the laboratory physician (or approved substitute) of the situation^{1,2}. The laboratory should maintain an up to date list of contact numbers and alternate contact numbers for referring physicians. The laboratory physician (or approved substitute) should decide when it is appropriate for him/her to contact the patient directly. If the laboratory physician (or approved substitute) decides to contact the patient directly but is unable to do so, he/she should decide if it is appropriate to ask the police or other agency to help locate

¹ The Hematology Science Subsection specifically recommends "Call or page three times over 1.5 hours. Failing that, inform the pathologist on call."

² COLLEGE OF PHYSICIANS & SURGEONS OF BRITISH COLUMBIA comments on this guideline. "If the physician cannot be contacted within an hour and a half or two hours, the patient should be contacted directly. I would suggest that the patient be informed that his or her physician or their alternate has not responded to the call, and that it is important for the patient to seek immediate care. Of course the urgency of care and the type of care required depends on the particular situation. That is left to the clinical judgment of the pathologist."

the patient³. The laboratory physician has a responsibility to see that the patient has the opportunity to receive/seek the appropriate care for the life threatening result⁴. While a report may be faxed to the ordering physician's office, this does not relieve the laboratory of the responsibility of contacting the ordering physician (or an approved surrogate) personally.

Documentation

The documentation should conform to the *Guidelines for Reporting of Results by Telephone* published by the Diagnostic Accreditation Program of British Columbia. To substantiate that the laboratory has notified or attempted to notify the ordering physician immediately, a record of the relevant transactions should be maintained. Entries should include the date, time, responsible staff member, person notified and the test results. Any problem encountered in accomplishing this task should be recorded. If the ordering physician cannot be notified, the laboratory physician (or approved designate) should document the steps taken subsequently.

Critical Values List

The list on the following page reflects the consensus reached by the Chemistry and Hematology Subsections.

³ CANADIAN MEDICAL PROTECTIVE ASSOCIATION rendered this opinion. "The question then becomes, how far would the lab/pathologist have to go? It is likely that a court would attempt to balance the relative burden on the pathologist to notify, against the potential danger to the patient for failure to do so. The pathologist might have to exercise his/her judgment in deciding what would be reasonable under the circumstances given the information they have. In such a situation a decision must be made without delay based on limited known and unknown factors."

⁴ CANADIAN MEDICAL PROTECTIVE ASSOCIATION rendered this opinion. "So long as the lab has a reasonable notification system in place, the lab/pathologist will be less likely to find him/herself in the difficult position of having to make a decision about what to do with critical test results that must be urgently addressed. Where the physician who requested the test is not reachable, and the test results are critical, the system should provide that contact be made with a backup or alternate health care provider. The lab might consider requiring the referring physicians to provide backup contact information and numbers, which might be kept on record at the laboratory. If this fails, the notification system should provide that reasonable efforts be made to relay the information to the lab/physician (pathologist) who should then attempt to get into direct contact with the patient. Difficulties in locating the patient could be avoided by ensuring that the lab and the requesting physician have an information protocol whereby the lab is given sufficient information to enable contact to be made directly with the patient should that become necessary."

Critical Values List

Analyte	Threshold
pH	< 7.20 > 7.60
pCO ₂ , mmHg	< 20 > 70
pO ₂ , mmHg	< 50
Hemoglobin, g/L	< 50 > 230 (except neonates)
WBC X 10 ⁹ /L	< 1 > 100 (adults and children)
Platelets X 10 ⁹ /L	< 20
Neutrophils X 10 ⁹ /L	< 0.5
Blood Film	Malaria parasites, falciparum or unspiciated
Kleihauer, /mL	> 5
Prothrombin time, INR	> 6
Fibrinogen g/L	< 0.6
Sodium, mmol/L	<120 >160
Potassium, mmol/L	< 2.8 > 6.2 (except for hemodialysis patients or neonates where > 6.5)
Bicarbonate, mmol/L	< 10 > 40
Glucose, mmol/L	< 2.0 > 30 (>11.1 for <17 years)
Calcium, total, mmol/L	< 1.50 > 3.25
Calcium, ionized, mmol/L	< 0.8 > 1.6
Magnesium, mmol/L	< 0.3 > 3.0
Phosphorus, mmol/L	< 0.32
Bilirubin, neonatal, umol/L	> 260 (< 4 d) > 290 (4 - 28 d)
Cortisol, nmol/L	< 100 (< 1 y)
Acetaminophen, μmol/L	> 200
Salicylates, μmol/L	> 4.0
Lithium, mol/L	> 2.0 (>1.5 for individuals over 65 y)
Theophylline, μmol/L	> 165
Digoxin, nmol/L	> 3.5 (>8 h post dose)

Appendix

College Of Physicians & Surgeons Of British Columbia

Opinion from Deputy Registrar

RE: Notification of physicians and patients when critical lab values are identified

The protocol that you have outlined is reasonable and I agree that in critical situations, if the physician cannot be contacted within an hour and a half or two hours, the patient should be contacted directly. I would suggest that the patient be informed that his or her physician or their alternate has not responded to the call, and that it is important for the patient to seek immediate care. Of course the urgency of care and the type of care required depends on the particular situation. That is left to the clinical judgment of the pathologist.

I can not imagine why the pathologist would be liable if the patient has an untoward outcome. In fact, I suspect that the reverse is more likely. If the pathologist does not make efforts to contact the physician, and in turn the patient is harmed, a legal challenge is more likely. I should qualify that the College can not provide you with legal advice and you may wish to contact CMPA about that matter.

I can recall two or three situations where the pathologist or the radiologist felt obliged to contact the patient directly to advise the patient to seek immediate care. I think such an action can only be regarded as a positive action. Diagnostic physicians have the same ethical responsibilities as all other physicians, which include that they must act in the patient's best interest. In some situations, this may require a direct contact with the patient if the primary care physician or the physician ordering the diagnostic determination can not be reached. In these situations, if there is no acceptable reason for the physician's lack of response, the College should be notified that appropriate after-hour care is not being provided.

October 2000

Canadian Medical Protective Association

Opinion from Legal Counsel

Re: Duty of Laboratory Physician-Pathologist relating to notification of critical lab results

I am writing in response to your request for an opinion on the issue of appropriate notification of critical lab results. Specifically, what are the obligations of a lab/pathologist with respect to the prompt notification of the requesting physician and/or the patient, where the results are critical. You are also concerned about the liability of the lab/pathologist if the requesting physician and/or the patient cannot be reached.

Shared Responsibility

The physician who orders a test on a patient is generally responsible for ensuring that the test results are received and if there is any abnormality, for ensuring that the patient is duly

informed and treated, whether directly by the ordering physician or by arranging for a backup if necessary. This issue has come up before the Ontario College when physicians were refusing or avoiding receipt of critical test results after hours. The College had this to say:

"The College has become aware of instances in which members are either not available to receive a report of an abnormal result of a laboratory test phoned to them by a laboratory or actually refuse to accept the report. While the tests may have been ordered by another physician whose practice the member is covering, the on-call physician has a responsibility to accept the report and to assess whether the patient concerned should be contacted to determine if further action is indicated. Although the on-call physician may not have access to the patient's medical record, he is better able to assess the urgency of the situation than is the laboratory staff. Failure to act on the report of a significant abnormal test result might lead to preventable harm to a patient for which the member could be held accountable."

But what if neither the requesting physician nor a backup physician can be reached? The lab also has a measure of responsibility for ensuring that test results are received especially where they are abnormal and demand immediate attention. According to a Guideline prepared by the Diagnostic Accreditation Program, a standing committee of the College of Physicians and Surgeons of BC governed by the Rules Made Under the Medical Practitioners' Act, laboratories in BC must all have a written policy regarding the communication of critical results. These must be telephoned immediately to the physician or to an alternate health care provider (this could include nurses or an emergency unit) a message left on an answering machine or voice mail is not considered sufficient notification. If contact cannot be made the laboratory physician must be notified. What obligation would the laboratory physician (pathologist) then have? Once the pathologist is aware of an abnormal test result, which they know or ought to know could be critical for the patient, a court may well find that they have a duty to ensure that the patient is made aware of the result and the need to follow up where, under the circumstances, the patient would otherwise not be informed.

Extent of the Obligation

The question then becomes, how far would the lab/pathologist have to go? It is likely that a court would attempt to balance the relative burden on the pathologist to notify, against the potential danger to the patient for failure to do so. The pathologist might have to exercise his/her judgment in deciding what would be reasonable under the circumstances given the information they have. In such a situation a decision must be made without delay based on limited known and unknown factors.

Reasonable Notification System

So long as the lab has a reasonable notification system in place, the lab/pathologist will be less likely to find him/herself in the difficult position of having to make a decision about what to do with critical test results that must be urgently addressed. Where the physician who requested the test is not reachable, and the test results are critical, the system should provide that contact be made with a backup or alternate health care provider. The lab might consider requiring the referring physicians to provide backup contact information and numbers, which might be kept on record at the laboratory. If this fails, the notification system should provide that reasonable efforts be made to relay the information to the lab/physician (pathologist) who should then attempt to get into direct contact with the patient. Difficulties in locating the patient could be avoided by ensuring that the lab and the requesting physician have an information protocol whereby the lab is given sufficient information to enable contact to be made directly with the patient should that become necessary. If that too fails, the pathologist might well have to exercise his/her judgement in

deciding what measures would be reasonable under the circumstances. This could include contacting the police if the pathologist feels it is warranted, but so long as their decision is a reasonable exercise of judgement under the circumstances, they should not be held liable. The laboratory should ensure that it maintains an accurate log of all efforts made to relay the test results.

November 2000

Diagnostic Accreditation Program Of British Columbia

Clinical Pathology Division

Guidelines for reporting of results by telephone

NOTE: This guideline is a requirement for accreditation.

Laboratories must have a written policy regarding the communication of stat and critical results.

Stat results must be reported as soon as available according to laboratory policy.

Critical results must be telephoned immediately to a physician or to an alternative health care provider (this may be a nursing or emergency unit). If contact cannot be made, the laboratory physician must be notified. A message left on an answering machine or voice mail is not sufficient notification.

It is the responsibility of the laboratory to ensure results are applied to the correct patient by giving two unique patient identifiers with each telephoned result.

The laboratory must record the following information whenever a result is telephoned:

1. The date and time of the call.
2. The names or initials of the person who phoned the result.
3. The names or initials of the person who received the call.

The laboratory must have either a paper or electronic record or log of this information. Records must be retained for 7 years.

Approved October 1999

References

1. Emancipator K. *Critical Values: ASCP Practice Parameter*. AJCP 1997;108(3):247-253.
2. Steindel SJ, Heard NV. *Critical Values: Q-Probes 92-04*. Northfield, Ill: College of American Pathologists; 1992.
3. *Laboratory Practice Guidelines from the Ontario Society for Clinical Chemists*.
4. Canadian Pediatric Society Statement. *Approach to the management of hyperbilirubinemia in term newborn infants*. Paediatr Child Health 4(2) 161-164 1999.