DISASTER POINT OF CARE TESTING: FUNDAMENTAL CONCEPTS TO ENHANCE CRISIS STANDARDS OF CARE

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[Disclaimer: Device use must adhere to federal and state regulations within the context of appropriate accreditation. Illustration of devices, including suggestions for disaster caches, does not imply endorsement. Research results may be preliminary. Final conclusions may differ. Please consult published papers.]

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Please visit our YouTube site at http://www.youtube.com/POCTCTR
http://www.ucdmc.ucdavis.edu/pathology/poctcenter/
THE GLOBAL VISION

“Point-of-care testing will improve crisis standards of care,* disaster preparedness, and at the same time, healthcare in small-world networks.”

*The fundamental concept of the standard of care is based on the US case, *Vaughan v Menlove* (1837), wherein the judge instructed the jury to reason whether the defendant “proceed[ed] with such reasonable caution as a prudent man would have exercised under such circumstances.”
Point-of-Care Testing (POCT)

• **Definition**
  
  *POCT is medical testing at or near the site of care.*

• **Fundamental Goals**

  **Significance**  Identify critical diagnoses, screen quickly

  **Evidence**  Produce test results for decision-making

  **Speed**  Accelerate triage and treatment

  **Approach**  Enhance response using new technologies

  **Impact**  Improve medical and economic outcomes

**Resources**

3. *Point of Care*—the primary journal in the field, 10th year of production.
PRINCIPLES: 6 FUNDAMENTALS

- **Solution:** Past disasters demonstrate the role and feasibility of using POC testing.

- **Balance:** Needs assessment guides POC invention, innovation, and technology development.

- **Efficiency:** POC test clusters allow “mission matching”—one can select instruments and tests for triage, diagnosis, treatment, and/or monitoring.
EVIDENCE, INTEGRATION, SYNTHESIS

• **Evidence**: POC technologies enable evidence-based decision-making at the point of need.

• **Integration**: Strategic planning optimizes small-world networks where healthcare teams and patients become experienced with POC testing through education, training, and everyday use.

• **Synthesis**: Value propositions generate tactics for placing POC testing appropriately in physical, demographic, and geographic settings.
Past disasters demonstrate the role and feasibility of using POC testing.

Example—

- Hurricane Katrina in New Orleans, 2005
- Bangkok Flood, 2011
- Hurricane Sandy in New York, 2012
SHELTERS: Acute Monitoring, Chronic Diseases, and Public Health
## Responder POC Testing Inventory

<table>
<thead>
<tr>
<th>Category</th>
<th>Types of Test(s)</th>
<th>Disaster Medical Assistance Teams</th>
<th>Local Emergency Medical Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Transfusion</td>
<td>ABO blood typing</td>
<td>Wet chemistry(^1) (test set 1)</td>
<td>None</td>
</tr>
<tr>
<td>Cardiac Monitoring</td>
<td>Electrocardiogram</td>
<td>ProPaq CS(^2) (test set 2)</td>
<td>LifePak 12(^5) (test set 3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LifePak 10 or 12(^{3,4}) (test set 3)</td>
<td></td>
</tr>
<tr>
<td>Coagulation</td>
<td>Prothrombin Time</td>
<td>i-STAT analyzer PT/INR cartridge(^{1,6})</td>
<td>None</td>
</tr>
<tr>
<td>Diagnostic Imaging</td>
<td>Ultrasound</td>
<td>Sonosite MicroMaxx (test set 4)</td>
<td>Not adopted uniformly(^7)</td>
</tr>
<tr>
<td>Glucose Monitoring</td>
<td>Capillary blood glucose</td>
<td>One Touch Ultra(^4)</td>
<td>Accu-Chek Advantage(^8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Precision Xtra(^9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Precision XceedPro(^{10})</td>
</tr>
<tr>
<td>Hematology</td>
<td>Hemoglobin and</td>
<td>i-STAT analyzer with EC8+</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Hematocrit</td>
<td>cartridge(^{1,6}) (test set 5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hemoglobinometer(^3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>White blood cell count</td>
<td>Microscopy, hemocytometer(^{1,3})</td>
<td></td>
</tr>
<tr>
<td>Non-invasive Sp(^O)(_2) Monitoring</td>
<td>Pulse oximetry</td>
<td>ProPaq CS(^2) (test set 2)</td>
<td>LifePak 12(^6) (test set 3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nonin Onyx 9550(^{1,3})</td>
<td></td>
</tr>
<tr>
<td>Non-invasive pCO(_2) Monitoring</td>
<td>Capnography</td>
<td>LifePak 10 or 12(^{3,4}) (test set 3)</td>
<td>LifePak 12(^6) (test set 3)</td>
</tr>
<tr>
<td>Bacteriology</td>
<td>Gram’s stain</td>
<td>Gram positive and Gram negative</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>bacterial differentiation with</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>microscopy(^1)</td>
<td></td>
</tr>
<tr>
<td>Whole-Blood Analysis</td>
<td>Electrolytes and</td>
<td>i-STAT analyzer with EC8+</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Metabolites</td>
<td>cartridge(^{1,6}) (test set 5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blood gases</td>
<td>i-STAT analyzer with EC8+</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>cartridge(^{1,6}) (test set 5)</td>
<td></td>
</tr>
<tr>
<td>Vital Signs</td>
<td>Blood pressure</td>
<td>LifePak 10 or 12(^{3,4}) (test set 3)</td>
<td>LifePak 12(^6) (test set 3)</td>
</tr>
<tr>
<td></td>
<td>Heart rate</td>
<td>ProPaq CS(^2) (test set 2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Respiratory rate</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Temperature</td>
<td></td>
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</tr>
</tbody>
</table>

WHAT CAN BE EXPECTED

16 billion M$^3$
will flow down from upstream provinces over one month

October 15-16:
Run-off from the North at 4,000 M$^3$ per second combined with
1.13-metre-high inflow from the sea is expected to have the
Chao Phraya River rise 2 metres +/- 5 centimetres.

- Ayutthaya now has six billion cubic metres
- Pathum Thani, Nonthaburi, Chachoengsao and Samut Prakan together have two billion cubic metres

October 29-31:
Run-off from the North at 4,000 M$^3$ per second combined with
1.13-metre-high inflow from the sea is expected to have water levels in Chao
Phraya River rise by 2.22 metres +/- 5 centimetres.

50 m$^3$ of water/daily

80-100 m$^3$ of water/daily

550 m$^3$ daily

THE REASONS WHY THEY ARE CONFIDENT:
- Levels of run-off water from the North have stabilised and big dams are actually reducing the amount of reservoir water being released.
- Unlike ill-fated Ayutthaya, Nonthaburi and other flood-prone provinces, Bangkok boasts high and strong concrete flood walls running along both banks of the Chao Phraya. These walls – between 2.5 and 3.5 metres high – should be able to withstand 5,800 cubic metres of water per second.
- For every canal draining water from Pathum Thani or Nonthaburi, there are solid floodgates to stop or control the flow. Efficient handling of the numerous floodgates can allow water to pass Bangkok on its way to the sea with minimum flooding in nearby areas.
- The Bangkok-run doomed camp makes this one of the key strategies that experts say will prevent flooding in the city.
- The Bangkok flood gates are more likely to happen than not, and the impact on daily life and economy could be substantial.

THE REASONS WHY THEY ARE SCARED:
- Flood barriers are vulnerable, mainly because no flood wall has ever been tested with water of this magnitude.
- Human error could lead to destruction of flood barriers or flood gates. All it takes for a wall to collapse is one hole. Many key flood gates are guarded by troops, but angry villagers could easily destroy the structures.
- Rain is unpredictable. Heavy downpours are expected in the city and surrounding areas over the next few days and could simply become the last straw that breaks Bangkok's resilience.

FLOOD MAP
- High risk
- Medium risk
- Low risk

Source: Department of Drainage and Sewerage, BMA and Flood Relief Operation Command

Gulf of Thailand
Permanent embankment along the Chao Phraya River (construction of 75,774 kilometres completed).
Thailand Flood, October 23, 2011\textsuperscript{1,2}

- 28 provinces flooded, 2.45m people affected, 113,000 in shelters, and \textasciitilde400 deaths as of this date and increasing
- Transportation infrastructure swamped, 1,000 factories shut down, 14,000 firms affected—widespread food, water, and supplies shortages
- Bangkok: “If we issue too early warning, we could cause panic.” Yingluck Shinawatra, Prime Minister\textsuperscript{2}
- Disaster Prevention and Mitigation Act 2007 activated
- “Once the natural flooding was coupled with non-systematic management, it resulted in a national disaster.” Poramate Minsiri, Thailand.com\textsuperscript{1}
- Diagnostic laboratory multidisciplinary working group formed October 21\textsuperscript{st} at the request of the Division of Medical Sciences, Ministry of Public Health
- Planning and recommendations in progress regarding the current response and future POC and laboratory diagnostics resiliency
- High priority tests for an alternate care facility response: Pulse oximetry, chemistry/electrolytes, blood bank/transfusion, cardiac biomarkers, blood gases, hematology, rapid microbiology, and coagulation\textsuperscript{3}

\textsuperscript{1} \url{http://www.bangkokpost.com/}
\textsuperscript{2} \url{http://www.nationmultimedia.com/}
\textsuperscript{3} Kost G, Katip P. Strategic needs of community hospitals, public health, and the Naval and regional hospitals in Phang Nga Province: Impact for laboratory and point-of-care testing in disasters. 2011; in progress.
NEWDEMICs: The Future is now!

• Definition: “Unexpected and disruptive problems that affect the health of large numbers of individuals in a crowded world.”

• World population is 7 billion, 7 million children who did not exist found in China (parents hide children), humans reproduce at a rate of 25,000 every 10 seconds, first UN count started with 2.5 billion in 1950, & expect 9 billion in 2050, slowing to 10 billion by 2100.

• Flood perils and tests: contamination (Leptospirosis, fungi), bites (centipedes, reptiles, crocodiles), infections (Hepatitis A, E. Coli, Staphylococcus endotoxin, enteroviruses, typhoid fever, cholera, poliomyelitis, malaria, Dengue fever), and stress (e.g., chest pain in ERs in Queensland, Australia--R/O AMI).

References
PRINCIPLE #2

Needs assessment guides POC invention, innovation, and technology development... ...but as Henry Ford said, “If I had asked people what they wanted, they would have said a faster horse!”

References
Quote:
Respondents preferred disaster-ready POC devices that sample blood directly into a test cassette, which stores all biohazard material for easy disposal.

When asked to explain, they said minimize contamination when performing infectious disease testing outside of the laboratory.

Respondents also wanted to draw a single sample and have multiple testing options to fully evaluate each patient.

They wanted fast results, battery operation, handheld devices, and high sensitivity testing that they could perform themselves.

PRINCIPLE #3

POC test clusters allow “mission matching”—one can select instruments and tests for triage, diagnosis, treatment, and/or monitoring…but devices and reagents must be operated within environmental tolerances and legal constraints specified by the manufacturer.
# Crisis Care Profile

<table>
<thead>
<tr>
<th>Function/Target</th>
<th>Point of Care Pivot(s) or Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Energy</strong></td>
<td>Glucose, β-hydroxybutyrate</td>
</tr>
<tr>
<td></td>
<td>Hemoglobin</td>
</tr>
<tr>
<td></td>
<td>pO₂, O₂ saturation</td>
</tr>
<tr>
<td><strong>Conduction</strong></td>
<td>Potassium</td>
</tr>
<tr>
<td></td>
<td>Sodium</td>
</tr>
<tr>
<td></td>
<td>Ionized calcium (free calcium, Ca²⁺), ionized magnesium (Mg²⁺)</td>
</tr>
<tr>
<td><strong>Contraction</strong></td>
<td>Ionized calcium, ionized magnesium</td>
</tr>
<tr>
<td><strong>Perfusion</strong></td>
<td>Lactate</td>
</tr>
<tr>
<td><strong>Acid-Base</strong></td>
<td>pH</td>
</tr>
<tr>
<td></td>
<td>CO₂ content (TCO₂), pCO₂</td>
</tr>
<tr>
<td></td>
<td>End-tidal CO₂ tension</td>
</tr>
<tr>
<td></td>
<td>Bicarbonate (calculated HCO₃⁻)*</td>
</tr>
<tr>
<td><strong>Osmolality</strong></td>
<td>Measured osmolality</td>
</tr>
<tr>
<td></td>
<td>Calculated osmolality</td>
</tr>
</tbody>
</table>
## Crisis Care Profile

<table>
<thead>
<tr>
<th>Function/Target</th>
<th>Point of Care Pivot(s) or Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hemostasis</strong></td>
<td>Hematocrit, hemoglobin</td>
</tr>
<tr>
<td></td>
<td>Prothrombin time (PT), international normalized ratio (INR)</td>
</tr>
<tr>
<td></td>
<td>Activated partial thromboplastin time (aPTT)</td>
</tr>
<tr>
<td></td>
<td>Activated clotting time (ACT)</td>
</tr>
<tr>
<td></td>
<td>D-dimer</td>
</tr>
<tr>
<td></td>
<td>Platelet count and function (thromboelastogram)</td>
</tr>
<tr>
<td><strong>Homeostasis</strong></td>
<td>Creatinine, urea nitrogen</td>
</tr>
<tr>
<td></td>
<td>B-type natriuretic peptide (BNP)</td>
</tr>
<tr>
<td></td>
<td>Chloride, inorganic phosphate</td>
</tr>
<tr>
<td></td>
<td>White blood cell count, hemoglobin E, fragility (thalasemia)</td>
</tr>
<tr>
<td></td>
<td>Co-oximetry variables</td>
</tr>
<tr>
<td><strong>Biomarker</strong></td>
<td>Cardiovascular risk (cholesterol, HDL, LDL, tryglycerides; CRP, hs-CRP)</td>
</tr>
<tr>
<td></td>
<td>Bone formation (bone-specific Alk Phos)* and resorption (NTx)*</td>
</tr>
<tr>
<td></td>
<td>Cancer (prostate-specific antigen, urine NMP22– bladder cancer)</td>
</tr>
<tr>
<td></td>
<td>Cardiac injury (troponin I/T, myoglobin, CK-MB mass/isoforms)</td>
</tr>
<tr>
<td></td>
<td>Endocrine (intraoperative parathyroid hormone)</td>
</tr>
<tr>
<td></td>
<td>Trauma (S100 [brain injury marker])</td>
</tr>
<tr>
<td><strong>Sepsis</strong></td>
<td>Lactate, procalcitonin*, C-reactive protein*</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Function/Target</th>
<th>Point of Care Pivot(s) or Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Birthing</strong></td>
<td>Prenatal testing (glucose, urine protein, sexually transmitted diseases)</td>
</tr>
<tr>
<td></td>
<td>Antenatal screening (genetic disorders)</td>
</tr>
<tr>
<td></td>
<td>Delivery monitoring (fetal heart rate, group B <em>Streptococcus</em>) and transcutaneous neonatal bilirubin, pO₂, and pCO₂</td>
</tr>
<tr>
<td><strong>Women’s Health</strong></td>
<td>Fertility (FSH)</td>
</tr>
<tr>
<td></td>
<td>Pregnancy (β-hCG)</td>
</tr>
<tr>
<td></td>
<td>Bone resorption (NTx)*</td>
</tr>
<tr>
<td></td>
<td>Human papillomavirus*</td>
</tr>
<tr>
<td></td>
<td>Cervical cancer*</td>
</tr>
<tr>
<td><strong>Emergency Blood Donor Screening</strong></td>
<td>HIV-1/2, Hepatitis B, and Hepatitis C</td>
</tr>
<tr>
<td><strong>Transfusion</strong></td>
<td>ABO blood typing, Rh class</td>
</tr>
<tr>
<td><strong>Infectious Disease</strong></td>
<td>HIV-1/2, <em>H. pylori</em>, Dengue, <em>others</em>—rapid Dx-Rx with multiplex assays</td>
</tr>
<tr>
<td></td>
<td>Primary care, public health, surveillance—prevention and control</td>
</tr>
<tr>
<td><strong>Influenza Pandemic</strong></td>
<td>Influenza A, influenza B, and subtypes (H1N1, 2009 H1N1, H3, H5N1)</td>
</tr>
<tr>
<td></td>
<td>Drug resistance (oseltamivir, zanamivir, amantadine, rimantadine)</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Function/Target</th>
<th>Point of Care Pivot(s) or Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidemic</td>
<td>Cholera (stool test, rectal swab)</td>
</tr>
<tr>
<td></td>
<td>Tuberculosis (PPD skin test)</td>
</tr>
<tr>
<td></td>
<td>Avian influenza* (FDA emergency use authorization, EUA)</td>
</tr>
<tr>
<td>Newdemic</td>
<td>Diabetes: glucose, hemoglobin A1c, estimated average glucose (eAG), urine albumin to creatinine ratio (ACR), fructosamine*</td>
</tr>
<tr>
<td>Biothreat</td>
<td>Anthrax, botulism, plague, tularemia, Ebola, West Nile</td>
</tr>
</tbody>
</table>

An asterisk ("*") indicates that a POC test is needed or in development. CLIA-waived test are indicated by the green lettering.

<table>
<thead>
<tr>
<th>Knowledge</th>
<th>Training and Experience</th>
<th>Reagents and Materials Preparation</th>
<th>Characteristics of Operational Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal scientific and technical knowledge is required to perform the test; and Knowledge required to perform the test may be obtained through on-the-job instruction.</td>
<td>Minimal training is required for preanalytic, analytic and postanalytic phases of the testing process; and Limited experience is required to perform the test.</td>
<td>Reagents and materials are generally stable and reliable; and Reagents and materials are prepackaged, or premeasured, or require no special handling, precautions or storage conditions</td>
<td>Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Calibration, Quality Control, and Proficiency Testing Materials</th>
<th>Test System Troubleshooting and Equipment Maintenance</th>
<th>Interpretation and Judgment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibration materials are stable and readily available; Quality control materials are stable and readily available; and External proficiency testing materials, when available, are stable</td>
<td>Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed</td>
<td>Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and Resolution of problems requires limited independent interpretation and judgment</td>
</tr>
</tbody>
</table>
Temperature Extremes in Disasters

Hurricane Katrina¹, 2005
Temp: 20 to 43.3°C

Haiti Earthquake², 2010
Temp: 20 to 35°C

Japan Earthquake³, 2011
Temp: -5 to 20°C

² Cavallo EA, et al. Inter-American Development Bank. 2010
³ http://www.npa.go.jp/archive/keibi/biki/higaijokyo_e.pdf
Point-of-need Challenges

• 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)

3) Case Study, Courtesy of Dr. James Nichols, Baystate Health, Springfield, MA
Application of Weather Profiling for Haiti

• Limited Operating Range of i-Stat is 16-28°C

• Emergency response teams devised storage solution to cool the POC analyzer to enable usage for 15 - 20 minutes before it overheated again.

Testing a Storage Solution

• Purpose: Determine the insulating properties of the storage container used during the disaster relief effort in Haiti.

• Method: Placed in environmental chamber for 3 days using the profile modeling the conditions of Haiti.

• Did not replace cold pack each night.

Materials Used
• Aluminum foil
• Cardboard Box
• Styrofoam Box
• Ice pack
Environmental Stress Testing

POC Reagent Test Strips & Cartridges → Environmental Stress Testing Chamber & Profile → Evaluate Test Strips & Cartridges

- Facilitate Device Design
- Enhance Development of Disaster Guideline

Tenney T2RC

Graph showing temperature and humidity over time.
Effects of Dynamic Temperature and Humidity Stresses on Point-of-Care Glucose Testing for Disaster Care


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.

Ensuring Quality Control of Point-of-Care Technologies: Effects of Dynamic Temperature and Humidity Stresses on Glucose Quality Control Solutions


Objective: The objective of this study was to characterize the effects of dynamic temperature and humidity stresses on quality control (QC) reagents used for 2 glucose meter systems. Methods: Quality control solutions tested on glucose meter systems GMS1 (StatStrip; Nova Biomedical, Waltham, Mass) and GMS2 (Accu-Chek; Roche Diagnostics, Indianapolis, Ind) were stressed for up to 4 weeks using temperature and humidity profiles simulating conditions (maximum, minimum temperature: 45°C [113°F], 20°C [68°F]; humidity: 31%, 100%) during Hurricane Katrina. Paired measurements were obtained at each time point using 3 QC levels for GMS1 and 2 for GMS2. Results: Solutions stressed for durations of 24, 72, 168 (1 week), 336 (2 weeks), and 672 (4 weeks) hours were evaluated at an actual temperature of 23°C and humidity of 90.6%. Those stressed for durations of 8, 32, 80, 172, 344, and 680 hours were evaluated at a temperature of 45°C and humidity of 31.0%. For GMS1, glucose median paired differences (stressed – control) decreased for QC levels 1 and 3 after 8 hours \((P < 0.05)\) and increased for level 1 after 336 \((P < 0.01)\) and 344 hours \((P < 0.05)\). For solutions tested on GMS2, median paired differences in QC reagents were decreased for both levels at each time point tested at 45°C \((P < 0.01)\). Conclusions: Dynamic stresses affected the performance of QC solutions and, consequently, results given by GMS1 and GMS2. To protect the efficacy and accuracy of POC technologies in emergency and disaster settings, proper monitoring, handling, and storage of QC reagents must be ensured.

Japan—A Cold Disaster!

- Magnitude 9.0 earthquake followed by tsunami and nuclear accidents on March 11, 2011

- Over 15,000 deaths and more than 125,000 buildings damaged or destroyed

- About 80 percent of the combined 380 hospitals in Iwate, Miyagi, and Fukushima prefectures were completely or partially incapacitated

- The temperature dropped to -5°C

- Scheduled power outages caused problems for the medical institutions in the disaster area

- POCT was not adequately prepared

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1 http://www.npa.go.jp/archive/keibi/biki/higaijokyo_e.pdf
2 http://search.japantimes.co.jp/cgi-bin/nn20110609a1.html
3 National Climate Data Center
4 http://www.med.or.jp/english/report/20110324.html
Epoc Blood Analysis System

- Handheld device heats test cards to 37°C before measurements are performed

- Test cluster includes pH, pCO₂, pO₂, Na⁺, K⁺, Ca+++, glucose, and hematocrit

- Storage temperature for test cards is 15-30°C
Figure 2: Rust MJ, Carlson NA, Nichols JH. A thermo-modulating container for transport and storage of glucose meters in a cold weather environment. *Point Care*. 2012;11:157-160.
POC technologies enable evidence-based decision-making at the point of need...and also can transfer ownership for personalized medicine there!
MMU Regional Span in Province SWN
Mobile Medical Unit (MMU): Rural Thailand
Empirical Judgment → POCT → Evidence-based Medicine
MMU Ownership and Empowerment
PRINCIPLE #5

Strategic planning optimizes small-world networks where healthcare teams and patients become experienced with POC testing through education, training, and everyday use.
Roadmap of Khon Kaen Regional Hospital and Heart Center Referral System in Isaan, Northeast Thailand.

Small-World Network Integration

Orange: SWNs
Green: Route to Khon Kaen Heart Center
Red: Ambulance connector
**Small-World Networks**

Small-World Networks... are “like your family and friends... you have fun and work with them every day, and in times of need, you call on them for assistance!”

Examples—six degrees of separation between people, social influence networks, food chains, electric power grids, airline flights, and road maps.

Attributes—most network nodes connected by at least one short path, over abundance of hubs with high number of connections, and common connections mediating short path lengths between edges.

Features—develop demographically, match geography, interconnect regionally, reveal health resource disparities, and guide POCT allocations.
Transformation of Distance to Time

PRINCIPLE #6

Value propositions generate tactics for placing POC testing appropriately in physical, demographic, and geographic settings.

Corollary

If POC testing does not impact decision-making or add value, then do not use it!
Value Proposition
Reduce Therapeutic Turnaround Time (TTAT) to Speed Critical Paths

Evidence-based research shows that POC testing and *in vivo* monitoring decrease TTAT. Fast TTAT improves field and emergency room patient triage, treatment, and transfer, which observers deemed important during the Thai Tsunami response. Thus, rapid TTAT adds value and preparedness to the SWN.
Value Proposition
Use POC Testing in High Impact Sites During Emergencies and Disasters

**Physical:** Community hospitals, alternate care facilities, and shelters

**Demographic:** Rural areas, primary care, and regions with poor health resource scores

**Geographic:** Healthcare systems with challenging regional topographies at high risk of isolation
## Top Ranked Diagnostic Test Groups for Near-Patient Testing within an Alternate Care Facility

<table>
<thead>
<tr>
<th>For Near-Patient Testing</th>
<th>Weighted Rank</th>
<th>Scores</th>
<th>Weighted Scores</th>
<th>For Bedside Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Oximetry</td>
<td>80</td>
<td>1</td>
<td>63</td>
<td>Blood Gases</td>
</tr>
<tr>
<td>Chemistries/Electrolytes</td>
<td>58</td>
<td>2</td>
<td>57</td>
<td>Pulse Oximetry</td>
</tr>
<tr>
<td>Blood Bank/Transfusion</td>
<td>43</td>
<td>3</td>
<td>52</td>
<td>Chemistry/Electrolytes</td>
</tr>
<tr>
<td>Cardiac Biomarkers</td>
<td>36</td>
<td>4</td>
<td>29</td>
<td>Cardiac Biomarkers</td>
</tr>
<tr>
<td>Blood Gases</td>
<td>35</td>
<td>5</td>
<td>28</td>
<td>Hematology</td>
</tr>
<tr>
<td>Hematology</td>
<td>17</td>
<td>6</td>
<td>26</td>
<td>Rapid Microbiology Tests</td>
</tr>
<tr>
<td>Rapid Microbiology Tests</td>
<td>10</td>
<td>7</td>
<td>24</td>
<td>Coagulation</td>
</tr>
<tr>
<td>Coagulation</td>
<td>8</td>
<td>8</td>
<td>9</td>
<td>Blood Bank/Transfusion</td>
</tr>
</tbody>
</table>
Monitoring $O_2$ Saturation and Hemoglobin

Value Proposition
Optimize Practitioner Experience with POCT

Tactical POCT should—
• complement healthcare delivery resources,
• fulfill needs for simultaneous emergency care and disaster preparedness, and
• match geographic isolation, current or anticipated.

Therefore, routine daily use of POCT assures the high quality of trained operators, who become “POC Coordinators” and integrate POCT within and between small-world networks.
POC Coordinator preparedness, post-disaster functions, leadership roles, duties, and telecertification

Operators

QC

Products/Devices

Test Site Management
Test Site ‘Compliance’ Standards & Regulations

Audit QC and patient results in EMR
Re-certification/validation
Support – coaching and troubleshooting
Initial training/competency validation, update operator database

Maintenance of instruments

Other: Industry liaison, technology advisor, coordinates & conducts lab studies, handles product recalls & alerts, Chair or representative for institutional committees, networks on behalf of institution, publishes & contributes to professional societies and listserves

POCC
Manager & Leader

Test Menu
Pre- and post-disaster

- POC A1c
- POC Hct
- POC Creatinine
- POC Hgb
- POC Glucose
- POC INR
- POC Occult Blood
- POC Rapid Streps
- POC Rapid Flu
- POC UA
- POC Urine hcg
- Non-invasive Bilirubin (Clia Exempt)

Essential Skills of the POC Coordinator for Readiness

• Perform needs assessment in advance of a crisis
• Participate in writing the emergency plan
• Periodically drill the emergency plan ➔ assess response ➔ revise plan
• Do annual “gap analysis” to identify and eliminate weak preparedness areas of high risk
• Communicate with surrounding communities in the small-world network and regionally
• Guarantee the competency of operators who respond outside the hospital
• Outline what is the process, who is in charge, and where is the command center
Essential Skills of the POCC (cont.)

- Include offsite training programs, telecertification, and validation
- Examine requirements such as power, durability, scan functions, and victim identification
- Standardize supplies for interchangeability during responses
- Consider the impact of environmental conditions on supplies and test performance
- Assess periodically the quality control of materials in caches
- Solve problems and troubleshoot
- Alert colleagues to username and password preservation and accessibility
Essential Skills of the POCC (cont.)

- Adapt resources to meet the needs of health care teams in the field
- Be mindful of regulatory requirements and any practice exceptions that occur
- Connect test results with the electronic medical record in real time and after the event
- Preplan using a reference laboratory and the supply chain for specimen transport
- Conduct table top all hazards disaster and pandemic isolation drills
- Maintain personnel, government agencies, and industry contact call lists
- Practice communicating via text, long-range radios, and analog phones
Emergency Plan

Written plan

Event or Drill

Document effectiveness or corrective action needed

Revise plan with changes

Drill plan to include changes

If ‘pass’, accept changes

Value Proposition
Assess POC Testing in Context

Critical information has value exceeding the costs of tests. Physicians assign high value because test results impact decisions. Nurses assign higher value than laboratorians. Speed has value, and often is life-saving. Patient self-care and responder welfare garner value as well! Total value depends on the sum of benefits minus costs—

Value = Σ [Benefits – Costs]
United States Disaster Caches
Lab Basic Package
[≤ 50 lbs]
Portable

Chem 8+ and G3+ Cartridges (i-STAT)

LifeSign MI (Quantitative)

Pregnancy Test Strip

OneTouch Ultra

Clinitek Urinalysis Test Strip
### POC Cardiac Troponin I Sensitivity

<table>
<thead>
<tr>
<th>Device</th>
<th>Limit of Detection (ng/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitsubishi PATHFAST®</td>
<td>8</td>
</tr>
<tr>
<td>Alere Triage®</td>
<td>10</td>
</tr>
<tr>
<td>Abbott i-STAT</td>
<td>20</td>
</tr>
<tr>
<td>Response Biomedical RAMP® Reader</td>
<td>30</td>
</tr>
<tr>
<td>Siemens Stratus CS</td>
<td>30</td>
</tr>
<tr>
<td>Roche Cardiac Reader</td>
<td>30 (cTnT Semi-Quantitative)</td>
</tr>
<tr>
<td>Roche Cobas h232</td>
<td>50 (cTnT Semi-Quantitative)</td>
</tr>
<tr>
<td>LifeSign MI®</td>
<td>1,500 (Qualitative)</td>
</tr>
</tbody>
</table>
Lab Plus Package
[~400 lbs]

Rapid tests for:
Strep Throat, Mono, and D-dimer

Hemoccult Immunochemical Chromatography Test

Piccolo Chemistry Analyzer
General Chem 13 Liver Panel

PT/INR Cartridge (i-STAT)

Coulter AcT diff 2

Triage TOX Drug Screen

Clinitek 50 Urine Analyzer
Disaster Point-of-Care
[Instruments ≤ 50 lbs]

- i-STAT with Chem 8+ (Electrolytes), G3+ (blood gases), PT/INR, and cTnl Cartridges
- Oraquick ADVANCE HIV 1/2
- Hemoccult Immunochemical Chromatography Test
- Clinitek Urinalysis Test Strip
- Pregnancy Test Strip
- Piccolo Chemistry Analyzer General Chem 13 Liver Panel
- Triage TOX Drug Screen
- ABORhCard® Blood Typing Test Card
- Onyx II 9560 Fingertip Pulse Oximeter
- Masimo Rad-57 Pulse Oximeter
- Ativa MicroCBC (Investigational Use Only)
- Nova Statstrip Glucose, Lactate, β-hydroxybutyrate, and Creatinine
Ativa MicroCBC Hematology Device

- Only device with three detection methods on board: optical light scatter, colorimetric and electrochemical.
- Uses single-use disposable test cards.

Reference: www.ativamed.com
MicroCBC Technology

Results in 3-5 minutes!

- Microfluidic flow control via micro-flow channels.

Reference: www.ativamed.com
Point of Care “Clusterettes”—Disaster Caches Customized for Decision-Making

- Alternate Care Facility

- Complex Emergencies (Radiation Exposure Detection, Monitoring, and Treatment)

- Crush Injury (electrolytes, hct/hgb, renal failure)

- Pandemic, Infectious Diseases, Sepsis, Biothreat, and Isolation Kits

- Whole-Blood Analysis—multiplex blood gases, pH, Hct/Hgb, electrolytes (Ca+2), & more
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
Theroretical Alternate Care Facility

...what is missing?

Test Cluster Needed:

Disaster Setting & Bloodstream infections MRSA, *Salmonella typhi*, *Vibrio cholerae*, *E. coli*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Streptococcus pneumoniae*, and carbapenem-resistant *enterobacteriaceae* (*POC* 2012;11:119.)

Whole-Blood Analysis
Electrolytes and blood gases (Cobas b123)

Blood donor screening
HIV, Hepatitis B and C virus (*POC* 2012;11:119.)

CONCLUSIONS AND IMPACT!

• Point-of-care coordinators can and should take responsibility for proper training, quality assurance, and test performance that will enhance standards of care.

• Needs assessment and research a) describe point-of-care designs for emergency and disaster settings, b) reveal which devices and reagents can be used in different climates, and c) identify test clusters necessary for critical decision-making.

• Regardless of location, innovative point-of-care technologies empower for personalized medicine and evidence-based practice under dire circumstances.

• Small-world networks + flexibly equipped hubs + strategically placed POC testing create value, that is, efficient urgent-emergency care and cost-effective disaster preparedness.
Haiti Earthquake—Need for Robust POC Testing & HIV-1/2 Tests
Sarah Brown, PhD, Symposium Chair
“Clinical Chemistry in Disaster Response and Resource-Poor Environments”

Dr. Kost, Speaker
“The Use of Small-World Networks and Technological Advances in Point of Care for Disaster Preparedness, Response, and Resilience”

Two Other Speakers
Carla Orner, MBA, MT, of Heart-to-Heart International, will present her experience with mobile laboratories in the U.S. and with quality assurance initiatives in Haiti. Sarah Halcomb, MD, will speak about test utilization by emergency physicians in disaster response and low-resource settings, share examples of what was available after the Haiti earthquake, and contrast them to ideal laboratory support.

Session 32214, Monday, July 29, 2:30 - 5:00pm
George R. Brown Convention Center
The Role of Point-of-Care Testing in a Disaster (Plan)

August 1, 2013 | 7:30 - 8:00 a.m.
Hot buffet breakfast | 8:00 - 10:00 a.m.
Presentation George Brown Convention Center
Sponsored by the AACC Critical and Point-of-Care Testing Division

AACC National Meeting

Needs Assessment


