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# Harmonization of critical result management in laboratory medicine

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ABSTRACT

Unsafe medical care is a major source of disabling injuries and death throughout the world. The failure to notify, follow up, and action critical results, which signify life threatening situations, is of particular concern and may cause avoidable morbidity and mortality. International accreditation standards require pathology laboratories to have a system for the timely and reliable communication of critical results to clinical personnel responsible for patient care. In response, various practices and a number of different terminologies have been described in the literature. Increased attention to patient safety standards and multinational surveys, however, highlighted shortcomings and inefficiencies in existing communication systems. These failures and variations in practice call for clear guidance and harmonization of approaches in order to improve communications and to provide safer patient care. The objectives of this review are to create a harmonized terminology and to learn from international practices by systematically reviewing the best available evidence on existing approaches. Based on literature review findings we highlight key areas where harmonization is necessary and feasible and offer a conceptual framework and methods for designing better and more evidence-based systems for the timely notification of laboratory results that represent potential patient safety hazards.



## 1. Introduction

Medical tests should only be requested if the results of the tests will be used to influence subsequent management decisions of the patient. As trivial as it may sound, laboratory professionals all over the world know too well that many of the test results that are released to clinicians in vast numbers with rapid turn-around times are not followed up in a timely manner and may have no beneficial impact on patient management. This is of particular concern when critical results are involved, as they signify situations which may be life threatening or lead to irreversible damage or harm to the patient and which therefore require immediate or timely medical intervention. Unsafe medical care is a major source of disabling injuries and death throughout the world. In 2008 a report, published by the World Health Organization World Alliance for Patient Safety, identified poor test follow-up as one of 23 topics that have a substantial impact on the safety of medical care [1]. The rate of test follow-up was found to be suboptimal across the globe, with communication of test results between the laboratory and physicians being one area that needs improving. A systematic literature review of evidence between 1990 and 2010 revealed a lack of test follow-up for up to 60% of hospital inpatients, and up to 75% for patients treated in the emergency department [2]. Critical test results were identified as one area where problems were particularly evident. In the United States the National Quality Forum's list of serious reportable events in 2011 included two new laboratory-related errors leading to serious injury or death of patients. One of these reportable errors was due to the failure to follow-up or communicate laboratory, pathology or radiology results [3]. In 2010, the Clinical Excellence Commission Patient Safety Team analyzed data collected from the New South Wales Incident Information Management System to review and identify how access and follow-up of diagnostic test results affected patient outcomes [4]. Findings of the review indicated that failure in processes associated with obtaining and using diagnostic test results has the potential to seriously compromise patient safety. Issues identified included timeframes for test reporting being poorly defined and unrelated to clinical urgency; pending results that are potentially critical never being reviewed by the treating team; no consistent mechanisms exist for clinicians to identify critical results which have not been reviewed; and considerable variability in the process for communicating unexpected or significantly abnormal results.

Automation and information technology revolutionized the delivery of laboratory services and we have almost limitless opportunities to communicate test results on various devices faster and closer to the clinician and patient than ever before. Paradoxically, the vast amount and rapid flow of data contribute to information overload and communication breakdowns and, as a consequence, to increasing medical error

*Abbreviations:* CLIA, Clinical Laboratory Improvement Amendments; EFLM, European Federation of Clinical Chemistry and Laboratory Medicine; ISO, International Organization for Standardization; USA or US, United States of America; UK, United Kingdom; WHO, World Health Organization.

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rates. Therefore laboratories have even greater responsibility of controlling post-analytical and post–post-analytical processes and offering solutions that help to reduce medical error rates and improve the effectiveness and timeliness of medical decisions [5].

It was over 40 years ago that Dr George D. Lundberg reported the implementation of the first formal critical result communication system in Pathology at the Los Angeles County USC Medical Center. Lundberg coined the term 'critical result' as a laboratory test result representing a pathophysiologic state so abnormal that it is life-threatening if action is not taken quickly and for which an effective action is possible [6]. A short list of critical limits (i.e., upper and/or lower thresholds for a test outside of which a result would be critical) was compiled, and once a critical result was recognized by a laboratory technologist, it became the responsibility of the laboratory to urgently and personally communicate it to the physician responsible for the patient. Although not initially published in a peer-reviewed journal, the critical result system gained rapid acceptance [7]. It was widely implemented in a very short time and soon became a laboratory accreditation requirement [8–11]. Lundberg claims that the rapid success of his critical result system was largely due to the initial critical list only containing limits that were clearly life threatening [7]. Subsequently, Lundberg proposed that laboratories should also have a system for communicating important (according to his terminology "vital") but less urgently reportable results [12].

Since Lundberg's pioneering work and in response to accreditation requirements, many laboratories have implemented critical result communication systems. Various practices and a number of different terminologies have been described in the literature, while increased attention to patient safety standards highlighted shortcomings and inefficiencies in existing communication systems. These failures and variations in practice triggered a number of national organizations to investigate their current practices and, based on findings, formulate recommendations for a more harmonized and systematic approach for notifying clinicians about abnormal test results that need urgent or timely medical attention. These published multinational surveys and recommendations provide the backbone of this review. We will discuss in more detail below what can be learnt from the synthesis of the evidence and how that information can support global harmonization initiatives in this area.

The objectives of this review are to 1/create a harmonized terminology; and 2/reflect on the current status of international practices. Based on findings of the review of the literature we 3/highlight key areas where harmonization is necessary and feasible; and 4/offer a conceptual framework and methods for designing better and more evidence-based systems for the timely notification of laboratory results that represent potential patient safety hazards.

## 2. Need for harmonized terms and definitions

Singh and Vij have made eight very useful practical recommendations for policies and practices of communicating abnormal test results [13]. Their first recommendation emphasizes the importance of clear definitions in order to provide credibility to the policy and to ensure a common understanding across a broad range of users. For clarity and harmonization of terminology we present currently used and published definitions together with their most common alternative synonyms and our proposed terms (Table 1).

Current patient safety goals require timely communication and follow-up of abnormal diagnostic test results to avoid medical errors, adverse events, and liability claims [13]. There is significant confusion in this area of what type of laboratory tests and results should be communicated to clinicians and how one should define the various categories of abnormal test results that need urgent or timely clinical notification. Due to differing clinical significance and priority, similarly to a number of authors [12,13], we highlight the importance of clearly differentiating life-threatening *critical results* from non-life threatening *significantly abnormal results*. *Critical results* may signify a pathophysiologic state that is potentially life threatening or that could result in significant patient morbidity or irreversible harm or mortality and therefore requires urgent medical attention and action [6,10,13–16]. *Significantly abnormal results* are not life threatening but they require medical attention and follow up action within a medically justified timescale, and for which timing is not as crucial as for critical results (Table 1) [12,13]. We suggest that no terms that refer to 'values' (i.e. critical, panic, crisis, alarm value) are used as not all laboratory results that need notification have quantitative values (e.g. microbiological cultures or semiquantitative tests are reported as positive or negative). We also propose that terms such as 'panic' or 'crisis' or 'alarm' are avoided because they suggest that no systems are in place for managing such results in a professional manner.

A simple umbrella term for these various categories of notification priorities would be helpful but no terms in the literature seem to be appropriate so far. The various meanings of the term 'alert' may probably be more suitable as this term describes in the broadest sense the actual problem and the typical actions that follow. In addition, this word can be used as a noun, adjective and verb and provides flexibility in describing subsequent definitions discussed below. According to various dictionaries the noun 'alert' refers to i) a signal that warns of danger; ii) a condition or period of heightened watchfulness or preparation for action. As an adjective it means i) vigilantly attentive, watchful; ii) mentally responsive and perceptive; iii) quick (http://www.thefreedictionary.com/alert); iv) watchful and prompt to meet danger or emergency; or v) quick to perceive and act (http://www.merriam-webster.com/dictionary/alert). As a verb it means to alarm, forewarn, inform, notify, signal, or warn someone (http://dictionary.reverso.net/english-synonyms/alert). We propose using the umbrella term of *alert results* and in this review we will also refer to this term when we discuss policies and practices related to both critical and significantly abnormal laboratory results. We propose retaining the well-embedded terms of 'critical results' and 'significantly abnormal results', when reference is specifically made to such scenarios and practices.

*Critical test* refers to a test that requires rapid communication of the result to guide further management decisions of medical urgency irrespective whether it is normal, significantly abnormal or critical [13] — e.g. troponin results in all requests from the emergency department, paracetamol results in suspected overdose cases, hematology and coagulation results in suspected disseminated intravascular coagulation, xanthochromia results in suspected subarachnoid hemorrhage, methotrexate results to guide the optimal timing of leucovorin rescue, or tests in cerebrospinal fluid when meningitis is investigated.

Kost and Hale define *critical limit*s as the lower and upper boundary values of diagnostic test results that represent life-threatening and also actionable knowledge for clinical therapeutic decisions [17–19]. This term has many synonyms, such as critical value limit, alarm or alert limit, critical or alert interval or range, critical decision limit or threshold, etc. (Table 1). Some authors propose the term, 'action limits' [16], but we (would prefer to) believe that all laboratory results requested, irrespective of their degree of abnormality, will lead to some form of medical decisions or actions, even if the decision or action is only watchful waiting or monitoring. In our view none of these alternative terms encapsulate the current requirements of achieving better patient safety goals by notifying not just life-threatening (i.e. critical) but also medically important, non-life-threatening (i.e. significantly abnormal) results. Another shortcoming of the current definitions is that they refer to single critical limits and do not include rapid changes in test results which could also be critical or significantly abnormal requiring timely medical intervention. Therefore we propose broadening this term to *alert threshold*s which define the upper and/or lower thresholds of a test result or the magnitude of change in a test result within a critical or clinically significant time scale beyond which the finding is considered to be a medical priority warranting urgent or timely action. We prefer using the word threshold rather than limit as, according to the