

# GP49

## Developing and Managing a Medical Laboratory (Test) Utilization Management Program

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This report provides guidance for initiating, developing, and maintaining an effective test utilization program.

A CLSI report for US application.

# Clinical and Laboratory Standards Institute

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Clinical and Laboratory Standards Institute  
950 West Valley Road, Suite 2500  
Wayne, PA 19087 USA  
P: +1.610.688.0100  
F: +1.610.688.0700  
[www.clsi.org](http://www.clsi.org)  
[standard@clsi.org](mailto:standard@clsi.org)

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# Developing and Managing a Medical Laboratory (Test) Utilization Management Program

Gary W. Procop, MD, MS  
Anne T. Daley, MS, CMQOE(ASQ), CSSBB, CLC(AMT),  
MT(ASCP), DLM  
Jason Baron, MD  
Christine Collier, PhD, FCACB  
Marilyn S. Hamilton, MD, PhD  
Nora L. Hess, MBA, MT(ASCP), PMP

Kent Lewandrowski, MD  
Ronald W. McLawhon, MD, PhD  
Peter L. Perrotta, MD  
Ron B. Schiffman, MD  
Robert L. Schmidt, MD, PhD, MBA  
Ila Singh, MD, PhD

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## Abstract

Clinical and Laboratory Standards Institute report GP49—*Developing and Managing a Medical Laboratory (Test) Utilization Management Program* provides guidance for initiating, developing, and maintaining an effective test utilization program.

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## Foreword

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Health care is dynamic. It has changed, is currently in the process of significant change, and will change again in the future. One of the current changes is a shift from a transaction- or volume-based system to a capitated, value-based system. Outpatient laboratory testing will become in many ways similar to laboratory-based testing in the inpatient setting. Although cost reductions will be associated with these changes, there are opportunities for pathologists and laboratory professionals to redefine themselves in this new era, as essential members of the health care delivery team.

New health care delivery models (eg, bundled payment, pay for performance, population health management) necessitate not only reducing cost through eliminating unnecessary testing but including the appropriate tests to drive value and improve quality and outcomes. Although eliminating unnecessary testing is an important compelling factor, there are also numerous medical reasons—beyond financial—supporting the need to eliminate unnecessary tests. Preventive measures, such as screening to detect early disease and providing appropriate care to individuals with chronic diseases to prevent progression, will become of paramount importance in these new health care delivery models and may necessitate adding tests. The overarching goal of population health initiatives is to keep individuals healthy. Therefore, appropriate test utilization, which focuses on underutilization as well as overutilization, is the charge of individuals and groups engaged in test utilization management.

This report provides information on building and managing a test utilization committee. One model does not fit all situations. Whether one individual at an institution is engaged in appropriate test utilization management or there is a formal committee established by the organization's leadership, this report is essential for growing and maintaining a test utilization program. Those managing the program should remain flexible and open minded to new and different ways of engaging colleagues to work on improving facility test utilization.

This report lays the foundation for the rationale for test utilization management, exploring the benefits and risks. The optional structures and functions of a utilization management program are discussed, followed by an assessment of the types of investments needed for success, the foremost of which is commitment from dedicated individuals.

Readers will discover reasons for misutilization, as well as solutions that may be readily employed in a variety of health care settings. This report also discusses strategies for managing test utilization.

Although individuals involved in laboratory medicine implement important patient care initiatives, they often do not measure or report the outcomes of these initiatives. This practice will be unacceptable in the new health care delivery models. Health care providers should quantitatively demonstrate to leadership contributions to the system through appropriate use of resources and optimization of health care delivery. Reporting on initiatives helps establish the

laboratory's worth and builds trust among coworkers and leadership, which serves as collateral when new initiatives are proposed. This report thoroughly investigates what to measure, how to measure selected metrics, and how to construct meaningful reports.

Finally, challenges and barriers are discussed, along with recommendations and lessons learned from authors who have made significant contributions to test utilization management.

CLSI consensus documents are developed through an open process that ensures wide review and broad application. This unique approach leads to consensus documents for medical testing and health care services that include identified needs of both global and national constituents. Most CLSI consensus documents are intended for global application. Under certain circumstances, however, a CLSI document may be intended for primary use in a specific country or region.

GP49 is one such consensus document. Although GP49 is a useful resource for a wider audience, it is intended primarily to help the user navigate the US environment with respect to test utilization. Because relevant practices are widely country specific, it was determined it would not be feasible to develop a document intended for global application at this time. CLSI hopes the development of such a document may be possible in the future, as part of a long-term effort to harmonize practices.

The imprint of the US flag (below the abstract and throughout the document footer) and the unique tagline on the cover call attention to its national focus and differentiate GP49 from our global consensus documents.

**NOTE:** The content of this report is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

## KEY WORDS

Evidence-based medicine

Test management

Utilization management

Laboratory utilization

Test utilization

# Chapter 1

## Introduction

This chapter includes:

- ▶ Report's scope and applicable exclusions
- ▶ Background information pertinent to the report's content
- ▶ Terms and definitions used in the report
- ▶ Abbreviations and acronyms used in the report



# Developing and Managing a Medical Laboratory (Test) Utilization Management Program

## NOTE:

This report provides guidance for initiating, developing, and maintaining an effective test utilization program.

## 1 Introduction

### 1.1 Scope

This report provides guidance for initiating, developing, and maintaining an effective test utilization program. It is intended for use by:

- ▶ Laboratory leadership, including medical directors, technical directors, doctoral-level laboratory scientists, pathologists, administrators, and managers
- ▶ Hospital administrators, clinical leaders, and medical staff leaders
- ▶ Medical group practices

Although this report is primarily focused on health care in the United States, it contains information from numerous countries with basic concepts and tools intended for global application.

### 1.2 Background

Laboratory services compose a significant portion (approximately 2% to 3%) of the total expenditures for health care in the United States and other countries. Most of these services are laboratory tests that are used to diagnose disease, determine appropriate treatments, and follow response to therapies.

Interest in how clinicians use laboratory services was first documented when automated analyzers became available for clinical chemistry testing.<sup>1</sup> Laboratories that implemented these technologies experienced increased testing volumes. Soon after, concerns were expressed that a portion of these tests were not necessary for patient care. Specific issues included the high demand for chemistry testing by medical staff in teaching institutions<sup>2</sup> and the performance of unnecessary duplicate testing,<sup>3</sup> resulting in the development of interventions to curb the use of some laboratory services. The earliest strategies—which are still used today—included educational programs targeted at ordering providers<sup>4</sup> and the review of test orders by pathologists and other specialists for medical appropriateness.<sup>5</sup>

More recently, professional organizations in developed nations have created evidence-based recommendations for the most appropriate medical tests and treatments in various clinical scenarios. One of the major goals of these initiatives is to avoid wasteful and unnecessary medical testing.<sup>6</sup> The most visible of these was initiated by the American Board of Internal Medicine Foundation.<sup>7</sup> Since its founding in 2012, more than 70

## The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system (QMS) approach in the development of standards and guidelines that facilitates project management, defines a document structure using a template, and provides a process to identify needed documents. The QMS approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any health care service’s path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The QSEs are:

|                       |                          |                        |                                |
|-----------------------|--------------------------|------------------------|--------------------------------|
| Organization          | Personnel                | Process Management     | Nonconforming Event Management |
| Customer Focus        | Purchasing and Inventory | Documents and Records  | Assessments                    |
| Facilities and Safety | Equipment                | Information Management | Continual Improvement          |

GP49 covers the QSE indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section.

| Organization | Customer Focus | Facilities and Safety | Personnel | Purchasing and Inventory | Equipment | Process Management | Documents and Records | Information Management | Nonconforming Event Management | Assessments | Continual Improvement |
|--------------|----------------|-----------------------|-----------|--------------------------|-----------|--------------------|-----------------------|------------------------|--------------------------------|-------------|-----------------------|
|              |                |                       |           |                          |           | X                  |                       |                        |                                |             |                       |
|              |                |                       |           |                          |           |                    |                       |                        | QMS11                          |             |                       |
| QMS20        |                |                       |           |                          |           |                    |                       |                        |                                |             |                       |

## Related CLSI Reference Materials\*

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- QMS11**    **Nonconforming Event Management. 2nd ed., 2015.** Grounded in the principles of quality management, risk management, and patient safety, this guideline provides an outline and content for developing a program to manage a laboratory's nonconforming events.
- QMS20**    **Understanding the Cost of Quality in the Laboratory. 1st ed., 2014.** This report provides guidance to a laboratory in understanding and managing the different types of costs that affect processes, services, and financial well-being.

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\* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

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950 West Valley Road, Suite 2500, Wayne, PA 19087 USA

P: +1.610.688.0100 Toll Free (US): 877.447.1888 F: +1.610.688.0700

E: [customerservice@clsi.org](mailto:customerservice@clsi.org) [www.clsi.org](http://www.clsi.org)

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