Is This a Critical, Panic, Alarm, Urgent, or Markedly Abnormal Result?

To the Editor:

Medical laboratories often produce clinically unexpected results that require timely clinical evaluation because they herald an imminent life-threatening condition or major clinical deterioration. Laboratories therefore need to proactively identify and report such results sooner than would routinely occur, and have policies and procedures that minimize the possibility of patient harm due to delayed clinical awareness.

Since Lundberg’s first description of so-called panic values (1), a variety of other terms have appeared in the literature, for example: urgent, critical, acute, alert, emergent, abnormal, markedly or significantly abnormal, clinically significant, vital, red-orange-yellow zone values, and various combinations thereof. Most of these definitions are reworded alternatives of Lundberg’s original description (2, 3). Two recent literature reviews emphasize the need for an agreed terminology to assist global harmonization of the laboratory management of such test results (4, 5).

Current definitions focus on the degree of result abnormality, timeliness of communication, and likely patient outcomes (e.g., mortality, morbidity) rather than on the risk to patient safety. Although it is true that unexpected results requiring urgent reporting are often very abnormal, it is not always true that such results represent imminent high risk to patient safety and well-being; examples include high creatinine and chronic elevation of troponin concentrations in stable chronic renal failure and long-term hemodialysis patients, respectively. In our view, categorizing unexpected urgent results on the basis of the magnitude of their abnormality does not allow for individual patients in specific clinical circumstances for whom slightly or moderately abnormal results, or too-rapid normalization of results, suggest impending high risk to their well-being, or for those patients with stable chronic conditions in whom very abnormal results do not pose imminent risk of significant clinical deterioration. Another shortcoming of existing terms is that they often combine results that represent different degrees of risk to patient safety and thus may lead to patient harm due to alert fatigue.

From these considerations, it is clear that none of the currently used terms adequately reflect the core attribute of such results. For example, the most common term, “critical result,” does not identify the characteristic that is critical. In our view, the primary attribute of such results is that they represent high and imminent risk to patient safety and well-being. Therefore we propose a clinically more appropriate terminology that emphasizes the degree of risk to patients.

We propose to differentiate two risk categories. Critical-risk result is defined as results requiring immediate medical attention and action because they indicate a high risk of imminent death or major patient harm (e.g., neonatal hyperglycemia). The other risk category, significant-risk results, labels test results that are less urgent but need to be reported within a shorter timeframe than that for routine results (e.g., positive blood cultures). Significant risk results are defined as results that are not imminently life-threatening, but signify significant risk to patient well-being and therefore require medical attention and follow-up action within a clinically justified time limit. We also propose high-risk results as an appropriate umbrella term for critical and significant risk results.

Introduction of the concept of patient-focused risk in the proposed terminology should encourage laboratories to fundamentally review their criteria for identifying high-risk results, so that alert thresholds are not defined simply by magnitude of abnormality but are set more flexibly and by consideration of relevant patient characteristics, clinical conditions, and the needs of clinical staff. By focusing on patient risk, the proposed terms highlight that the management of such results should be informed by risk assessment processes.

Risk-based definition of results is also expected to reduce alert fatigue and may encourage the development of more flexible and user-friendly automated alert systems. Such an approach will require close consultation with clinical users to identify specific high-risk parameters for specific clinical conditions, patient subgroups, and individual patients. To assist laboratories, a guideline for managing high-risk results is currently being developed by the CLSI. Establishing the criteria for these risk-based and more personalized categories will require close interactions between laboratories and key clinicians as well as future studies to determine their impact on response times and organizational, economic, and patient outcomes.

In summary:

- Immediate high risk to patient well-being is the defining attribute of unexpected test results requiring urgent reporting.
- The level of patient risk determines whether results require immediate or less rapid reporting.
- The proposed terms critical-risk results, significant-risk results, and the umbrella term high-risk results provide a harmonized terminology that addresses the

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shortcomings of currently used terms.

References


Graham H. White1,2*
Craig A. Campbell3,4
Andrea R. Horvath3,4

1 Chemical Pathology Directorate
SA Pathology
Flinders Medical Centre
Bedford Park, Australia
2 Medical Biochemistry
Flinders University
Bedford Park, Australia
3 SEALS North
Department of Clinical Chemistry and
Endocrinology
Prince of Wales Hospital

Sydney, Australia

4 School of Medical Sciences
University of New South Wales
Sydney, Australia.

*Address correspondence to this author at:
Chemical Pathology Directorate
SA Pathology
Flinders Medical Centre
Bedford Park, Australia
Fax +61-8-8374-0139
E-mail graham.white@health.sa.gov.au.

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