CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

CLSI POCT16™

Emergency and Disaster Point-of-Care Testing

CLSI POCT16 provides guidance on the use of point-of-care testing devices in emergency and disaster settings.

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

CLSI POCT16-Ed1
May 2025

Emergency and Disaster Point-of-Care Testing

Gerald J. Kost, MD, PhD, MS, FACB
James H. Nichols, PhD, DABCC, FADLM
Cynthia Foss Bowman, MD
Sarah M. Brown, PhD
Natalie Campbell, RT
Mick Cote, MS, CEM
Corbin Curtis, BS
Claudia Derse-Anthony, RN
Sharon S. Ehrmeyer, PhD, MLS(ASCP)
William Ferguson
Mary J. Gilchrist, PhD, D(ABMM)
Audrey Gillette, BS, ASCP, MBA
Kerstin A. Halverson, MS
Daniel Hesselgesser, MLS(ASCP)
Roberta E. Hirsch
Rosemary Humes, MS, MLS(ASCP)SM
T. Scott Isbel, PhD, DABCC, FACB
Kyu-Tae Lee, BS
Richard Louie, PhD
Peggy Mann, MS, MLS(ASCP)
Ann Sakaguchi, PhD, MPH
Mark Shephard, PhD, MAACB, OAM
Roxanne G. Shively, MS
Eleanor M. Travers, MD, MHA, FCAP
Richard Y. Wang, DO, FACEP, FACMT
Thomas Williams, MD, FACB, FASCP, FCA
Lou Ann Wyer, MS, MLS(ASCP), ASQ, CQA

Abstract

Clinical and Laboratory Standards Institute POCT16—*Emergency and Disaster Point-of-Care Testing* provides guidance on the use of point-of-care testing (POCT) devices in emergency and disaster settings. CLSI POCT16 serves as a resource by providing a framework for POCT use in emergencies and disasters, recommendations for selecting appropriate devices, and criteria to assess device performance. The recommendations described in CLSI POCT16 will increase user confidence and benefit patients by improving the reliability of test results. Additionally, government agencies can use CLSI POCT16 as a resource to equip emergency and disaster response teams with POCT devices and the knowledge needed to operate them properly.

Clinical and Laboratory Standards Institute (CLSI). *Emergency and Disaster Point-of-Care Testing*. 1st ed. CLSI guideline POCT16 (ISBN 978-1-68440-278-6 [Print]; 978-1-68440-277-9 [Electronic]). Clinical and Laboratory Standards Institute, USA, 2025.

Suggested Citation

CLSI. *Emergency and Disaster Point-of-Care Testing*. 1st ed. CLSI guideline POCT16. Clinical and Laboratory Standards Institute; 2025.

CLSI POCT16-Ed1

ISBN 978-1-68440-278-6 (Print)

ISBN 978-1-68440-277-9 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 45, Number 6

Contents

Contents (Continued)

Foreword

CLSI POCT16 describes good practices for deploying point-of-care testing (POCT) devices in emergency and disaster settings. POCT is defined as medical testing at or near the site of patient care. For the purposes of CLSI POCT16, these sites encompass field sites, temporary structures, emergency departments, and all methods of transportation. POCT is used for screening, diagnosis, and monitoring by means of handheld, portable, and transportable devices and test kits. CLSI POCT16 identifies key criteria for regulatory requirements, quality management, device performance, operators, and medical application of POCT in emergency and disaster settings. CLSI POCT16 will increase user confidence and benefit patients by improving the reliability of examination results and enhance the performance and quality of POCT devices, reagents, and test kits deployed to emergency and disaster settings. The recommendations in CLSI POCT16 apply to any country where existing medical infrastructure necessitates the use of POCT for emergency and disaster care.

NOTE: The content of CLSI POCT16 is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

disaster

disaster planning and mitigation

emergency

emergency management

incident command system

point-of-care testing

public health preparedness

recovery

response

Chapter 1

Introduction

Emergency and Disaster Point-of-Care Testing

1 Introduction

1.1 Scope

CLSI POCT16 provides recommendations for improving performance and quality of point-of-care testing (POCT) used in complex emergency and disaster settings. It provides criteria for POCT use in emergencies and disasters and a framework for POCT device performance assessment.

In CLSI POCT16, POCT refers to devices with measurement capabilities beyond blood glucose.

CLSI POCT16 is useful to the following groups and is appropriate for broad global application:

- Point-of-care coordinators (POCCs), laboratory directors, and hospital administrators
- Laboratorians, disaster responders, emergency care personnel, and other groups who respond to adverse medical crises worldwide
- Point-of-care (POC) device manufacturers, as a source of performance expectations for their devices and test kits
- Government agencies, nongovernmental organizations, and other organizations

CLSI POCT16 does not discuss the use of POCT devices in planning for hospital laboratory downtimes, electrical outages, or other situations covered in CLSI GP36.[1] CLSI POCT16 is not intended to be all encompassing or to preempt other disaster plans. Rather, this guideline is intended to complement existing local, regional, and national disaster management strategies. Testing for chemical and bioterrorism is not described.

1.2 Background

According to Margareta Wahlström, the Secretary-General's special representative for Disaster Risk Reduction at the United Nations,[2] disasters in 2011 were the highest in history at $380 billion, mainly owing to earthquakes in Japan and New Zealand. This figure is two-thirds higher than the previous record in 2005, when Hurricane Katrina hit the southern United States. Major floods in Thailand and other countries also caused extensive damages and economic losses. Wahlström additionally noted that "fifty percent of the world's population is exposed to disasters because they live in highly vulnerable areas." Hence, emergency and disaster preparedness in low-resource, challenging, and remote settings will become increasingly important in the future. In an updated report for the period 1998 to 2017, the same UN office[3] reported $2.9 trillion (US) in direct economic losses. A total of $2.2 trillion (US), or 77% of total economic losses, were due to climate-related disasters in disaster-hit countries, an increase of 2.5 times in the last 20 years.

Furthermore, the 2004 Asian tsunami, Hurricane Katrina in 2005, the novel H1N1 2009 influenza pandemic, and the COVID-19 pandemic illustrated the need for POCT in emergency and disaster care.[4,5] Disaster response teams in each setting were ill-equipped to meet demands for diagnosis, monitoring, and targeted treatment. Field experience showed that responders lacked key tests for bloodstream pathogen detection, cardiac biomarkers, glucose monitoring, and influenza viruses. Deficiencies may have contributed to excess mortality.[6]

Emergencies and disasters can disrupt laboratory and health care operations. Thus, POCT is frequently used in these settings based on various factors, including portability, rapid results, small sample volumes, and ease of use. Care often needs to be administered immediately during an emergency or disaster. POCT plays a unique role in the delivery of laboratory services, and POCT devices should be widely available for immediate use during crises.[7]

Chapter 2

Point-of-Care Testing in an Emergency or Disaster

2 Point-of-Care Testing in an Emergency or Disaster

The disasters of Hurricanes Katrina and Rita and the Thailand tsunami illustrate that mobile medical diagnostic services are necessary for an emergency or disaster medical response team. They also can be beneficial for medical laboratories. POCT can supplement the services provided by the laboratory in the event of an emergency or disaster.[4]

POCT devices have several attributes especially suitable for emergency or disaster operations, such as portability, internal battery power, and analytical robustness. They frequently have liberal internal process monitors and simple, single-use, unitized reagent cartridges. By enabling bedside analysis, they simplify the on-site testing process.

The value of fast, portable, and on-site POCT results is substantial: it can lead to rapid diagnosis, triage, monitoring, therapy, and decision-making in an emergency or disaster. The more focused and evidence-based approach of POCT may alleviate potential workforce shortages. The incorporation of POCT practices as a standard response approach should clearly enhance overall preparedness and response capabilities during emergency or disaster situations.

2.1 Preparedness Overview

Preparedness activities help ensure that a POCT program will be ready to launch in the event of an emergency or disaster. To develop and implement emergency and disaster POCT with the most efficient use of resources, as well as to effectively meet applicable regulatory and accreditation requirements for such programs, a logical and thorough plan is needed that includes requirements and recommendations for good practice in support of effective patient care. A well-prepared plan, practiced periodically to reinforce the appropriate actions and reveal any potential problems, will help ensure effective implementation when needed.

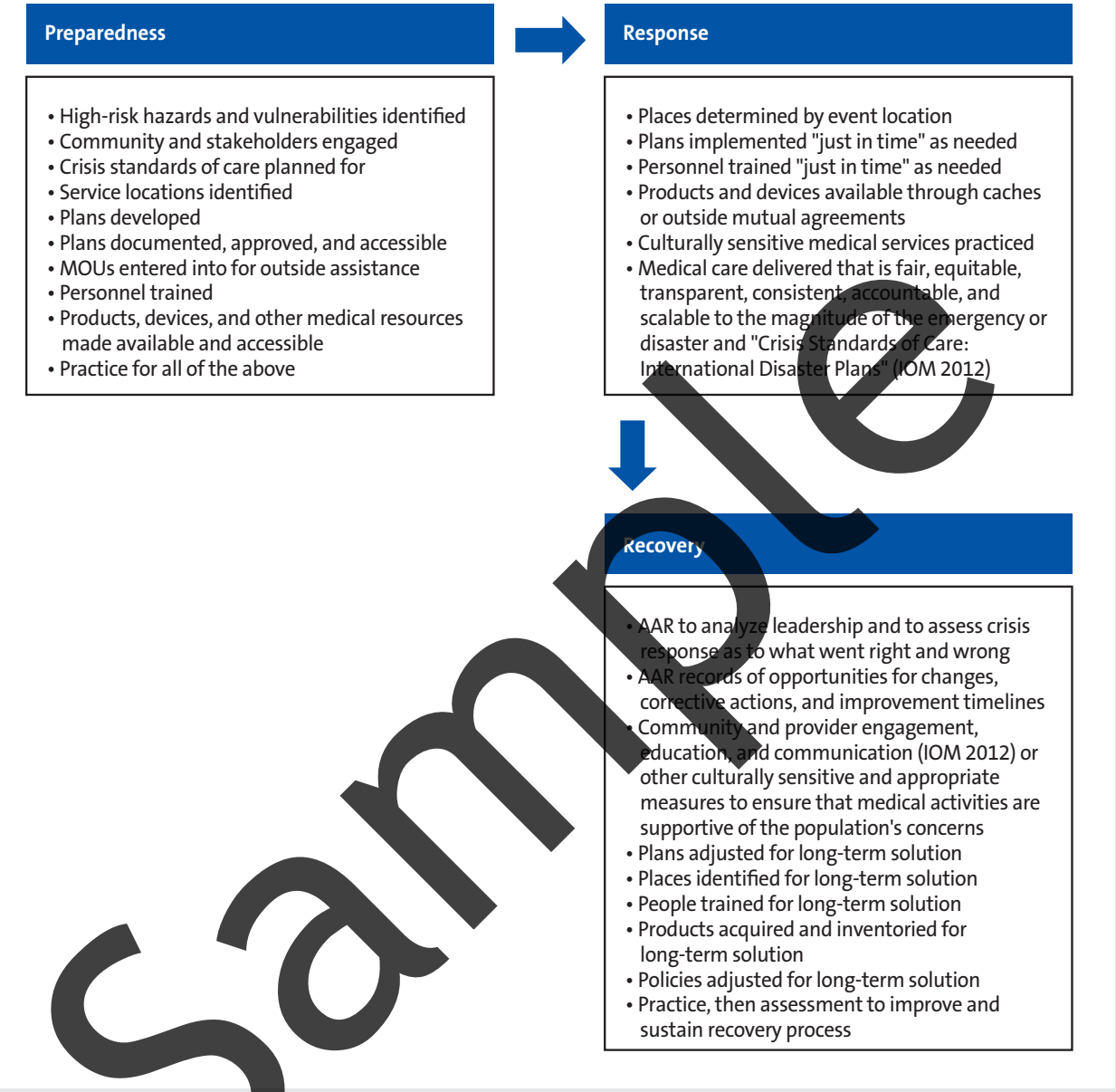
2.2 Response Overview

The plan is activated in an emergency or disaster. Personnel know their respective roles and responsibilities per the plan. Chapter 4 provides details and guidance on support of POCT in response to an emergency or disaster.

2.3 Recovery Overview

After the emergency or disaster, operations transition back to normal. An after action review (AAR) provides information about what went well and where problems arose. Chapter 5 provides details and guidance on support of POCT in the transition after an emergency or disaster.

Figure 1 describes a simplistic three-phase categorization of logistics involved in preparation, response, and recovery of delivery of POCT that serves as a high-level structure for the contents of CLSI POCT16.[41]



Abbreviations: AAR, after action review; IOM, Institute of Medicine; MOU, memorandum of understanding.

Figure 1. Three Phases of Emergency or Disaster Planning

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

PRINT ISBN 978-1-68440-278-6

ELECTRONIC ISBN 978-1-68440-277-9

CLSI POCT16-Ed1