CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

GP47

Management of Critical- and Significant-Risk Results

This guideline provides current best practice recommendations for developing and implementing a policy and procedures for the identification, reporting, and management of critical- and significant-risk laboratory results. Emphasis is placed on management responsibilities such as development of the policy, the process, procedures, job descriptions, and monitoring systems that ensure effective reporting and compliance with regulatory requirements.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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Management of Critical- and Significant-Risk Results

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Abstract

Clinical and Laboratory Standards Institute document GP47—*Management of Critical- and Significant-Risk Results* describes systems for effective communication of laboratory results that need urgent clinical review. These laboratory results signify risk of major adverse patient outcomes. Therefore, mechanisms for their rapid identification and timely reporting are essential for patient safety. This guideline emphasizes management responsibilities for the development of the policy, the process, procedures, job descriptions, and monitoring systems that promote effective, timely reporting and compliance with regulatory requirements.

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Foreword

The timely reporting of results that need urgent clinical review is a fundamental responsibility of medical laboratories. This practice is essential for patient safety and is mandated by regulatory and accreditation requirements for laboratories and health care organizations. Laboratory and anatomic pathology results need urgent clinical review when they represent a high risk to patient health and safety. When the results indicate risk of immediately life-threatening conditions, they need to be communicated without delay to a responsible caregiver for urgent patient evaluation and management. GP47 recommends this result category be called "critical-risk" results. In addition, the concept of patient risk can be applied to a broader range of results that may not be immediately life-threatening, but still represent a risk to patients unless they are clinically evaluated and managed within a specific time frame sooner than would occur through routine reporting. GP47 recommends that this result category be called "significant-risk" results.

Due to the high risk to patient safety and the need for timely communication, the reporting of critical- and significant-risk results typically involves special procedures characterized by:

- Direct, person-to-person communication
- Verification of accurate receipt of information
- Occurrence within clinically appropriate time frames
- Documentation in the patient record

Many regulatory and accreditation organizations require processes for reporting results that need urgent clinical review as well as monitoring systems and quality goals to ensure reporting is timely and effective. Compliance with these regulatory and accreditation requirements is often a focal point during inspections of laboratories and health care organizations.

This guideline defines key processes in the reporting of critical- and significant-risk laboratory results. It recommends processes and procedures that are compliant with regulatory and accreditation requirements and consistent with patient safety best practices.

NOTE: The findings and conclusions in this document are those of the authors and do not necessarily reflect the views of the organizations they represent.

KEY WORDS

Alert lists
Alert thresholds
Communication
Critical-risk results
Critical values
Patient safety
Quality management
Risk management
Significant-risk results

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Chapter 1

Introduction

This chapter includes:

- Document scope and applicable exclusions
- Background information pertinent to the document content
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the document
- Abbreviations and acronyms used in the document

Management of Critical- and Significant-Risk Results

1 Introduction

1.1 Scope

This guideline is intended for laboratory directors, managers, and personnel who develop and implement policies and processes for reporting laboratory results that need urgent clinical review. This guideline is also intended for health care administrators who oversee compliance with regulatory and accreditation requirements and clinical practice standards related to patient safety. This information is aligned with standards existing at the time of publication. This guideline is appropriate for all health care environments that conduct laboratory examinations for patient care. Materials are appropriate for laboratories associated with hospitals, clinics, or physician offices as well as independent referral laboratories. The recommendations cover every laboratory discipline and pertain to medical laboratories of every size, scope, and complexity, including point-of-care testing sites.

The process for reporting critical- and significant-risk results is emphasized. The document also describes evidence-based quality metrics and methods to monitor the effectiveness of the reporting process. Common organizational challenges to reporting these laboratory results, and new approaches that apply informatics to make the process more effective and efficient are discussed. The appendixes include a sample policy, sample forms, specific information for specialty laboratories, and a sample flow chart for an escalation process. A summary of commonly reported critical- and significant-risk results, which are compliant with regulatory and accreditation requirements, is provided for organizations to consider for use. Because no single approach applies to every health care environment, organizations are encouraged to modify their policy and processes to reflect the clinical needs of their patient populations.

This guideline does not cover the reporting of results from other diagnostic services such as radiology or cardiology. However, the general recommendations may be relevant to these services. In addition, this document does not focus in depth on the reporting of routine laboratory results; however, organizations should recognize that a breakdown in the receipt and follow-up of all result categories may also be a source of patient harm and medicolegal actions.

1.2 Background

Reporting laboratory results needing urgent clinical review was originally highlighted by Lundberg, who defined a critical laboratory result as one suggesting imminent danger to a patient unless appropriate action was promptly initiated.[1] Since this initial description, hospitals and laboratories