THE ROLE OF POINT-OF-CARE TESTING DURING AN EMERGENCY OR DISASTER SITUATION

Presented by Gerald J. Kost, MD, PhD, MS, FACB, in collaboration with EST Core Research Leader, Richard F. Louie, PhD, FACB, and contributions by William Ferguson, Corbin Curtis, and Students

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University of California, Davis

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http://www.ucdmc.ucdavis.edu/pathology/poctcenter/
ROLES—YOURS AND POCT!

• **Determine Needs:** Needs assessment helps define the role of POCT in pandemics, complex emergencies, and disasters.

• **Improve Performance:** Environmental stresses affect test results and must be understood, in order that POCT can be used appropriately in crises.

• **Design Caches (mini-workshop):** Disaster caches should be designed for collaborative use throughout the world!—Please see handout....

  ➔➔➔➔ ....comment, then submit to Dr. Kost.
NEEDS ASSESSMENT FOR RAPID DECISION MAKING IN PANDEMICS, COMPLEX EMERGENCIES, AND DISASTERS: A GLOBAL PERSPECTIVE

GERALD J. KOST, RICHARD F. LOUIE, ANH-THU TRUONG, AND CORBIN M. CURTIS

OVERVIEW

Clinical needs assessment defines unmet healthcare needs and determines how to fill them. The goal of this chapter is to describe the process of performing needs assessment in the context of translating needs into innovative point-of-care (POC) technologies. We performed need assessment surveys to identify diagnostic testing gaps in complex emergencies, disasters, and public health and used SurveyMonkey® to administer them. Literature searches were conducted using the PubMed database and keywords, such as points of care, needs assessment, and POC disaster needs assessment. An emerging technology logic model summed up our approach. Original research by the University of California, Davis POC Technologies Center and publications by other investigators revealed insights about POC testing (POCT) needs for emergency and disaster response. Laboratory, POC coordinators, medical doctors, researchers, disaster responders, disaster experts, and others indicated the importance of (a) having specific POC tests in emergencies and disasters, (b) desired sampling methods that preserve integrity of the sample while minimizing biohazard risks, and (c) defined essential test clusters for bloodstream and respiratory infections. Evidence also revealed strong need for influenza testing and resistance markers useful in public health. Developers can reduce product development risks by conducting formal needs assessment that helps identify end-user product features and requirements early on. Needs assessment guides the product development pipeline of new technologies by helping (a) to identify and prioritize diagnostic testing needs, (b) to determine technological gaps and deficiencies that impact patient care, and (c) to design specifications for new POC technologies. Needs assessment has been successfully applied to identify POC diagnostic testing in complex emergencies, disasters, and public health as illustrated in this review and therefore can be used broadly in the point of care field to accelerate progress.

Based on a 2012 World Health Organization Health Statistics report, a median of 61% of the world health expenditure was paid by the government in 2009 (1). Needs assessment can reduce global health care expenditures, improve healthcare resource, and enhance standards of care. Needs assessment, per se, represents a systematic process for determining and addressing what POCT users want, as well as for discovering gaps and deficiencies in the current delivery and practice of diagnostic testing at the sites of decision making (2).

Fundamentally, POCT grows out of satisfying clinical need for bedside glucose testing, coagulation monitoring, and intensive care, where the advent of ionized calcium (Ca²⁺), free calcium (Figure 1-1) (3-6) proved that whole-blood analysis (7) was necessary for the diagnosis and treatment of critically ill patients with rapid therapeutic turnaround time (3) that could not be accomplished with centrifuged samples processed distantly in the conventional clinical laboratory. Once speed was achieved within a comprehensive value proposition of convenience, impactful bedside information, and improved outcomes, the paradigm of testing shifted to the point-of-need where it is likely to remain.

Enhanced healthcare delivery in complex emergencies and disasters can improve crisis standards of care (6). The Southeast Asian Tsunami in 2004, Hurricane Katrina in 2006, Haiti Earthquake in 2010, and Sandy Superstorm in 2012 disrupted, flooded, and destroyed infrastructure, including hospital laboratories and microbiology testing services thereby prolonging patient treatment (7-9). Public health officials should understand the methods of needs assessment, its importance, and current healthcare delivery models in order to push developers to deliver appropriate POC technologies that will enhance standards of care (6).

Strategically integrated POCT can provide rapid diagnostic data, facilitate triage, and improve management of victims during disasters (10). POCT is testing performed at or near the site of the patient care (11). Recent disasters have demonstrated the feasibility of POCT, but POCT devices lack crucial test clusters and are vulnerable to harsh disaster environments (12-22). The goal of this chapter is to describe the process of performing needs assessment in the context of translating needs into innovative POC technologies.
Needs Assessment Results from AACC members

Top five pathogens selected for disaster settings

First Responders are the preferred group to perform POC testing in disasters.

Respondents preferred patient-side testing in the field over testing inside a vehicle or tent.

Respondents chose CBC, Lytes/Chemistry, Blood Bank, & O₂ Saturation as the highest priority diagnostic tests for a disaster.

How To: Monitor $O_2$ Saturation & Hemoglobin

### Tsunami Needs Assessment Survey Results

Pathogen Detection Must Flex for Future!

#### Table 1: Pathogen Test Menus for Emergency and Disaster Care

<table>
<thead>
<tr>
<th>Objective</th>
<th>Weighted Score</th>
<th>Pathogen</th>
<th>Objective</th>
<th>Weighted Score</th>
<th>Pathogen</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Civil disaster infections (n = 24)</td>
<td>53</td>
<td><em>S. aureus</em></td>
<td>(C) Bloodstream infections (n = 24)</td>
<td>95</td>
<td><em>S. pneumoniae</em></td>
</tr>
<tr>
<td></td>
<td>43</td>
<td><em>Klebsiella</em> sp</td>
<td></td>
<td>85</td>
<td><em>S. aureus</em></td>
</tr>
<tr>
<td></td>
<td>41</td>
<td>Dengue fever virus</td>
<td></td>
<td>75</td>
<td><em>Escherichia coli</em></td>
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<tr>
<td></td>
<td>36</td>
<td><em>Pseudomonas aeruginosa</em></td>
<td></td>
<td>72</td>
<td><em>Pseudomonas aeruginosa</em></td>
</tr>
<tr>
<td></td>
<td>34</td>
<td>Human immunodeficiency virus types 1 and 2</td>
<td></td>
<td>65</td>
<td><em>Streptococcus sp</em></td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>Hepatitis B virus</td>
<td></td>
<td>52</td>
<td><em>Klebsiella</em> sp</td>
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<tr>
<td></td>
<td>28</td>
<td><em>Enterobacter</em> sp</td>
<td></td>
<td>48</td>
<td>Methicillin-resistant <em>S. aureus</em></td>
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<td></td>
<td>27</td>
<td><em>Vibrio cholerae</em></td>
<td></td>
<td>43</td>
<td><em>Enterobacter</em> sp</td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>Plasmodium vivax</td>
<td></td>
<td>31</td>
<td><em>Acmetochna baumannii</em></td>
</tr>
<tr>
<td></td>
<td>20</td>
<td><em>Plasmodium falciparum</em></td>
<td></td>
<td>30</td>
<td>Coagulase-negative <em>Staphylococcus</em></td>
</tr>
<tr>
<td>(B) Respiratory pandemics (n = 24)</td>
<td>60</td>
<td>SARS</td>
<td>(D) Emergency blood donor screening (n = 24)</td>
<td>155</td>
<td>Hepatitis B virus</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>Avian influenza (H5N1)</td>
<td></td>
<td>150</td>
<td>Human immunodeficiency virus types 1 and 2</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>Respiratory syncytial virus</td>
<td></td>
<td>138</td>
<td>Hepatitis C virus</td>
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<td></td>
<td>39</td>
<td><em>S. pneumoniae</em></td>
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<td></td>
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<tr>
<td></td>
<td>32</td>
<td>Influenza A/B virus</td>
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<td></td>
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<td>31</td>
<td><em>Mycobacterium tuberculosis</em></td>
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<td>68</td>
<td>Epstein-Barr virus</td>
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<td><em>Haemophilus influenzae</em></td>
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<td><em>Mycoplasma pneumoniae</em></td>
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<td>57</td>
<td><em>Cytomegalovirus</em></td>
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<td>26</td>
<td><em>S. aureus</em></td>
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<td>49</td>
<td>Parvovirus B19</td>
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<tr>
<td></td>
<td>26</td>
<td><em>Klebsiella</em> sp</td>
<td></td>
<td>49</td>
<td>Chikungunya virus</td>
</tr>
<tr>
<td></td>
<td>26</td>
<td>Pandemic (H1N1) 2009 influenza</td>
<td></td>
<td>43</td>
<td>Human T-cell lymphotropic virus 1 and 2 (HTLV 1 and 2)</td>
</tr>
</tbody>
</table>

Different pathogens targeted for each objective. Now, N7N9 & MERS CoV—moving targets, custom POC!

How To: New Influenza POC Device

- Automated
- Integrated POC platform for molecular diagnostic testing
- Influenza subtyping
- Antiviral resistance testing (i.e., Tamiflu)

Provided Courtesy of David Kelso at Northwestern University & Karen Kaul at NorthShore University Health System
MERS CoV (209 dead/699 + 113 in Saudi Arabia)
Recently SE Asia and the USA (travel associated)
Respondents chose 3 physical challenges as the most important environmental factors to overcome in future POC device designs for extreme conditions.

Hurricane Katrina, 2005
Temp: 20 to 43.3°C

Haiti Earthquake, 2010
Temp: 20 to 35°C

Christchurch, New Zealand, 2011
Temp: 8 to 31°C

Japan Earthquake / Tsunami, 2011
Temp: -5 to 20°C
Impact on Recent Emergency Response

• During Hurricane Katrina new shipments of POCT failed after one week of use. (43.3°C)

• In Springfield, Massachusetts, paramedics complained that cold temperatures caused glucose meter systems to shutdown during emergency response. (<12.8°C)

• In Port-au-Prince, Haiti, i-STAT whole blood analyzers were inoperable due to high temperatures. (35°C)

Global Point of Care Strategies for Disasters, Emergencies, and Public Health Resilience

Edited by
Gerald J. Kost & Corbin M. Curtis

AACCPress

THE IMPACT OF ENVIRONMENTAL STRESS ON DIAGNOSTIC TESTING AND IMPLICATIONS FOR PATIENT CARE DURING CRISIS RESPONSE

RICHARD F. LOUIE, WILLIAM J. FERGUSON, CORBIN M. CURTIS, ANH-THU TRUONG, MANDY H. LAM, AND GERALD J. KOST

OVERVIEW

Strategic integration of point-of-care (POC) diagnostic tools during crisis response can accelerate triage and improve management of victims. Timely differential diagnosis is essential wherever care is provided to rule out or rule in disease, expedite life-saving treatment, and improve utilization of limited resources.

POC testing (POCT) needs to be accurate in any environment in which it is used. Devices are exposed to potentially adverse storage and operating conditions, such as high and low temperature and humidity during emergencies and field rescues. Therefore, characterizing environmental conditions allows technology developers, operators, and responders to understand the broad operational requirements of test reagents, instruments, and equipment in order to improve the quality and delivery of care in complex emergencies, disasters, and austere environmental settings.

This chapter aims (a) to describe the effects of environmental stress on POCT performance and its impact on decision making; (b) to describe how to study the effects; and (c) to summarize approaches to minimize or nullify the effects of environmental stresses through good laboratory practice, development of robust reagents, and producing novel thermal packaging solutions.

ENVIRONMENTAL STRESSORS AND POCT TESTING

In crisis response, strategic integration of POC diagnostic tools, such as portable multiplex cardiac biomarker testing, at alternate care facilities can accelerate triaging and improve management of victims (1). Timely differential diagnosis is essential wherever care is provided to rule out or rule in disease, expedite appropriate life-saving treatment, and improve utilization of limited resources (2).

Between 1980 and 2013, the United States experienced 640 disaster events. Of these events (435), 413 (64.5%) were weather-related (2). Deaths associated with weather-related events account for 87.8% of all disaster deaths (2). Table 23-1 (3-5) summarizes the environmental conditions observed in recent disasters. With careful implementation and integration of POC tests for onsite triaging and diagnosis, lives potentially could have been saved.

To ensure accurate and safe use, POCT needs to deliver excellent performance in any environment in which it is used (6). Error-prone test results can cause serious harm and alter clinical decision making, such as improper insulin dosage (7). Emergency and disaster responders equipped with POC technologies for rapid triage, diagnosis, and monitoring must function effectively in adverse conditions. These conditions may exceed the storage and operating specifications of both POCT test reagents and the instruments.

Tables 23-2 and 23-3 (8) summarize the storage and operating specifications of select POC devices. Test reagents typically are refrigerated or stored in ambient conditions between 15-30 °C (59-86 °F). Reagents requiring refrigeration can be stored at ambient conditions (e.g., room temperature), but are then stable for a shorter duration. The US Pharmacopeia defines room temperature as 20-25 °C (68-77 °F) with allowable short-term excursions spanning 15-30 °C (59-86 °F), and a mean kinetic temperature (MKT) not more than 25 °C (77 °F).

Mean Kinetic Temperature.

MKT, a simplified way of expressing the overall temperature impact on first-order chemical reactions, weights the effects of temperature variations over an extended period of time according to the following equation (9).

\[
MKT = \frac{\Delta E}{R} = -\ln\left(\frac{e^{\Delta H \gamma} + e^{\Delta H \gamma} + \ldots + e^{\Delta H \gamma}}{n}\right)
\]
Thermal Stress and Point-of-Care Testing Performance: Suitability of Glucose Test Strips and Blood Gas Cartridges for Disaster Response

Richard F. Louie, PhD, Stephanie L. Sumner, Shaunyel Belcher, Ron Mathew, BS, Nam K. Tran, PhD, and Gerald J. Kost, MD, PhD, MS, FACB

ABSTRACT

Objective: Point-of-care testing (POCT) devices are deployed in the field for emergency on-site testing under a wide range of environmental conditions. Our objective was to evaluate the performance of glucose meter test strips and handheld blood gas analyzer cartridges following thermal stresses that simulate field conditions.

Methods: We evaluated electrochemical and spectrophotometric glucose meter systems and a handheld blood gas analyzer. Glucose test strips were cold-stressed (−21°C) and heat-stressed (40°C) for up to 4 weeks. Blood gas cartridges were stressed at −21°C, 2°C, and 40°C for up to 72 hours. Test strip and cartridge performance was evaluated using aqueous quality control solutions. Results were compared with those obtained with unstressed POCT strips and cartridges.

Results: Heated glucose test strips and blood gas cartridges yielded elevated results. Frozen test strips and cooled cartridges yielded depressed glucose and blood gas results, respectively. Frozen cartridges failed.

Conclusions: The performance of glucose test strips and blood gas cartridges was affected adversely by thermal stresses. Heating generated elevated results, and cooling depressed results. Disaster medical assistance teams should be aware of these risks. Field POCT devices must be robust to withstand adverse conditions. We recommend that industry produce POCT devices and reagents suitable for disaster medical assistance teams and emergency medical responders. (Disaster Med Public Health Preparedness. 2009;3:13-17)

Key Words: blood gas, error, glucose meter, handheld blood gas analyzer, stress duration

During disasters, emergency medical responders equipped with point-of-care testing (POCT) instruments, such as handheld devices and oxygen saturation monitors, are deployed to disaster sites. Local health system infrastructure may be inoperable or overwhelmed by the number of victims needing rapid on-site testing for triage and disaster management. Hurricane Katrina demonstrated the need for field POCT to facilitate evidence-based triage and directed rescue. The portability of POCT instruments makes them ideal for use by emergency responders, such as disaster medical assistance teams (DMATS), to facilitate diagnosis, treatment, and appropriate backup care.

Disaster settings demand POCT under adverse conditions, such as high and low temperature and high humidity. Our objective was to assess whether glucose meter test strips and handheld blood gas analyzer cartridges can provide accurate results after exposure.

METHODS

POCT Systems and Reagents

The glucose meters and handheld blood gas analyzer were operated at room temperature. Meters and analyzer were not thermally stressed. Only the reagent test strips and cartridges were stressed. Stressed strips and cartridges were immediately tested while they were in the heated, cooled, or frozen state. Three glucose meter systems (GMS) were evaluated: 2 electrochemical (GMS 1-EC, GMS 2-EC) and 1 spectrophotometric (GMS 2-S) with 1 lot of glucose test strips for each. Test strips are single use and disposable. Glucose test strips were evaluated using aqueous quality control (QC) solutions supplied by the manufacturers. One glucose QC level was selected for each GMS to span the clinical range of glucose results commonly encountered. One lot of aqueous QC was used for each GMS.

We used a handheld blood gas analyzer (HHBG) with 1 lot of test cartridges. Single-use disposable cartridges were evaluated with level 1 RapidQC Control QC solution (Bayer Healthcare), which is composed of buffered bi...
Reagent test strips for three hospital and commercial glucose meter systems were stressed at 40°C for four weeks. Thermally stressed strips were compared to results obtained from room temperature control strips.

Heated test strips generated elevated glucose results, but which varied and were inconsistent with GMS 2-EC and GMS 2-S.

Mean glucose differences were reported as high as 11.2 mg/dL on GMS 1-EC, 12.8 mg/dL on GMS 2-, EC, and 16.4 mg/dL on GMS 2-S.

Louie RF. *Disaster Med Public Health Prep* 2009;3:13-17
Freeze and Thaw Effects

- Glucose reagent test strips were stressed at -21°C for four weeks. Frozen strips and thawed strips were tested and results compared to results obtained from room temperature control strips.

- Frozen test strips generated lower glucose results. The mean glucose difference was -15.6 mg/dL on GMS 1-EC. GMS 2-S reported a singular observed bias of -41 mg/dL.

- Thawed test strips for GMS 1-EC and GMS 2-S demonstrated partial recovery in performance. However, GMS 2-S performed worse.

Louie RF. *Disaster Med Public Health Prep* 2009;3:13-17
Effects of Humidity on Foil and Vial Packaging to Preserve Glucose and Lactate Test Strips for Disaster Readiness

Anh-Thu Truong; Richard F. Louie, PhD; John H. Vy; Corbin M. Curtis; William J. Ferguson; Mandy Lam; Stephanie Sumner; Gerald J. Kost, MD, PhD

ABSTRACT

Objective: Efficient emergency and disaster response is challenged by environmental conditions exceeding test reagent storage and operating specifications. We assessed the effectiveness of vial and foil packaging in preserving point-of-care (POC) glucose and lactate test strip performance in humid conditions.

Methods: Glucose and lactate test strips in both packaging were exposed to mean relative humidity of 97.0 ± 1.1% in an environmental chamber for up to 168 hours. At defined time points, stressed strips were removed and tested in pairs with unstressed strips using whole blood samples spiked to glucose concentrations of 60, 100, and 250 mg/dL (n = 20 paired measurements per level). A Wilcoxon signed rank test was used to compare stressed and unstressed test strip measurements.

Results: Stressed glucose and lactate test strip measurements differed significantly from unstressed strips, and were inconsistent between experimental trials. Median glucose paired difference was as high as 12.5 mg/dL at the high glucose test concentration. Median lactate bias was -0.2 mmol/L. Stressed strips from vial (3) and foil (7) packaging failed to produce results.

Conclusions: Both packaging designs appeared to protect glucose and lactate test strips for at least 1 week of high humidity stress. Documented strip failures revealed the need for improved manufacturing process. (Disaster Med Public Health Preparedness. 2014;8:51-57)

-point-of-Care (POC) devices such as glucose meters and test strips can facilitate triaging and screening of patients at sites of care during crises in which temperature and humidity can fluctuate and may exceed the manufacturer's storage and operating specifications. Environmental stress can cause erroneous measurements and jeopardize patient management, treatment, and safety.1-9

Responders at recent disasters, such as Hurricane Katrina in New Orleans and the earthquake in Haiti, reported POC reagents and instruments failing in austere conditions.3-10 Reagent test strips typically are packaged in vials or individually sealed in foil or polyester film (Mylar) packaging. Therefore, the objective of the study was to evaluate the effectiveness of foil and vial packaging in safeguarding and preserving the performance of glucose and lactate test strips when stored and operated in an environment with high humidity.

MATERIALS AND METHODS

Point-of-Care Systems

Strips, 1 packaged in vials and 1 in foil (Figure 1), and 1 lot of lactate strips in vials were used. Lactate strips were not available in foil packaging.

Test Sample

This study received approval from the local ethics committee, University of California, Davis, institutional review board (IRB #294372-4). Venous whole blood samples (16 mL) were collected in lithium heparin evacuated collection tubes from healthy adult volunteers. Donor blood was pooled and tested to determine the initial baseline glucose concentration. The sample was partitioned into 3 tubes to create 3 different test concentrations.

To achieve a low glucose concentration (level 1), the sample was allowed to glycolyze in an environmental chamber at 37°C. High glucose concentration (level 3) was achieved by spiking the samples with either 10% or 20% dextrose solution. Lactate levels in the samples were not adjusted.

Experimental Design

ps in vial and foil packaging and lactate are split into control and stressed groups.
**Static Humidity Stress**

- **Objective**—to assess the effectiveness of vial and foil packaging in preserving point-of-care glucose and lactate test strip performance in humid conditions.

- **Methods**—glucose test strips in both vial and foil packaging, and lactate strips in vial packaging were exposed to mean relative humidity of \(97.0 \pm 1.1\%\) at a static temperature of \(19.0^\circ\text{C}\) in a Tenney BTRC environmental chamber for up to 168 hours (1 week).

- **Statistical Model**—Paired measurements were performed on stressed and unstressed test strips at defined time points (24, 72, and 168 hours of exposure). Whole blood samples spiked to glucose test concentrations of 60, 100, and 250 mg/dL were used for testing.
Dynamic Temperature and Humidity Environmental Profiles: Impact for Future Emergency and Disaster Preparedness and Response

William J. Ferguson, BS; Richard F. Louie, PhD; Chloe S. Tang, BS; Kyaw Tha Paw U, PhD; Gerald J. Kost, MD, PhD, MS, FACP

Abstract

Introduction: During disasters and complex emergencies, environmental conditions can adversely affect the performance of point-of-care (POC) testing. Knowledge of these conditions can help device developers and operators understand the significance of temperature and humidity limits necessary for use of POC devices. First responders will benefit from improved performance for on-site decision making.

Objective: To create dynamic temperature and humidity profiles that can be used to assess the environmental robustness of POC devices, reagents, and other resources (eg, drugs), and thereby, to improve preparedness.

Methods: Surface temperature and humidity data from the National Climatic Data Center (Asheville, North Carolina USA) was obtained, median hourly temperature and humidity were calculated, and then mathematically stretched profiles were created to include extreme high and low. Profiles were created for: (1) Banda Aceh, Indonesia at the time of the 2004 Tsunami; (2) New Orleans, Louisiana USA just before and after Hurricane Katrina made landfall in 2005; (3) Springfield, Massachusetts USA for an ambulance call during the month of January 2009; (4) Port-au-Prince, Haiti following the 2010 earthquake; (5) Sendai, Japan for the March 2011 earthquake and tsunami with comparison to the colder month of January 2011; (6) New York, New York USA after Hurricane Sandy made landfall in 2012; and (7) a 24-hour rescue from Hawaii USA to the Marshall Islands. Profiles were validated by randomly selecting 10 days and determining if (1) temperature and humidity points fell inside and (2) daily variations were encompassed. Mean kinetic temperatures (MKT) were also assessed for each profile.

Results: Profiles accurately modeled conditions during emergency and disaster events and encompassed 100% of maximum and minimum temperature and humidity points. Daily variations also were represented well with 88.6% (62/70) of temperature readings and 71.1% (54/70) of relative humidity readings falling within diurnal patterns. Days not represented well primarily had continuously high humidity. Mean kinetic temperature was useful for severity ranking.

Conclusions: Simulating temperature and humidity conditions clearly reveals operational challenges encountered during disasters and emergencies. Understanding of environmental stresses and MKT leads to insights regarding operational robustness necessary for safe and accurate use of POC devices and reagents. Rescue personnel should understand these principles before performing POC testing in adverse environments.

Environmental Stress Testing Workflow

- POC Reagent
  - Test Strips & Cartridges

Environmental Stress Testing Chamber & Profile

Test Stressed Strips & Cartridges

- Facilitate Device Design
- Enhance Guidelines Development for POCT in Emergency and Disaster Settings

Effects of Dynamic Temperature and Humidity Stresses on Point-of-Care Glucose Testing for Disaster Care

Richard F. Louie, PhD; William J. Ferguson; Stephanie L. Sumner; Jimmy N. Yu; Corbin M. Curtis; Gerald J. Kost, MD, PhD, MS

ABSTRACT

Objective: To characterize the performance of glucose meter test strips using simulated dynamic temperature and humidity disaster conditions.

Methods: Glucose oxidase- and glucose dehydrogenase-based test strips were dynamically stressed for up to 680 hours using an environmental chamber to simulate conditions during Hurricane Katrina. Paired measurements vs control were obtained using 3 aqueous reagent levels for GMS1 and 2 for GMS2.

Results: Stress affected the performance of GMS1 at level 1 (P<.01), and GMS2 at both levels (P<.001), lowering GMS1 results but elevating GMS2 results. Glucose median-paired differences were elevated at both levels on GMS2 after 72 hours. Median paired differences (stress minus control) were as much as −10 mg/dL (range, −65 to 33) at level 3 with GMS1, with errors as large as 21.9%. Glucose median-paired differences were as high as 5 mg/dL (range, −1 to 10) for level 1 on GMS2, with absolute errors up to 24.4%.

Conclusions: The duration of dynamic stress affected the performance of both GMS1 and GMS2 glucose test strips. Therefore, proper monitoring, handling, and storage of point-of-care (POC) reagents are needed to ensure their integrity and quality of actionable results, thereby minimizing treatment errors in emergency and disaster settings. (Disaster Med Public Health Preparedness. 2012;6:232-240)

Key Words: disaster preparedness, Hurricane Katrina, medical errors, austere environments, quality assurance

During emergencies and disasters, point-of-care testing (POCT) facilitates patient triage with rapid screening and monitoring tests at the site of care, such as the field, an alternate care facility, or an emergency department.1 Emergency responders need to be prepared to manage acute diseases and injuries, such as infections and trauma, and provide care for displaced victims with chronic ailments, such as diabetes.

POCT devices, such as glucose meter systems (GMS), are found in caches of disaster response teams. During Hurricane Katrina, shortages of diabetes supplies (eg, medicine, glucose test strips and meters) have been reported.2 Emergency responders are deployed to a variety of environments where conditions often may exceed the reagent and device storage and operating tolerance limits.

We hypothesize that dynamic temperature and humidity stresses affect the performance of glucose meter test strips. Therefore, the objective of this report is to characterize the performance of two commercial glucose test strips using a dynamic stress profile that models conditions in New Orleans during Hurricane Katrina.

METHODS

Point-of-Care Systems and Reagents

GMS1 is a glucose oxidase-based electrochemical meter containing 3 aqueous reagent levels. GMS2 is a glucose dehydrogenase-based test strip containing 2 aqueous reagent levels and a control strip. GMS1 and GMS2 test strips contain the reagents necessary for the glucose test, including glucose oxidase, peroxidase, and a number of enzymes, substrates, and inhibitors.

We used aqueous QC solutions supplied by the manufacturers to test performance. QC solutions are proprietary reagents manufactured by each company to allow the operator to check if the test strips and meter are working properly. The QC solutions typically are composed of glucose, buffer, dyes, salts, preservatives, and viscosity-adjusting agents. Three levels of QC were used for testing GMS1, and two levels of QC were used for testing GMS2.

Environmental Profile

We modeled the dynamic thermal and humidity conditions of New Orleans, Louisiana, during Hurricane Katrina (Figure 1) with data collected over a 31-day period from the National Climatic Data Center (NCDC). Data were compiled from two weather stations, New Orleans and Baton Rouge Metro. The Baton Rouge Metro had 1.5 days of missing values for the

Dynamic Temperature and Humidity Stress

- **Goal**—To characterize the effects of dynamic thermal and humidity stress on the performance of glucose meter measurements

- **Methods**—Glucose test strips were exposed to conditions simulating the temperature and humidity experienced in New Orleans following the Hurricane Katrina disaster for a duration of ~4 weeks

- **Statistical Model**—Paired measurements were obtained from stressed and unstressed glucose reagent strips at defined time points. Strips were tested with aqueous quality control solutions.

- **Results**—The duration of stress affected the performance of the glucose meter systems. One system provided lower measurements and the other elevated when stressed. As demonstrated on one system, the stress effects on test performance is cumulative with pronounced effect after 32 hours of exposure.
Maximum Absolute Paired Differences Between Stress & Control Glucose Test Strips

- For GMS1, errors as large as **27.6%** (16 mg/dL / 57.9 mg/dL) was observed when tested at mean glucose concentration of 57.9 mg/dL, **21.9%** (24/109.6) at 109.6 mg/dL, and **22.4%** (65/290.5) at 290.5 mg/dL.

- For GMS2, errors as large as **24.4%** (10/41) was observed when tested at mean glucose concentration of 41.0 mg/dL, and **11.1%** (34/305.3) at 305.3 mg/dL

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Short-Term Thermal-Humidity Shock Affects Point-of-Care Glucose Testing: Implications for Health Professionals and Patients

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Abstract
The objective was to assess the effects of short-term (≤1 hour) static high temperature and humidity stresses on the performance of point-of-care (POC) glucose test strips and meters. Glucose meters are used by medical responders and patients in a variety of settings including hospitals, clinics, homes, and the field. Reagent test strips and instruments are potentially exposed to austere environmental conditions. Glucose test strips and meters were exposed to a mean relative humidity of 83.0% (SD = 8.0%) and temperature of 42°C (107.6°F, SD = 3.2) in a Tenney BTRC environmental chamber. Stressed and unstressed glucose reagent strips and meters were tested with spiked blood samples (n = 40 measurements per time point for each of 4 trials) after 15, 30, 45, and 60 minutes of exposure. Wilcoxon's signed rank test was applied to compare measurements test strip and meter measurements to isolate and characterize the magnitude of meter versus test strip effects individually. Stressed POC meters and test strips produced elevated glucose results, with stressed meter bias as high as 20 mg/dL (17.7% error), and stressed test strip bias as high as 13 mg/dL (12.2% error). The aggregate stress effect on meter and test strips yielded a positive bias as high as 33 mg/dL (30.1% error) after 15 minutes of exposure. Short-term exposure (15 minutes) to high temperature and humidity can significantly affect the performance of POC glucose test strips and meters, with measurement biases that potentially affect clinical decision making and patient safety.

Keywords
clinical decision making, environmental stress, glucose test strip and meter performance, measurement error, patient safety, quality assurance

Glucose meter systems aid responders in triaging, screening, monitoring, and the diagnosis of victims and patients at the site of crisis care. Temperature and humidity conditions at the site of patient care, whether inside or outside the victims’ home or hospital, may exceed manufacturer specifications for storage and operation. Operation of devices outside of product specifications could produce inaccurate results.

Point-of-care (POC) devices deployed with disaster response teams are recommended to be housed in climate controlled settings. However, these devices may be exposed to austere conditions when mobilized for field testing. Temperature extremes can be found in a variety of settings including the patient home, disaster response center, transportation to hospital, and hospital storage. This study aims to simulate realistic operation of POC glucose devices in austere environments, to compare measurements obtained from unstressed devices and test reagents, and to characterize how short-term stress affects meter and test strip performance. We discuss the potential implications of these effects on clinical decision making.

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Effects of environmental conditions on point-of-care cardiac biomarker test performance during a simulated rescue: Implications for emergency and disaster response

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Abstract

Objective: To characterize the effects of environmental stress on point-of-care (POC) cardiac biomarker testing during a simulated rescue.

Design: Multiplex test cassettes for cardiac troponin I (cTnI), brain natriuretic peptide (BNP), CK-MB, myoglobin, and D-dimer were exposed to environmental stresses simulating a 24-hour rescue from Hawaii to the Marshall Islands and back. We used Tenney environmental chambers (T2RC and B2RC) to simulate flight conditions (25°C, 10 percent relative humidity) and ground conditions (22.3-33.9°C, 72-77 percent). We obtained paired measurements using stressed versus control (room temperature) cassettes at seven time points (T1, T2, T3, T4, T5, T6, T7) during flight and T7 on ground. We analyzed paired differences (stressed minus control) with Wilcoxon signed rank test. We assessed the impact on decision-making at clinical thresholds.

Results: cTnI results from stressed test cassettes (n = 10) at T4 (p < 0.05), T5 (p < 0.01), and T7 (p < 0.05) differed significantly from control, when testing samples with median cTnI concentration of 90 ng/L. During the ground rescue, 36.7 percent (11/30) of cTnI measurements from stressed cassettes generated significantly lowered results. At T7, 20 percent (2/10) of cTnI results were highly discrepant—stressed cassettes reported normal results, when control results were >100 ng/L. With sample median concentration of 108 pg/mL, BNP results from stressed test cassettes differed significantly from controls (p < 0.05).

Conclusion: Despite modest, short-term temperature elevation, environmental stresses led to erroneous results. False negative cTnI and BNP results potentially could miss acute myocardial infarction and congestive heart failure, confounded treatment, and increased mortality and morbidity. Therefore, rescuers should protect POC reagents from temperature extremes.

Keywords: austere environments, disaster preparedness, medical errors, Pacific Islands, and quality assurance

Introduction

Emergency medical responders are deployed with limited point-of-care (POC) tests during crises, which restricts triaging in the field. Quantitative measurement of cardiac troponin I (cTnI), brain natriuretic peptide (BNP), CK-MB, myoglobin, and D-dimer in whole blood and plasma specimens can aid in the diagnosis of myocardial infarction, heart failure, pulmonary embolism, and deep vein thrombosis. Environmental conditions present during rescue operations may exceed storage and operating specifications of POC devices and test reagents. The objective of this study was to characterize the performance of POC cardiac biomarker tests in a simulated rescue between the Hawaiian Islands and Marshall Islands.
Effects of Stress on cTnI Test Results

- During ground rescue 36.7% (11/30) of stressed test cards reported falsely low cTnI results interpreted as “normal”

- At T₅, 20% (2/10) results were highly discrepant: stress <0.05, control ≥0.10 ng/mL

- Median stressed cTnI at T₅ was <0.05 ng/mL

- During the return flight, stressed cards reported falsely elevated cTnI >0.1 ng/mL at T₇, which in our emergency department “alerts” possible AMI.

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THE CURRENT AND FUTURE DESIGN OF POINT OF CARE IN NATIONAL DISASTER CACHES

CORBIN M. CURTIS, RICHARD F. LOUIE, AND GERALD J. KOST

OVERVIEW

The objective of this chapter is to describe, innovate, recommend, and foster the implementation of point-of-care testing (POCT) in disaster caches in order to enhance crisis standards of care and improve triage, diagnosis, monitoring, treatment, and management of victims and volunteers in complex emergencies and disasters. The authors compared point-of-care (POC) technologies in US disaster caches to commercially available POC technologies to enhance the caches and reflect current state-of-the-art diagnostic capabilities. We also provided recommendations based on literature review and knowledge from newly developed POC technologies from the University of California, Davis Point-of-Care Technologies Center on designing POC caches applicable to meet global needs. US POC testing caches comprise chemistry/ electrolytes, pregnancy, hemoglobin, cardiac biomarkers, hematology, fecal occult blood, drugs of abuse, liver function, blood gases, and limited infectious disease tests. Deficiencies with existing POCs for cardiac biomarkers, hematology, and infectious diseases should be eliminated. POC resources can be customized for pandemics, complex emergencies, or disasters based on geographic location and the potential for pandemics. Additionally, new thermally stabilized containers can help alleviate environmental stresses that reduce test quality. Innovations in POC technologies can improve response preparedness with enhanced diagnostic capabilities. Several innovations, such as the i-STAT® Wireless (Abbott Point of Care, Princeton, NJ, USA), OraQuick ADVANCE® HIV-1/2 (OraSure Technologies, OraSure, PA, USA), VioTemp™ Lab-on-a-Chip (Viochus Laboratories, Singapore), and new compact hematology analyzers will improve test clusters that facilitate evidence-based decision making and crisis standards of care during national disaster responses. Additionally, strategic resources and operator training should be globally harmonized to improve the efficiency of international responses.

Our goal is to describe, innovate, recommend, and accelerate the implementation of POCT in disaster caches in order to (a) enhance crisis standards of care; (b) improve diagnosis, triage, and monitoring in complex emergencies and disasters; and (c) harmonize evidence-based decision making during responses globally. The Office of the Assistant Secretary for Preparedness and Response (ASPR) under the US Department of Health and Human Services (DHHS) maintains three Mission Support Centers (MSCs) located in the western, central, and eastern United States. The eastern region and largest cache warehouse (200,000 ft³) serves as a training facility, home base for cache management, and national headquarters. Disaster response supplies deploy by trucks from any of the three locations to reach a disaster site in the contiguous United States or by airplane to sites outside the landlocked states such as Hawaii, Alaska, and the Republic of the Marshall Islands, within 12 h.

The caches within each facility hold supplies that Disaster Medical Assistance Teams (DMATs) use to triage, diagnose, and monitor victims following catastrophic events. Each facility has an inventory of pharmaceuticals, DMAT response packages, Basic Load Resupply packages to replenish 3 days of supplies for 175 patients per day, temporary portable housing, electricity generators, communication supplies, and vehicles to deliver resources to disaster sites where they converge with DMATs. The packages load straight onto trucks or airplanes without needing further organization. POC devices

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* 1 ft² = xxx m².
Lab Basic Kit
Lab Plus Kit
CONCLUSION — "P & G"

- Uniquely combines policy and guidelines in one product
- Endorsed by the Ministry of Health for all of Malaysia
- One of the world’s first nationally harmonized approaches to point-of-care testing
- Needs extension based on “Emergency and Disaster POC Testing” (CLSI POCT16)
- National Policies and Guidelines should include pandemic, emergency, and disaster POCT!!
MINI-WORKSHOP!

Please—
1. Review the proposed disaster cache.
2. Consider how you would improve it and why.
3. Write down your ideas and country.
4. Submit your response to Dr. Kost.

Optional
Include your name and email address.
Point-of-Care Testing Center for Teaching and Research (POCT-CTR), founded 1995, and the UC Davis POC Technologies Center [U54, NIBIB, NIH], 2007-2014

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