Guideline

Use of POCT for Emergency and Disaster Preparedness & Recovery

North Country POCC Network Meeting
October 25, 2013
Minnesota
Peggy Mann, M.S., MT(ASCP)
Preparedness & Recovery... (from a POCC’s experience!)

Wishing won’t make it so...
Objective

Attendees will be updated on the efforts to create guidelines to help prepare for the use of POCT during disasters & emergencies.
Emergency and Disaster Point-of-Care Testing; Approved Guideline

**CLSI POCT 15 Members:**

Gerald J. Kost, MD, PhD, MS, FACB
James H. Nichols, PhD, DABCC, FACB
Natalie Campbell, RT
Sharon S. Ehrmeyer, PhD
Daniel Hesselgesser, MT(ASCP)
Peggy Mann, MS, MT(ASCP)
Ann Sakaguchi, PhD, MPH
Roxanne G. Shively, MS
Richard Y. Wang, DO
Dave Sterry, MT (ASCP) CLSI

Plus!
Roster includes 30 Contributors
CLSI Table of Contents

Committee Membership ................................................................. iii
Foreword ......................................................................................... vi
1 Scope ......................................................................................... 1
2 Introduction ................................................................................. 1
  2.1 Crisis Standards of Care ....................................................... 3
3 Standard Precautions ............................................................... 5
4 Terminology ................................................................................ 5
  4.1 A Note on Terminology ....................................................... 5
  4.2 Definitions ............................................................................. 5
  4.3 Abbreviations and Acronyms .............................................. 7
5 History – from the types of disaster ........................................ 7
6 Structure and Support of POC Laboratory Services ............... 7
  6.1 Planning for Laboratory Testing Operations During an Emergency and Disaster ............................................. 8
  6.2 Testing requirements/considerations ................................ 10
  6.3 Resource Rich Environment and Resource Poor Environment ................................................................. 10
  6.4 Regional Co-operations, Small World Networks, Regional Hubs ................................................................. 2
7 Role of POC Coordinator .......................................................... 7
8 Testing Sites/Alternative Care Sites ......................................... 9
  8.1 Portable Intensive Care Units .............................................. 14
9 Medical Needs During the Initial Response ............................. 15
  9.1 Point-of-Care Testing for Surgical and Medical Needs During the Initial Response ...................................... 15
  9.2 Critical Tests Promoting Survivability in Emergencies and Disasters ....................................................... 17
  9.3 Transition to Recovery for Patients .................................... 32
10 Resources/Logistics .................................................................. 33
  10.1 Supply Chain ..................................................................... 33
  10.2 Personnel and Job Action Sheets .................................... 36
  10.3 Connectivity ....................................................................... 40
11 Good Laboratory Practice in a Disaster Setting .................... 53
  11.1 Environmental Stresses and Reagent Handling ............... 53
  11.2 Verification of test system for new or replacement instrumentation .......................................................... 65
  11.3 Quality Assurance-Quality Control .................................. 66
  11.4 Biohazardous waste, PPE, Safety ..................................... 67
  11.5 Positive patient identification ......................................... 70
  11.6 Proficiency Testing ............................................................ 73
  11.7 Education, Training, and Competency ............................. 73
  11.8 Results reporting ............................................................... 84
12 Public Health Considerations, Emergency and Disaster POCT . . . . 87
  12.1 Early warning and Sentinel Case Investigations ............... 88
  12.2 Documenting Intervention Impact ................................. 90
  12.3 Monitoring Consequential Health Problems ................ 90
  12.4 POC Testing - Implications for Public Health ............... 90
  12.5 Isolation, Quarantine and Triage ..................................... 91
13 Transition from Response to Recovery for Site .................... 96
14 Conclusions and Recommendations .................................... 97
References .................................................................................... 98
Appendix A. Resupply Documentation and Forms .................... 99
Appendix B. Laboratory Training Checklist ............................. 100
Appendix C. Environmental stress testing results .................... 101
Appendix D. Example of a Supply Request Form ..................... 100
The Quality Management System Approach .......................... 111
Related CLSI Reference Materials ............................................. 112
Terminology Definitions increase understanding

definition: ‘Hunker down’ = refuse to leave (evacuate)
Definitions
Recovery = restoring the community

Murdoch’s Bathhouse on the seawall, Galveston
Definitions
Recovery = restoring the community
Definitions

Emergency
- a serious, unexpected, urgent, and often dangerous situation requiring immediate action

Disaster/Crisis
- a calamitous event occurring suddenly and causing great loss of life, damage, or hardship

Response
- acutely responding to and surviving a complex emergency or disaster while it is underway

Recovery
- restoring the community once outside help has departed

Preparedness
- the state of readiness achieved by possessing adequate resources for an unexpected event

Guideline Material **Features:**

- Crisis Standards of Care
- Structure and Support of POC Laboratory Services
  - Planning for Laboratory Testing Operations
  - Testing requirements/considerations
  - Resource Rich Environment and Resource Poor Environment
  - Regional Co-operations
    - Small World Networks
- Role of POC Coordinator
Features, Con’t:

✓ Testing Sites/Alternative Care Sites

✓ Medical Needs During the Initial Response
  o POCT for Surgical and Medical Needs - Initial Response
  o Critical Tests Promoting Survivability
  o Transition to Recovery for Patients

✓ Resources/Logistics

✓ Good Laboratory Practice

✓ Public Health Considerations

✓ Response to Recovery Transition
Guideline is user friendly!
Graphics, Tables, Charts, Checklists
Table 5. Point-of-Care Value Proposition for Small-World Networks

Reduce Therapeutic Turnaround Time (TTAT) to Speed Critical Paths

Optimize the Use of POCT

Monitor Continuously In Vivo for Emergency Care

Use Cardiac Biomarkers to Diagnose Acute Coronary Syndromes

Facilitate Acute and Chronic Diabetes Monitoring in Disasters and Afterward

Introduce New Infectious Diseases Testing

Guideline Materials
Tables – Charts - Checklists

Three Phases of Disaster

<table>
<thead>
<tr>
<th>Preparedness</th>
<th>Crisis</th>
<th>Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>People trained</td>
<td>People trained ‘just in time’ as needed</td>
<td>People trained for long term solution</td>
</tr>
<tr>
<td>Places (locations) identified for providing services</td>
<td>Places determined by event location</td>
<td>Places identified for long term solution</td>
</tr>
<tr>
<td>Policies and plans written, approved, accessible</td>
<td>Policies acquired ‘just in time’ as needed</td>
<td>Policies adjusted for long term solution</td>
</tr>
<tr>
<td>Products, devices available or within timely retrieval</td>
<td>Products, devices available through caches or outside mutual agreements</td>
<td>Products acquired &amp; inventoried for long term solution</td>
</tr>
<tr>
<td>Practice all of the above</td>
<td></td>
<td>Practice then assess to improve &amp; sustain recovery process</td>
</tr>
</tbody>
</table>

Guideline Materials
Tables – Charts - Checklists

Three Phases of Disaster

<table>
<thead>
<tr>
<th>Preparedness</th>
<th>Crisis</th>
<th>Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>People trained</td>
<td>People trained ‘just in time’ as needed</td>
<td>People trained for long term solution</td>
</tr>
<tr>
<td>Places (locations) identified for providing services</td>
<td>Places determined by event location</td>
<td>Places identified for long term solution</td>
</tr>
<tr>
<td>Policies and plans written, approved, accessible</td>
<td>Policies acquired ‘just in time’ as needed</td>
<td>Policies adjusted for long term solution</td>
</tr>
<tr>
<td>Products, devices available or within timely retrieval</td>
<td>Products, devices available through caches or outside mutual agreements</td>
<td>Products acquired &amp; inventoried for long term solution</td>
</tr>
<tr>
<td>Practice all of the above</td>
<td></td>
<td>Practice then assess to improve &amp; sustain recovery process</td>
</tr>
</tbody>
</table>

Guideline Materials
Tables – Charts - Checklists

Three Phases of Disaster

<table>
<thead>
<tr>
<th>Preparedness</th>
<th>Crisis</th>
<th>Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>People trained</td>
<td>People trained ‘just in time’ as needed</td>
<td>People trained for long term solution</td>
</tr>
<tr>
<td>Places (locations) identified for providing services</td>
<td>Places determined by event location</td>
<td>Places identified for long term solution</td>
</tr>
<tr>
<td>Policies and plans written, approved, accessible</td>
<td>Policies acquired ‘just in time’ as needed</td>
<td>Policies adjusted for long term solution</td>
</tr>
<tr>
<td>Products, devices available or within timely retrieval</td>
<td>Products, devices available through caches or outside mutual agreements</td>
<td>Products acquired &amp; inventoried for long term solution</td>
</tr>
<tr>
<td>Practice all of the above</td>
<td></td>
<td>Practice then assess to improve &amp; sustain recovery process</td>
</tr>
</tbody>
</table>
Example of POC15 tables: Essential Preparedness for Complex Emergencies and Disasters

CLSI POCT 15 Table 1.

- Improve crisis standards of care, preparedness, and recovery
- Develop the master plan for devices, regents, test menu, and quality assurance
- Produce a business plan for continuity, back-up, and alternate site testing
- Assist via incident command management with critical functions (communications, assets, safety, security, utilities, and clinical support)
- Understand the emergency management plan and the incident command system then apply accordingly
- Perform hazard vulnerability analysis (example: Table 2)
- Identify crucial systems, uninterruptable processes, and outages, and their impact
- Liaison with commercial partners for bidirectional community support
CLSI POCT15 Table 1. Essential Preparedness for Complex Emergencies and Disasters

- Analyze leadership, assess crisis response to determine what went right, and what did not
- Document drills, opportunities for change, corrective actions, and improvement timelines
- Prepare for accreditation, standardize oversight in outlying sites, and consider using CLIA waivers
- Make key decisions, such as need to stockpile, control expenditures, and involve contract suppliers
- Comply with regulations, laws, guidelines
The first draft has been completed, development was delayed due to shortage of CLSI staff availability.

The document is being prepared for Draft 1 vote at this time; using a 99 point checklist of items.

Expect the document to be distributed to the document development committee for Draft 1 vote by end of August 2013.

Public review (Draft 2 – 45 days) to begin in October 2013.

Now scheduled for publication in May 2014.
CLSI POC 15

Now scheduled for publication in May 2014

http://www.clsi.org/