GLOBAL POINT OF CARE DISASTER MANAGEMENT AND EBOLA PREPAREDNESS

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in collaboration with POCT•CTR Researchers

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University of California, Davis, USA

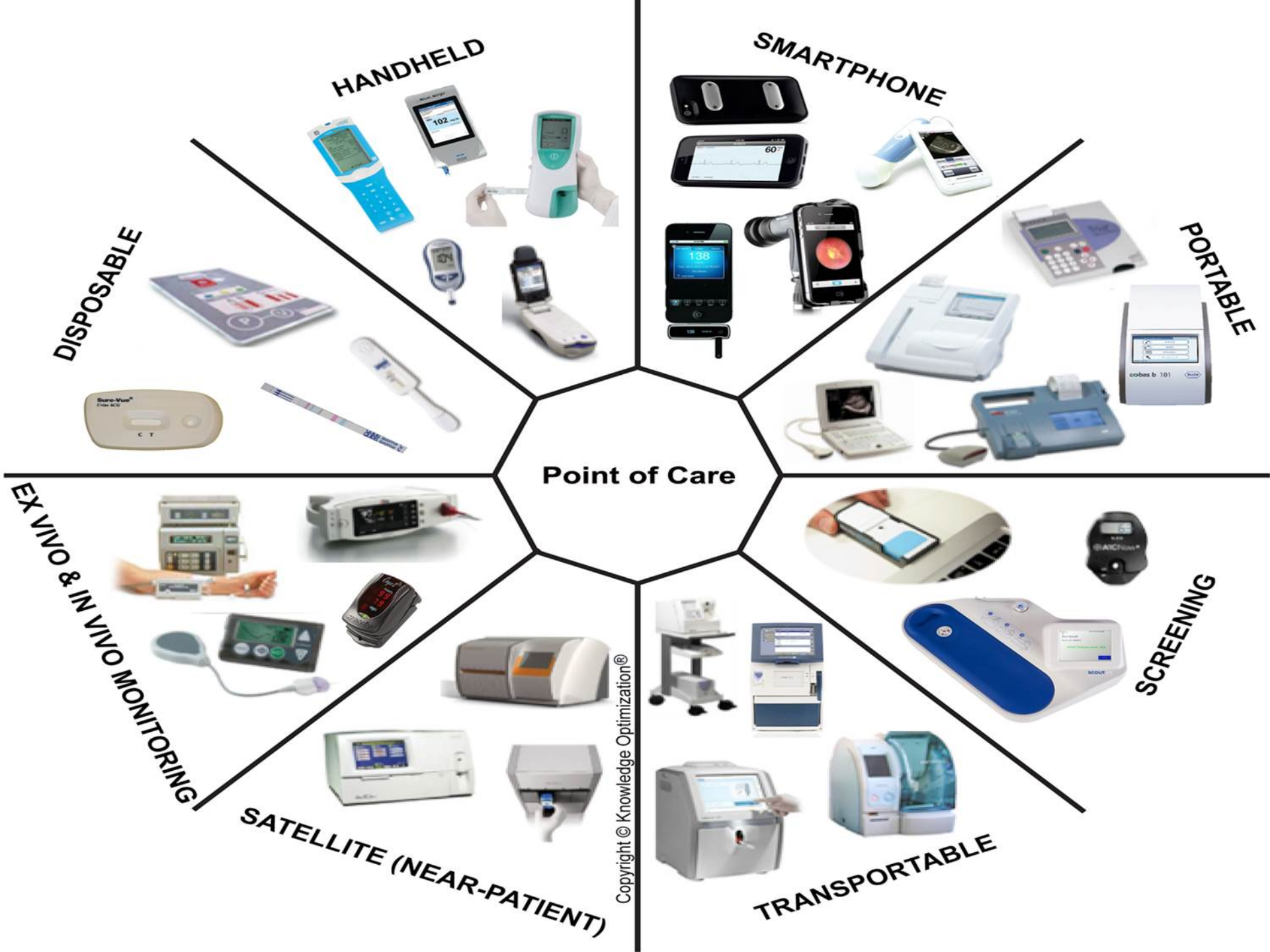
[Disclaimer: Research results may be preliminary. Final conclusions may differ. Please consult published papers. Device use must comply with regulatory & legal requirements.]

Please email questions to Dr. Kost at gjkost@ucdavis.edu. Thank you.

Point-of-Care Testing Center
for Teaching and Research

Disaster Management: Practical Needs

- Disaster protocol for the hospital & laboratory
- Personnel training, certification, & registry
- Understanding of environmental impact (IQCP)
- POC technologies to detect, triage, & monitor
- Disaster cache and deployment plan
- POC Coordinator for preparation & oversight
- Ancillary care facility—where people will go
- Isolation capability with appropriate laboratory
- Mobility and telecommunications
- Resilience for both acute and chronic care


Point of Care
HANDHELD
SMARTPHONE
PORTABLE
SCREENING
TRANSPORTABLE
SATELLITE (NEAR-PATIENT)
EX VIVO & IN VIVO MONITORING
DISPOSABLE
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LEARNING OBJECTIVES

- ***To demonstrate how to determine needs:*** *Needs assessment helps define the role of POCT in pandemics, complex emergencies, and disasters. "FAST POC" will help stop outbreaks.*

- ***To understand environmental stresses:*** *Environmental stresses affect test results and must be avoided, so that POCT can be effective for decision-making in crises.*

- ***To illustrate the design of POCT caches:*** *Disaster caches should be designed, expanded, and harmonized for worldwide collaborative use, in part, to address new threats, such as Ebola & MERS CoV.*

- ***To describe Spatial Care Paths™ (SCP) and point of care culture:*** *The spatial care path™ starts with the patient, positions POCT optimally, and accelerates care—one "tunes" testing for cultural acceptance. National POCT policy and guidelines in limited-resource and other settings then enhance community resilience effectively.*

Global Point of Care

Strategies for Disasters, Emergencies, and Public Health Resilience

Edited by

Gerald J. Kost

&

Corbin M. Curtis

AACCPress

1

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 administrate them. Literature searches also were conducted using the PubMed database and keywords, such as point 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. Laboratorians, 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.

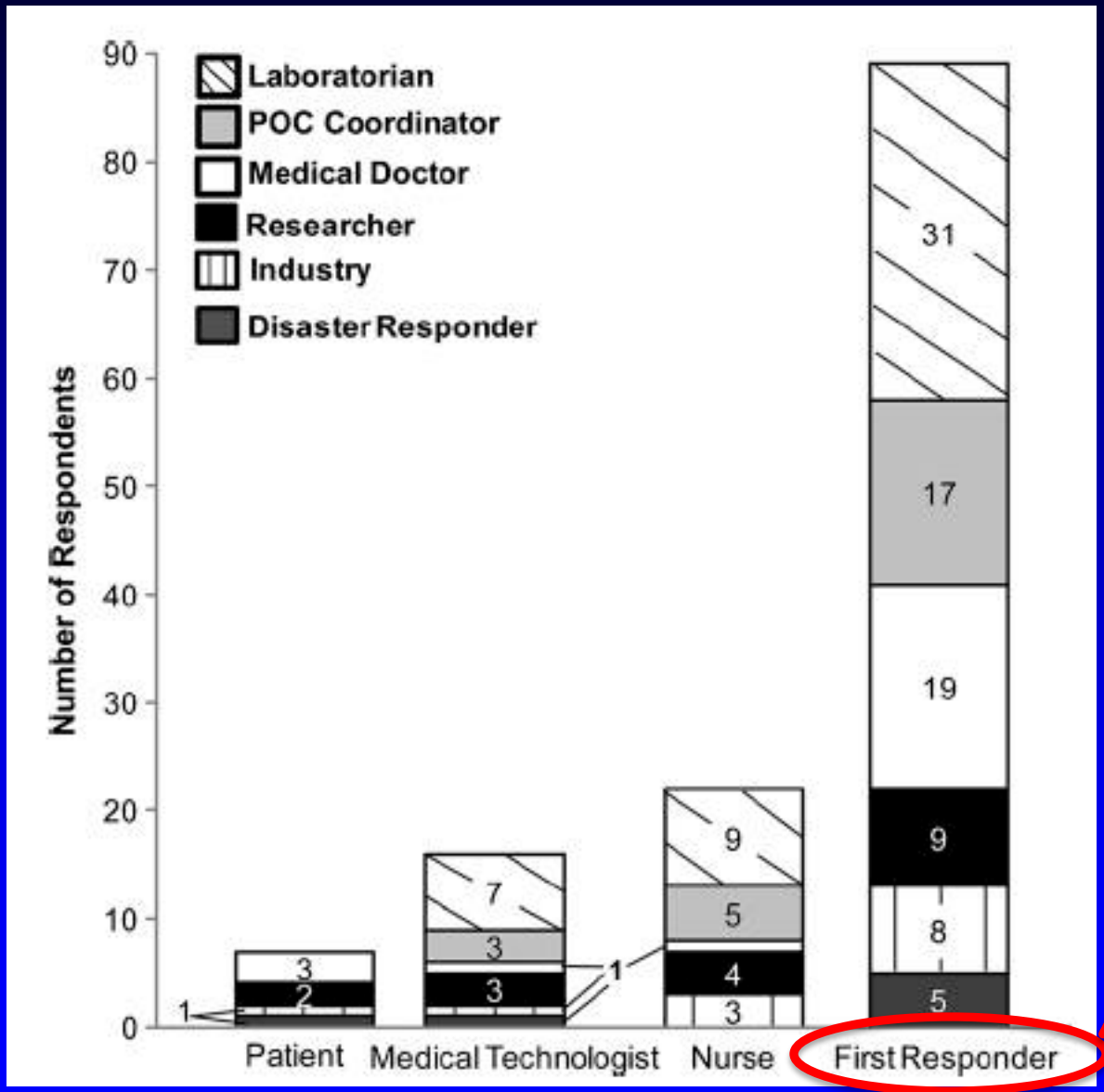
Based on a 2012 World Health Organization Health Statistics report, a median of 61% of the world health expenditure was paid by the government in 2009 *(1)*. Needs assessment can reduce global health care expenditures, improve healthcare resource, and enhance standards of care. Needs assessment, per se, represents a systematic process for determining and addressing what POC 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 grew out of satisfying clinical needs for bedside glucose testing, coagulation monitoring, and intensive care, where the advent of ionized calcium (Ca^{2+}, free calcium; Figure 1-1) *(3, 4)* proved that whole-blood analysis *(5)* 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 Asia 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)*. POC is testing performed at or near the site of the patient care *(11)*. Recent disasters have demonstrated the feasibility of POCT, but POC 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

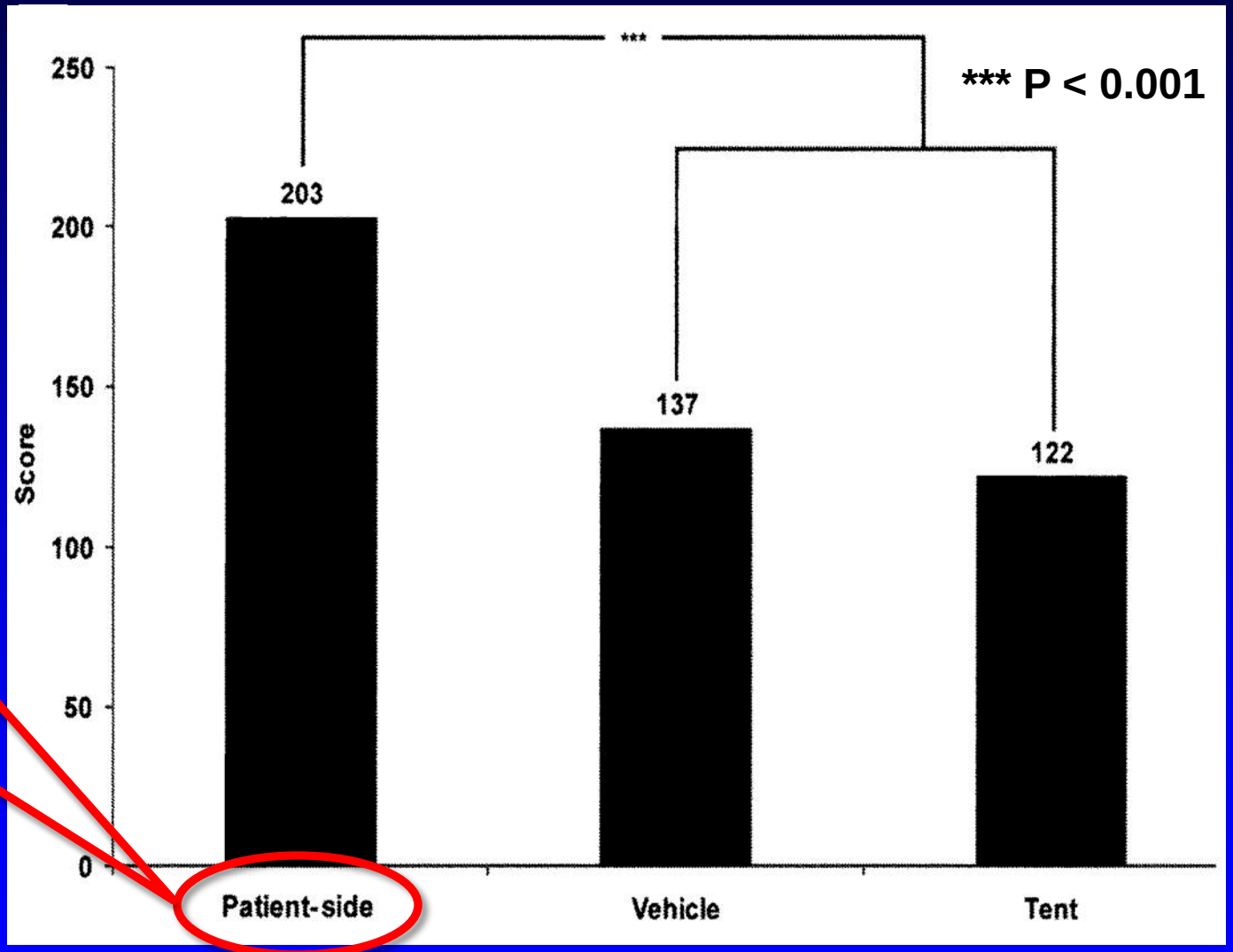


First Responders are the preferred group to perform POC testing in disasters

Reference: Kost GJ, et al. Assessing point-of-care device specifications and needs for pathogen detection in emergencies and disasters. *Point of Care*. 2012;11:119-125.

Needs Assessment Results from POC Journal Readers

Field Testing Location

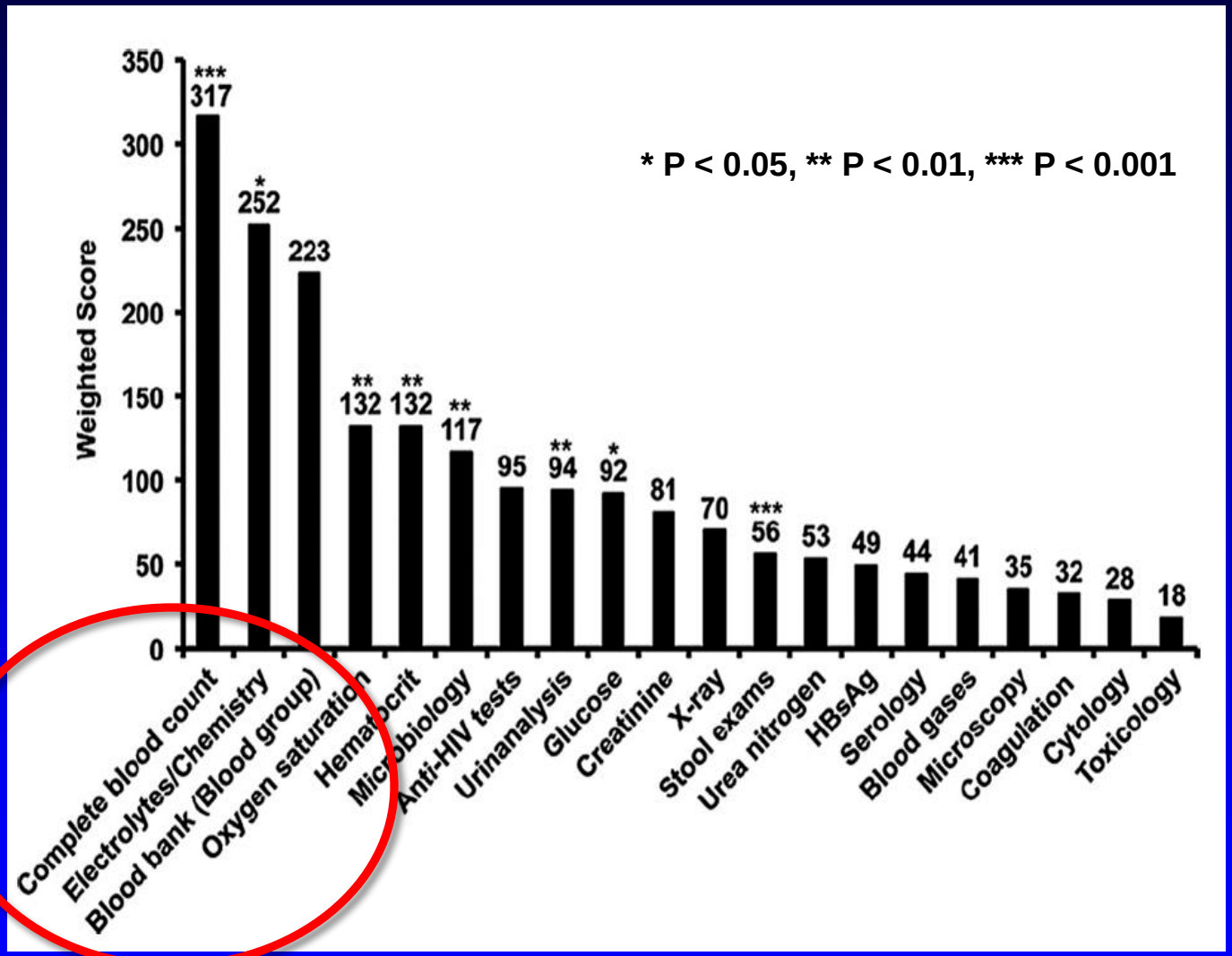


Respondents preferred patient-side testing in the field over testing inside a vehicle or tent.

Reference: Brock TK, et al. Evidence-based point-of-care tests and device designs for disaster preparedness. *Am J Disaster Med*. 2010;5:285-294.

Tsunami Needs Assessment Survey Results Phang Nga Coastal Province, Thailand

Respondents chose CBC, Lytes/Chemistry, Blood Bank, & O_2 Saturation as the highest priority diagnostic tests for a disaster

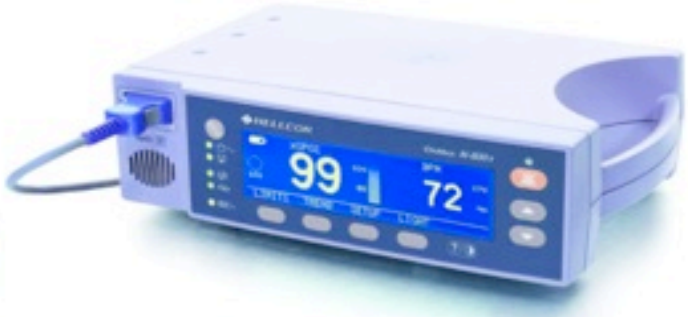


Reference: Kost GJ, et al. Strategic point-of-care requirements of hospitals and public health for preparedness in regions at risk. *Point of Care*. 2012;11:114-119.

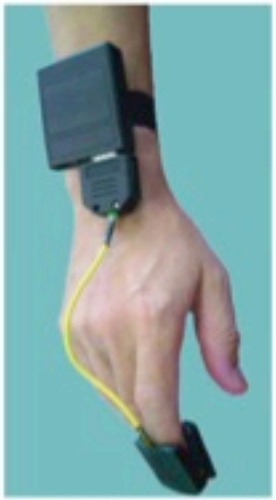
How To: Monitor O_2 Saturation & Hemoglobin

Cordless, Fingertip
Post-Tsunami, Thailand
(Nonin Onyx II 9550)

O2 Pulse Oximeters for adult and neonate
(Nellcor OxiMax N-600x)

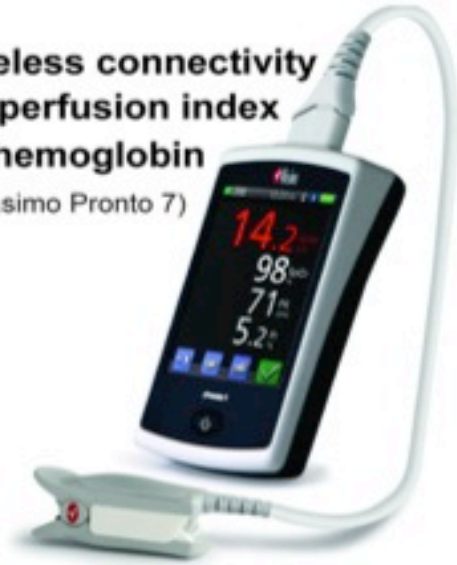


Embedded Printer
(BCI FingerPrint)



Pulse Oximeter with Bluetooth Module
(Alive Pulse Oximeter)

wireless connectivity
perfusion index
hemoglobin
(Masimo Pronto 7)

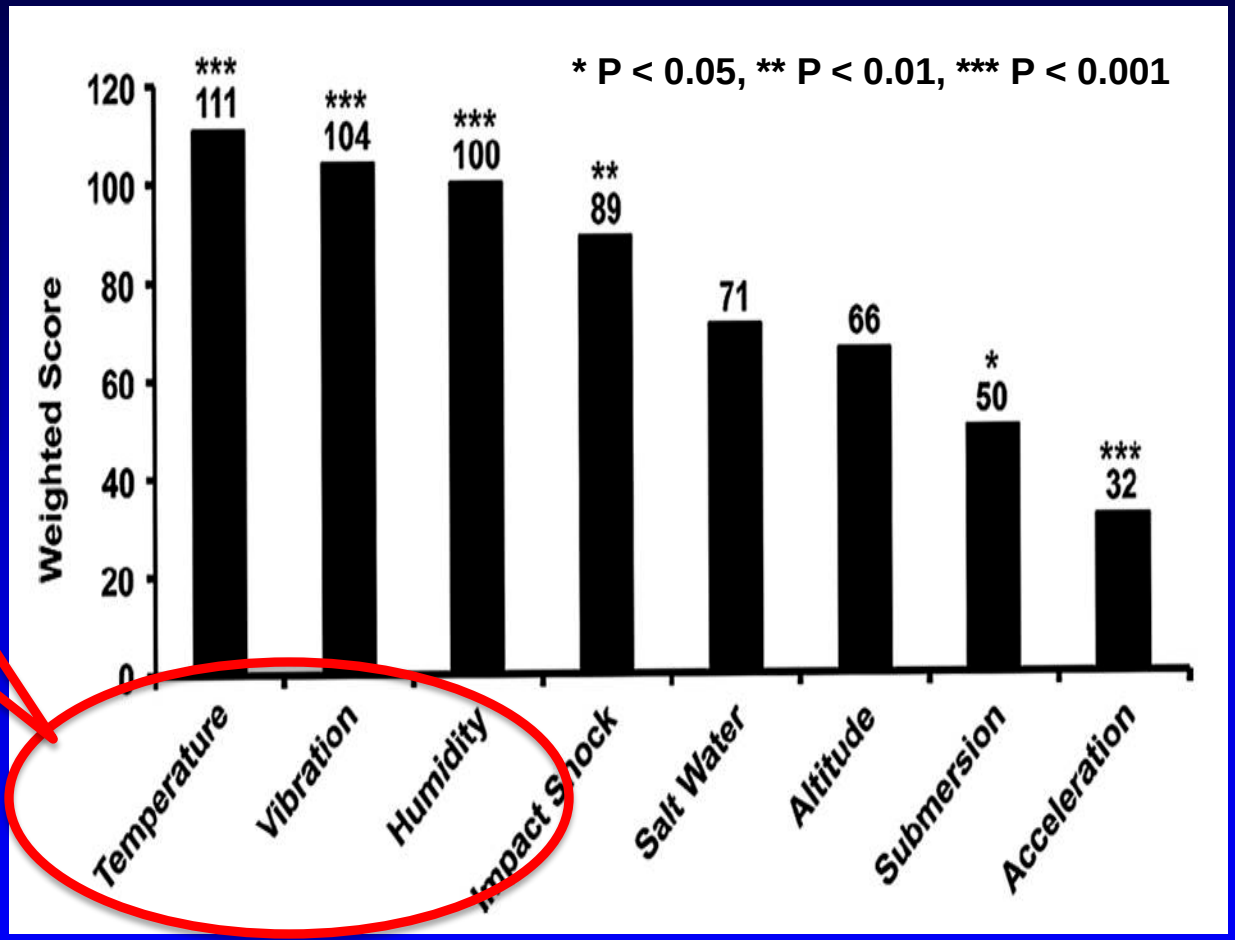


plethsmograph variability index
hemoglobin
carboxyhemoglobin
methemoglobin
perfusion index
(Masimo Rad-57)

Reference: Brock KT, et al. Disaster Point-of-Care: Non-Invasive Monitoring. YouTube Presentation. Available at: http://www.youtube.com/watch?v=9ELSR7z0U4w. [Accessed September 19, 2014.]

Tsunami Needs Assessment Survey Results Environmental Stresses

Respondents chose 3 physical challenges as the most important environmental factors to overcome in future POC device designs for extreme conditions



Reference: Kost GJ, et al. Strategic point-of-care requirements of hospitals and public health for preparedness in regions at risk. *Point of Care*. 2012;11:114-119.

Hurricane Katrina, USA, 2005

Haiti Earthquake, 2010

Yolanda/Hagupit, Philippines, 2013

Japan Earthquake / Tsunami, 2011

Global Point of Care

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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 POC 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 *(1)*.

Between 1980 and 2013, the United States experienced 640 disaster events. Of those events 64.5% (413/640) 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.

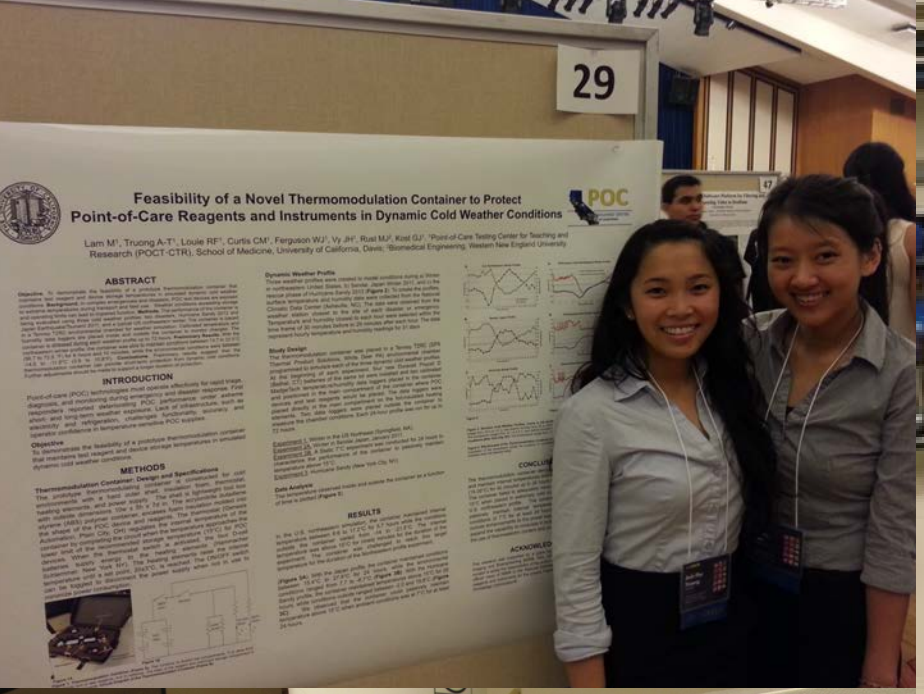
To ensure accurate and safe use, POCT needs to deliver excellent performance in any environment in which it is used *(6)*. Erroneous results can cause serious harm and alter clinical decision making, such as improper insulin dosage *(7)*. Emergency and disaster responders equipped with POC technologies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

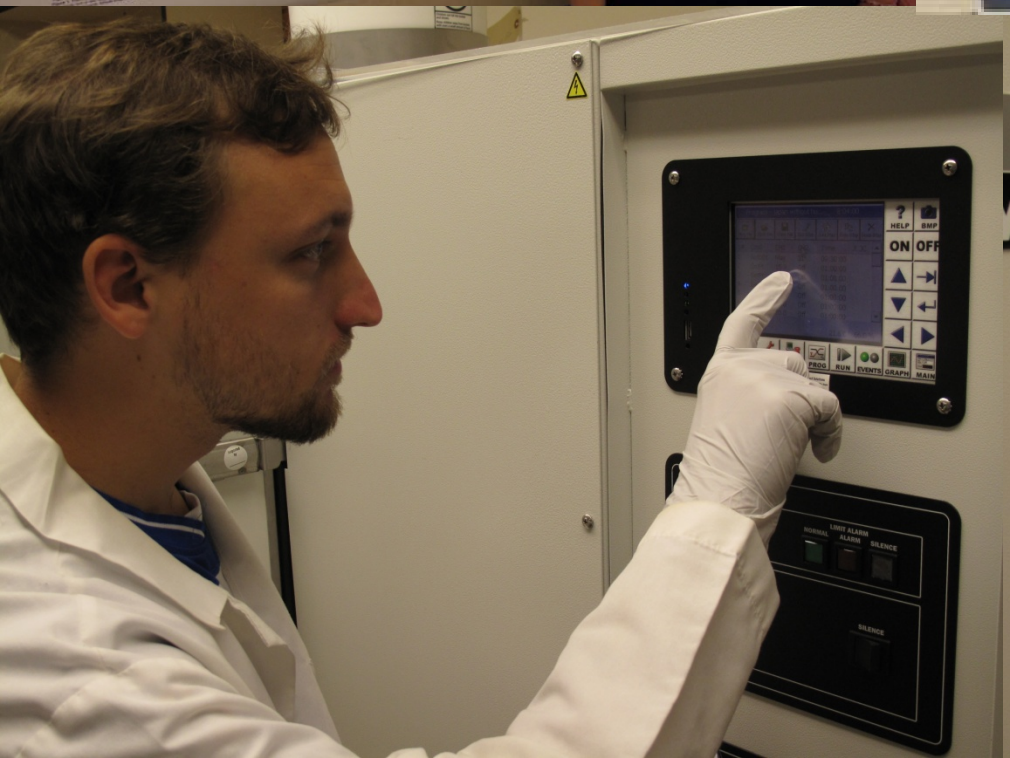
Tables 23-2, and 23-3 *(8)* summarize the storage and operating specifications of select POC devices. Test reagents typically are refrigerated or stored in ambient conditions between 15–30 °C (59–86 °F). Reagents requiring refrigeration can be stored at ambient conditions (e.g., room temperature), but 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, weighs the effects of temperature variations over an extended period of time according to the following equation *(9)*:

$$MKT = \frac{\Delta E / R}{-\ln\left(\frac{e^{\left(-\frac{\Delta E}{RT_1}\right)} + e^{\left(-\frac{\Delta E}{RT_2}\right)} + \ldots + e^{\left(-\frac{\Delta E}{RT_n}\right)}}{n}\right)}$$

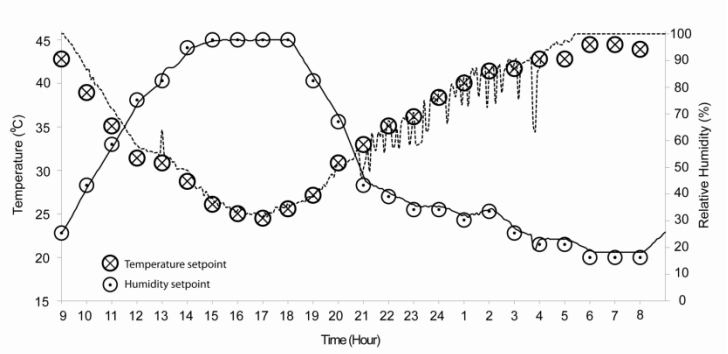

29
Feasibility of a Novel Thermomodulation Container to Protect
Point-of-Care Reagents and Instruments in Dynamic Cold Weather Conditions
POC
ABSTRACT
INTRODUCTION
METHODS
RESULTS


HELP
ON
OFF
ERROR
RUN
EVENTS
GRAPH
MAIN
NORMAL
LIGHT ALARM
ALARM
SILENCE
SILENCE

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

Reference: Louie RF, et al. *Disaster Med Public Health Prep*. 2012;6:232-240.

Journal of Diabetes Science and Technology
2014, Vol. 8(1) 83–88

DOI: 10.1177/1932296813514325
dst.sagepub.com
SAGE

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

Mandy Lam[1], Richard F. Louie, PhD, FACB[1], Corbin M. Curtis, BS[1], William J. Ferguson, BS[1], John H. Vy, BS[1], Anh-Thu Truong[1], Stephanie L. Sumner, BS[1], and Gerald J. Kost, MD, PhD, MS, FACB[1]

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.[1] 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's home, distinct geographic locations, and with the settings.

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.

[1]UC Davis POC Technologies Center, Point-of-Care Testing Center for Teaching and Research, Pathology and Laboratory Medicine, University of California, Davis, CA, USA

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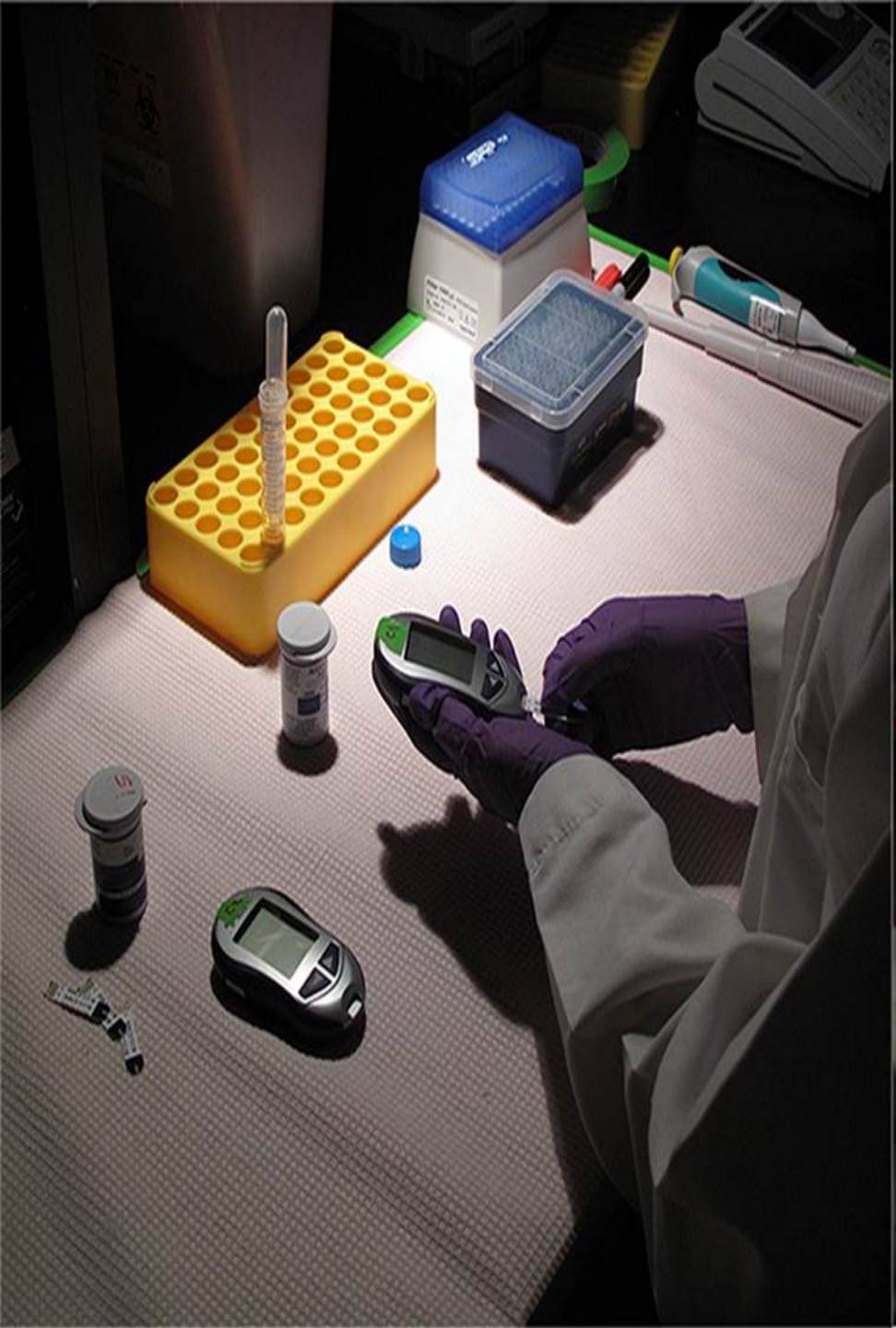
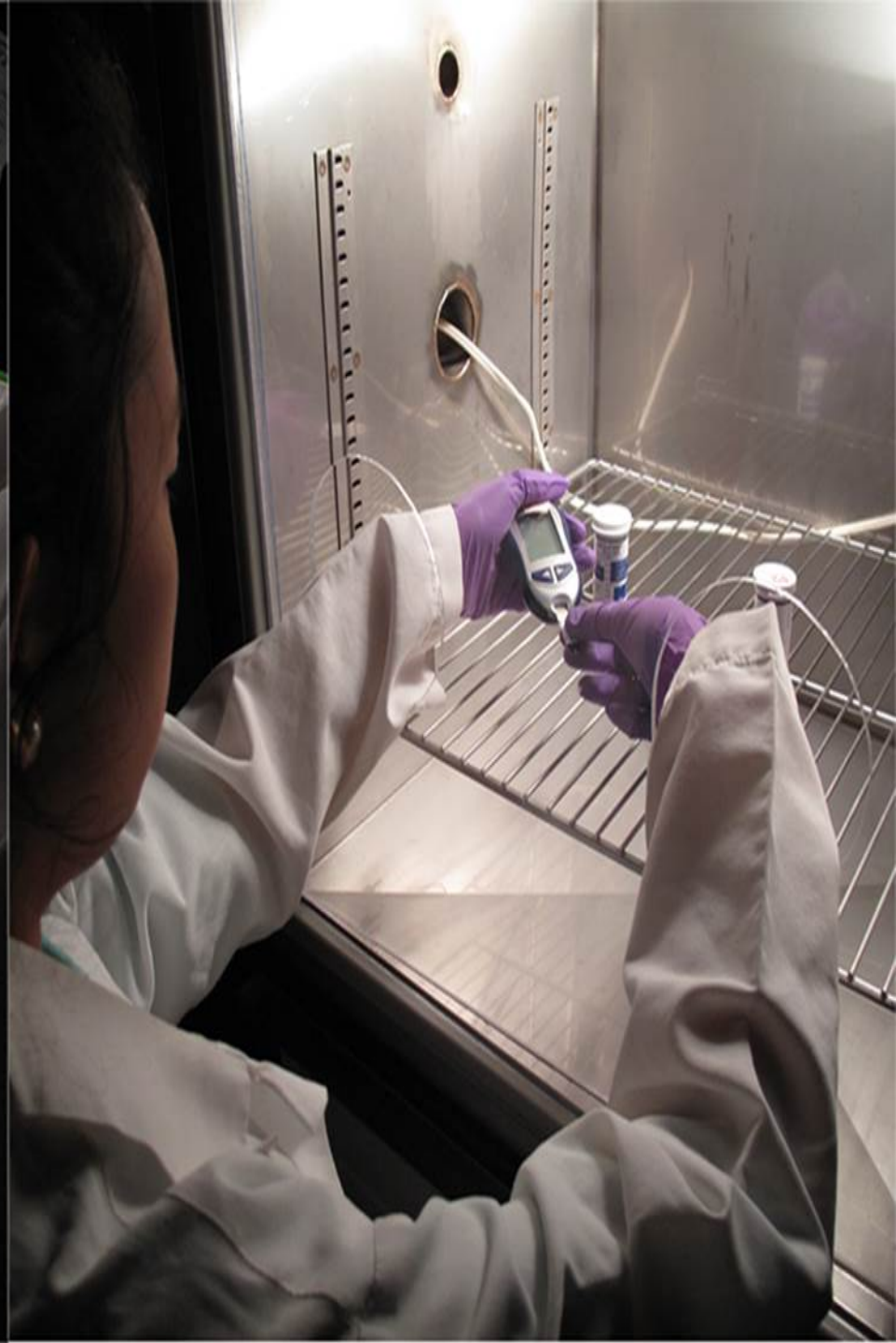
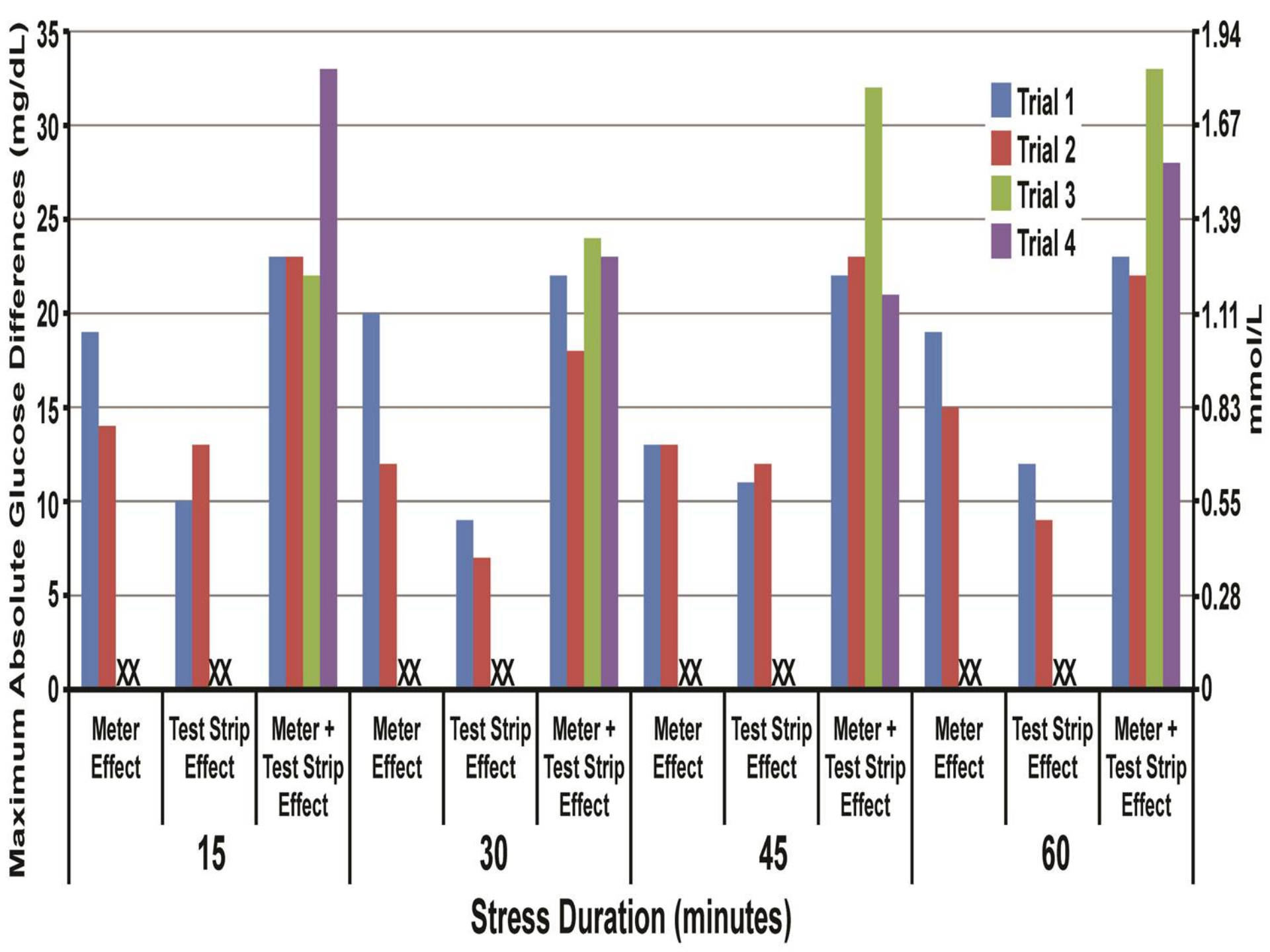
Richard F. Louie, PhD, FACB, Point-of-Care Testing Center for Teaching and Research, Pathology and Laboratory Medicine, University of California, 5, USA.

Lam M, et al. *J Diabetes Sci Technol.* 2014;8:81-88.






Maximum Absolute Glucose Differences (mg/dL)
35
30
25
20
15
10
5
0
1.94
1.67
1.39
1.11
0.83
0.55
0.28
0
mmol/L
Trial 1
Trial 2
Trial 3
Trial 4
XX
Meter Effect
Test Strip Effect
Meter + Test Strip Effect
15
30
45
60
Stress Duration (minutes)

DM

ORIGINAL ARTICLE

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

Richard F. Louie, PhD, FACB; William J. Ferguson, BS; Corbin M. Curtis, BS; John H. Vy, BS; Chloe S. Tang, BS; Gerald J. Kost, MD, PhD, MS, FACB

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 BTRC) to simulate flight conditions (20°C, 10 percent relative humidity) and ground conditions (22.3-33.9°C, 73-77 percent). We obtained paired measurements using stressed versus control (room temperature) cassettes at seven time points (T_{1-7} with $T_{1,2,6,7}$ during flight and T_{3-5} 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 T_4 ($p < 0.05$), T_5 ($p < 0.01$), and T_7 ($p < 0.05$) 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 T_5, 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.*

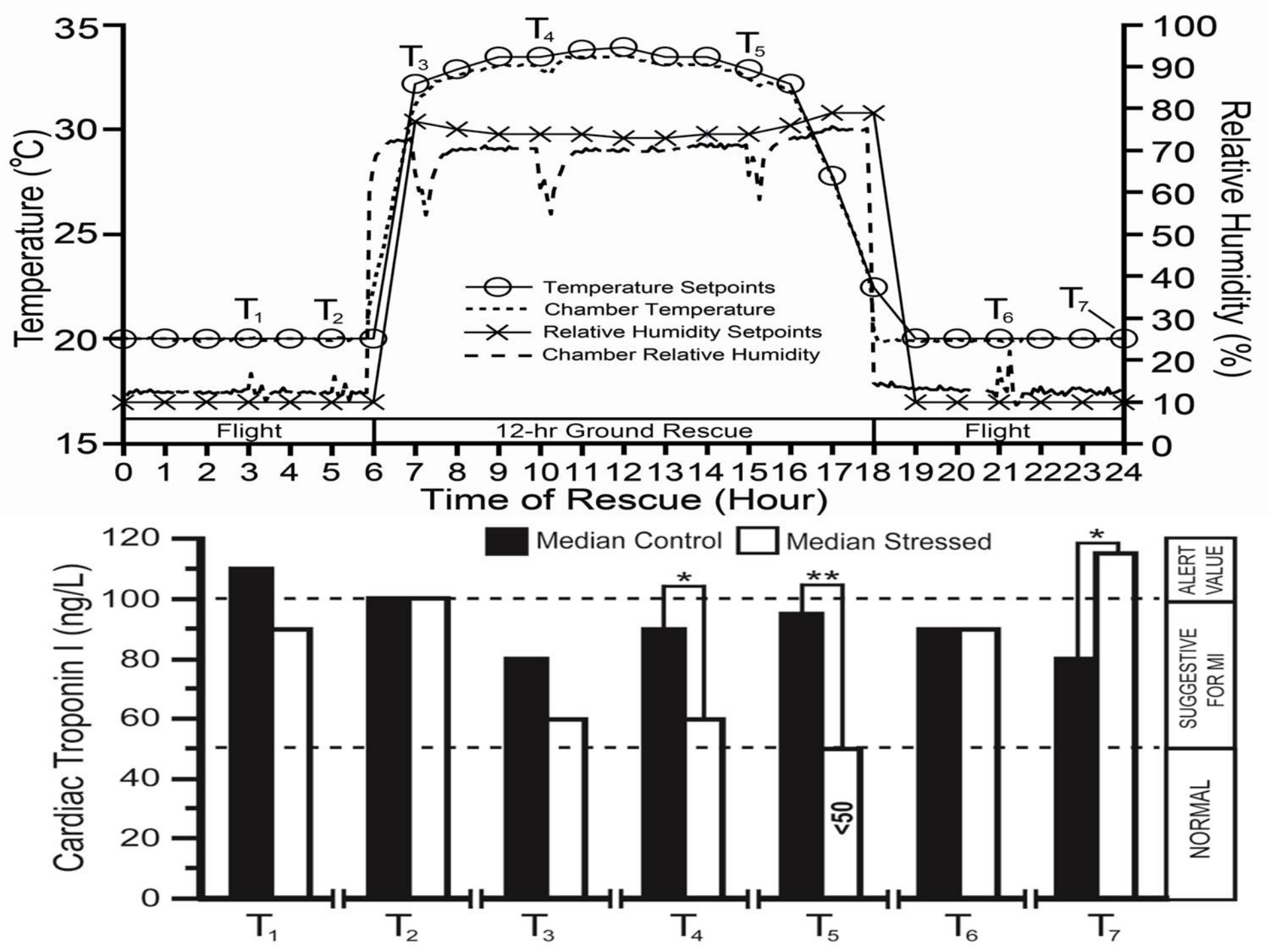
Key words: austere environments, disaster preparedness, medical errors, Pacific Islands, and quality assurance

Introduction

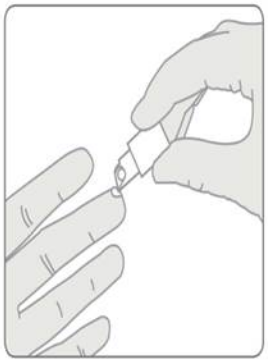
Emergency medical responders are deployed with limited point-of-care (POC) tests during crises, which restricts triaging in the field. Quantitative measurement of cardiac troponin I (cTnI), brain natriuretic peptide (BNP), CK-MB, myoglobin, and D-dimer in whole blood and plasma specimens can aid in the 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.[1-3] 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.

DOI:10.5055/a

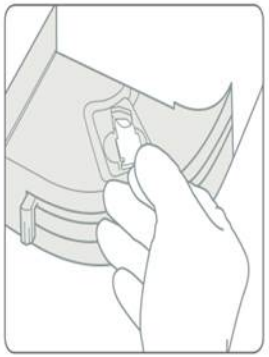
www.disasterme


Temperature (°C)
Relative Humidity (%)
Time of Rescue (Hour)
Temperature Setpoints
Chamber Temperature
Relative Humidity Setpoints
Chamber Relative Humidity
Flight
12-hr Ground Rescue
Flight
T1
T2
T3
T4
T5
T6
T7
Median Control
Median Stressed
Cardiac Troponin I (ng/L)
ALERT VALUE
SUGGESTIVE FOR MI
NORMAL
<50

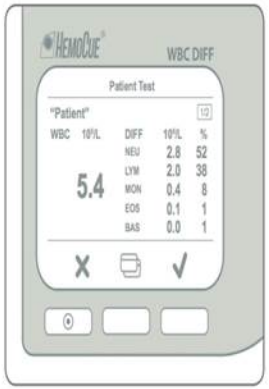
WBC & 5-PART DIFFERENTIAL— ENVIRONMENTAL STRESS VALIDATION IN PROGRESS



1 Fill microcuvette.

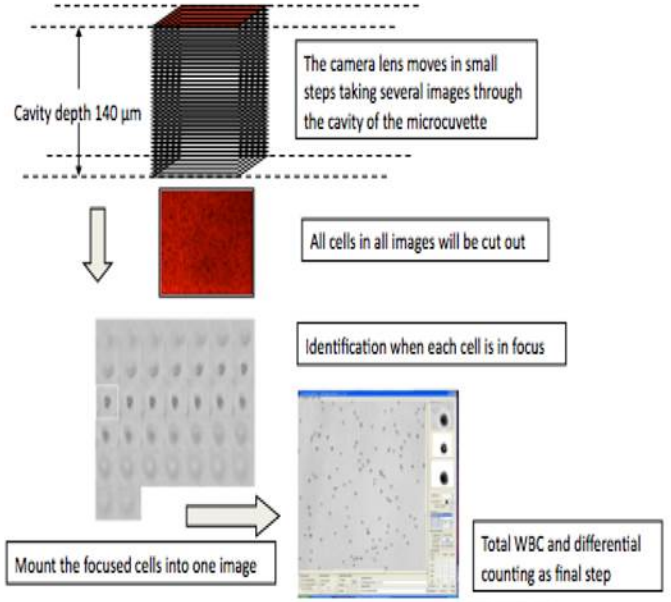


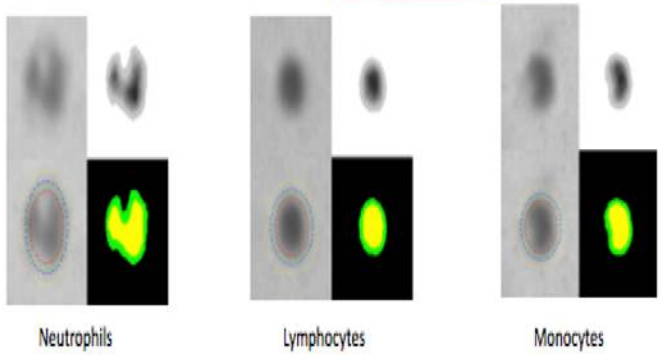
2 Place microcuvette into analyzer.



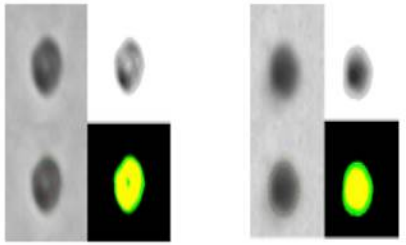
3 View results.

The microcuvette cavity is analyzed in separate layers to enable detection of cells at different depths



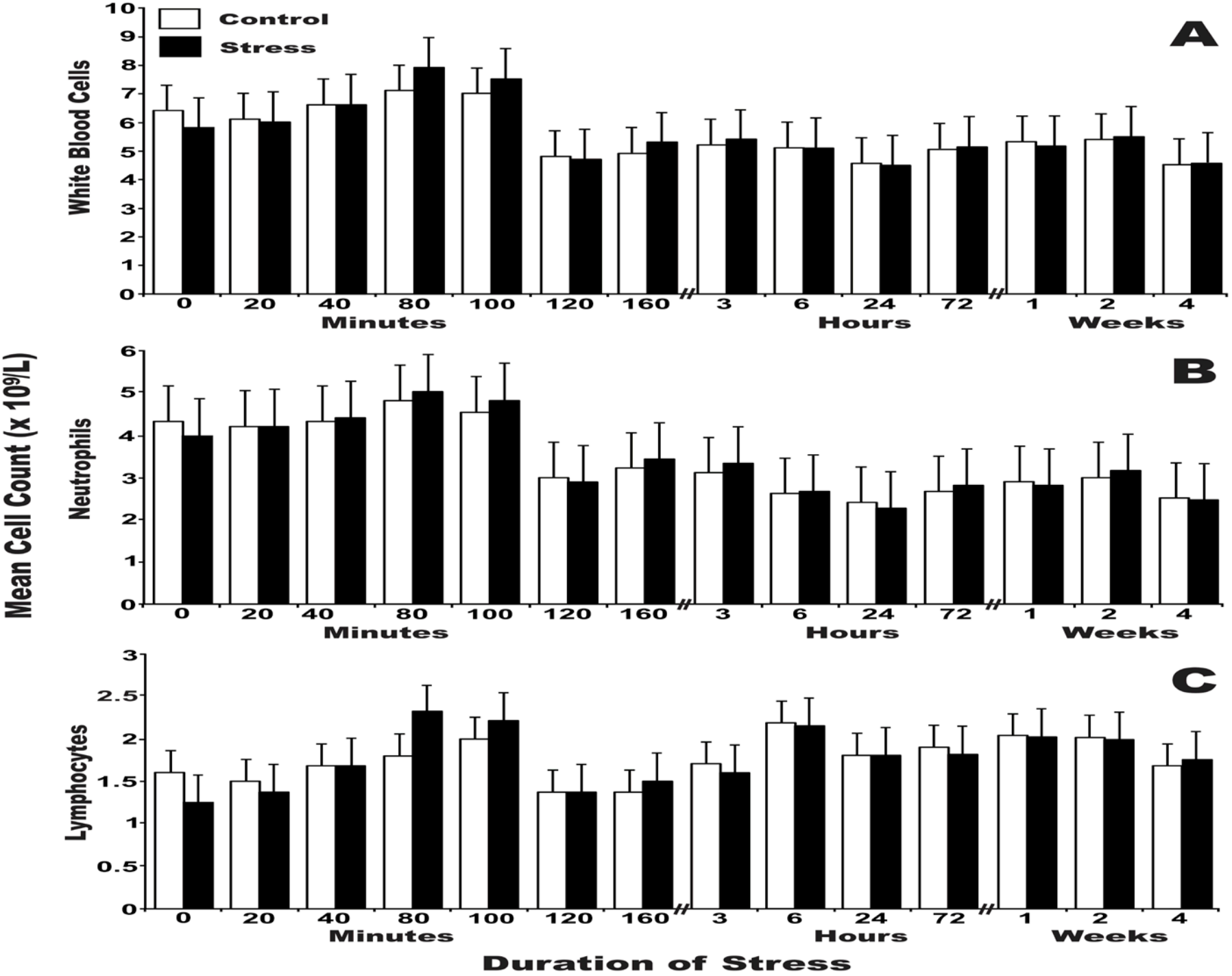


Neutrophils Lymphocytes Monocytes



Eosinophils Basophils

Transferring characteristics into mathematical algorithms. WBC DIFF uses over 30 features and state-of-the-art image analysis technology.


Control
Stress
A
White Blood Cells
0
1
2
3
4
5
6
7
8
9
10
0
20
40
80
100
120
160
3
6
24
72
1
2
4
Minutes
Hours
Weeks
B
Neutrophils
C
Lymphocytes
0
0.5
1
1.5
2
2.5
3
Mean Cell Count (x 10⁹/L)
Duration of Stress

Global Point of Care

Strategies for Disasters, Emergencies, and Public Health Resilience

Edited by

Gerald J. Kost

&

Corbin M. Curtis

AACCPress

38

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 POCTs 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, Bethlehem, PA, USA), VereTrop™ Lab-on-a-Chip (Veredus 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.

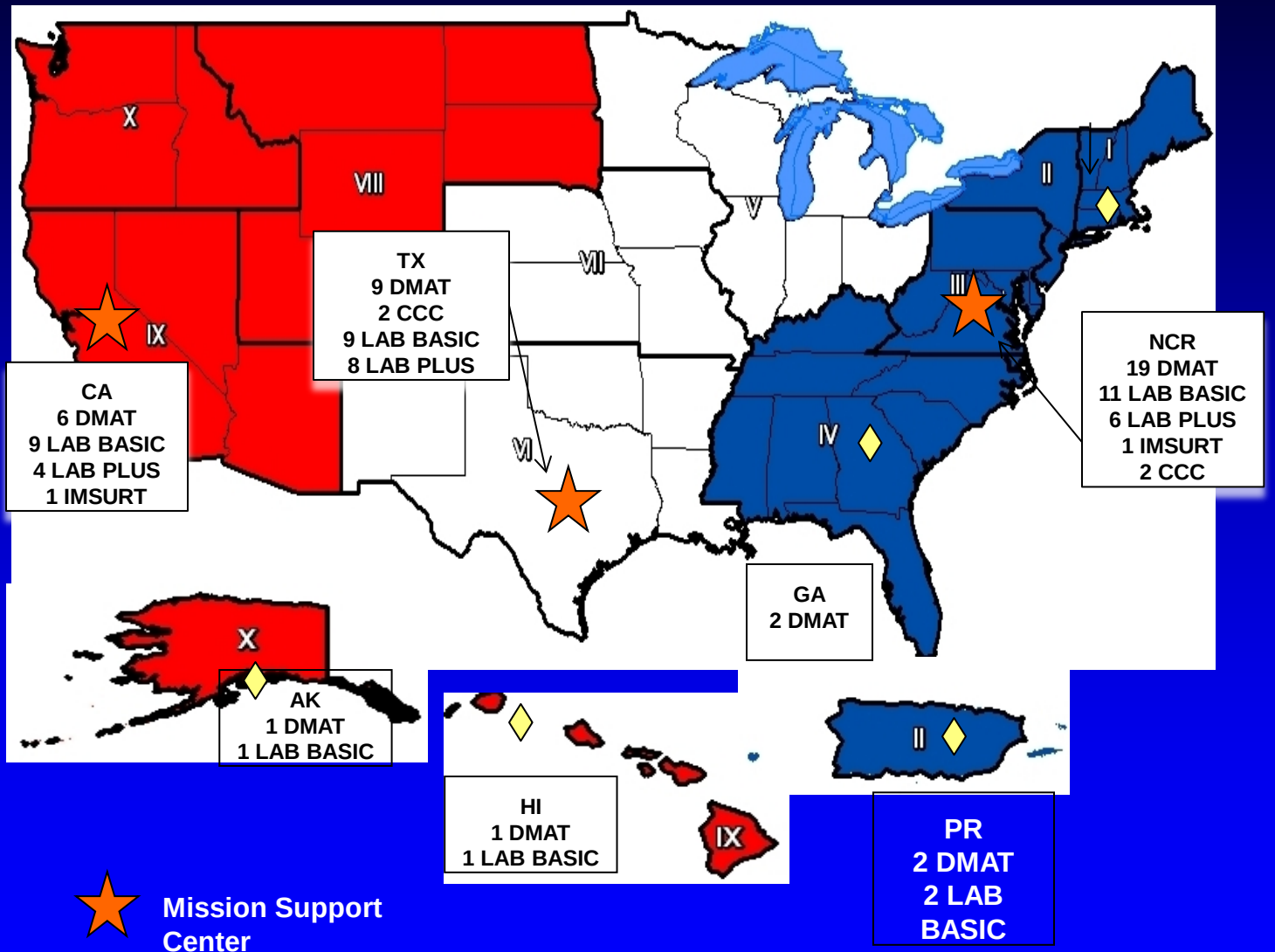
Our goal is to describe, innovate, recommend, and accelerate the implementation of POCT in disaster caches in order to (a) enhance crisis standards of care; (b) improve diagnosis, triage, and monitoring in complex emergencies and disasters; and (c) harmonize evidence-based decision making during responses 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 ft^2)* 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

This study was supported by the Point-of-Care Testing Center for Teaching and Research (POCT•CTR) and by a National Institute for Biomedical Imaging and Bioengineering (NIBIB) Point-of-Care Technologies Center grant (Dr. Kost, PI, NIH U54 EB007959). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIBIB or the National Institutes of Health.

*1 ft2 = xxx m2.

Locations of US National Caches



Lab Basic Kit

Lab Plus Kit


HHS
LAB PLUS
Cache
#18


Lab Plus
Cache #18
Fisher Scientific
WASTE CONTAINER

Disaster Point of Care

i-STAT® 1 Wireless with G3+ (blood gases), Chem 8+ (electrolytes), BNP, and cTnI Cartridges

Oraquick ADVANCE® HIV 1/2

Onyx® II 9560 Fingertip Pulse Oximeter

Sure-Vue® Urine hCG Cartridge

POC Hematology Analyzer

WBC, Differential, RBC, Plt, Hb, and Indices

Wi Fi

Coming: Orasure Ebola POC Test

CoaguChek® XS Plus System for PT/INR

Rapid tests for Strep Throat, Mono and D-dimer

Hemoccult®-Immunochemical Fecal Occult Blood Test

QuickVue® Influenza Test

Multistix® 10 SG Urinalysis Strips Bilirubin, Blood, Glucose, Ketone, Leukocyte Esterase, Nitrite, pH, Protein, Specific Gravity, Urobilinogen

ABORhCard® Blood Typing Test Card

Triage® Drugs of Abuse Test Card

StatStrip Glucose, Lactate, ß-hydroxybutyrate and Creatinine

Masimo Rad-57™ Oxygen Saturation and Hemoglobin plus pediatric probes

Min-Max Temp

Patient Health Security Card

Disaster Point of Care

CLINITEK® Urinalysis: Albumin (Al), Blood, Creatinine (Cr), Ketone, Leukocyte, Nitrite, pH, Protein, Al/Cr ratio and Protein/Cr ratio

i-STAT® 1 Wireless with G3+ (blood gases), Chem 8+ (electrolytes), and cTnI Cartridges

Oraquick ADVANCE® HIV 1/2

Onyx® II 9560 Fingertip Pulse Oximeter

StatStrip Glucose, Lactate, ß-hydroxybutyrate and Creatinine

WBC, RBC, PLT, Hb, MCV, Granulocytes, Lymphocytes, Monocytes Hematology Analyzer (investigational use only)

Masimo Rad-57™ Oxygen Saturation and Hemoglobin plus pediatric probes

Min-Max Temp

Patient Health Security Card

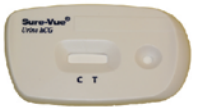
Triage® Drugs of Abuse Test Card

CoaguChek® XS Plus System for PT/INR

Rapid tests for Strep Throat, Mono and D-dimer

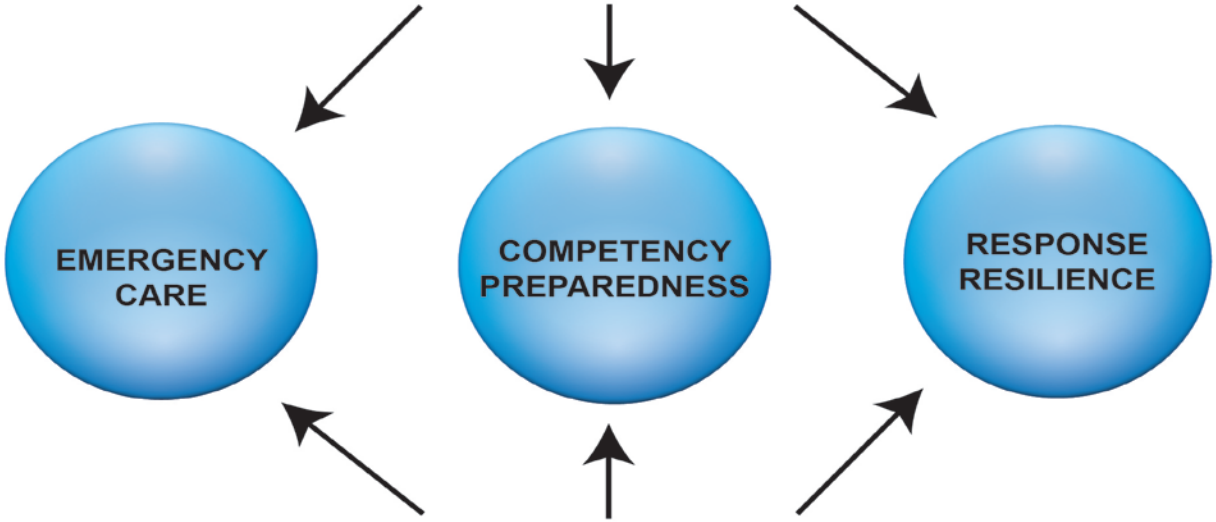
Hemoccult®-Immunochemical Fecal Occult Blood Test

ABORhCard® Blood Typing Test Card

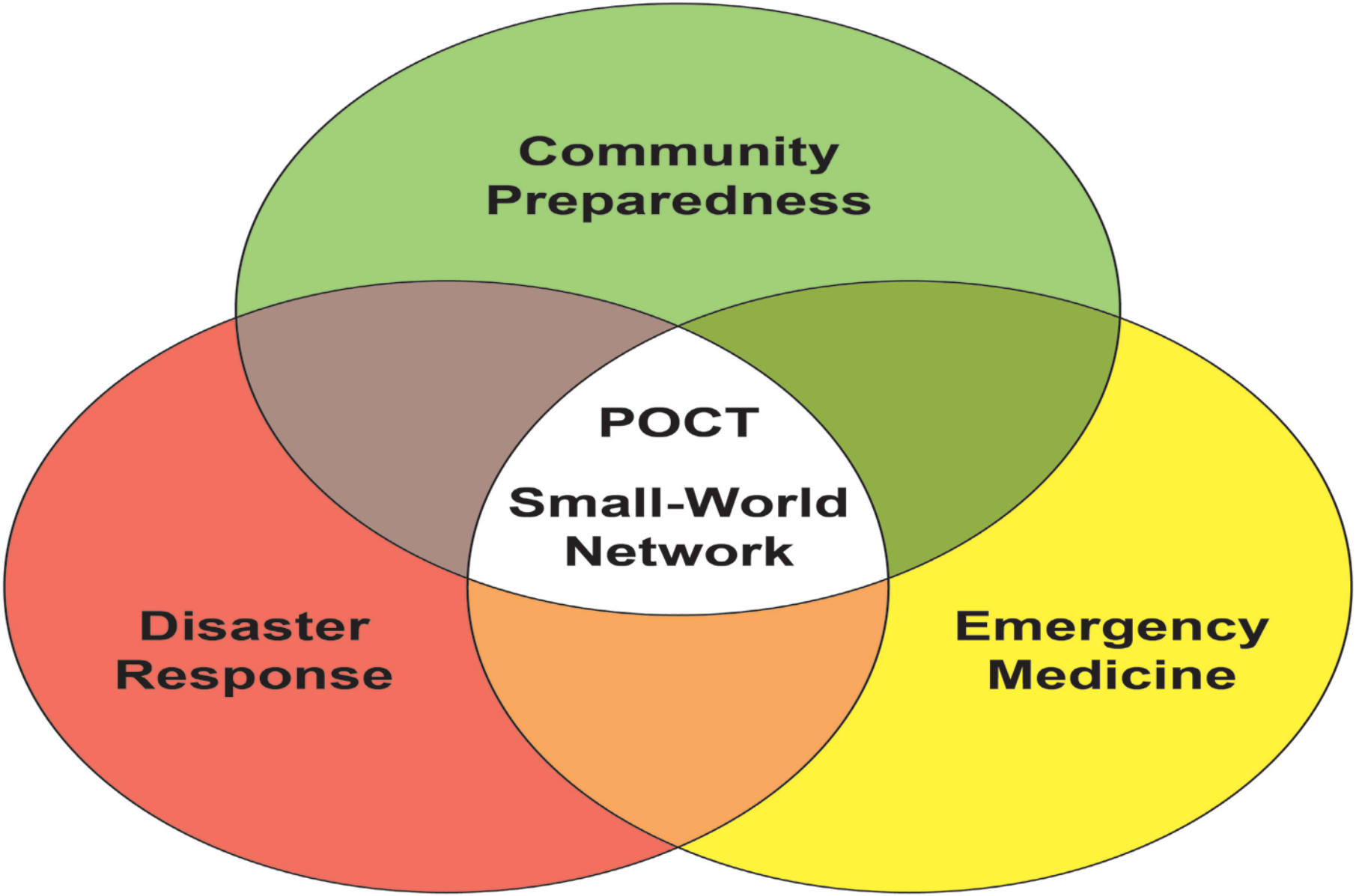


Sure-Vue® Urine hCG Cartridge

QuickVue® Influenza Test



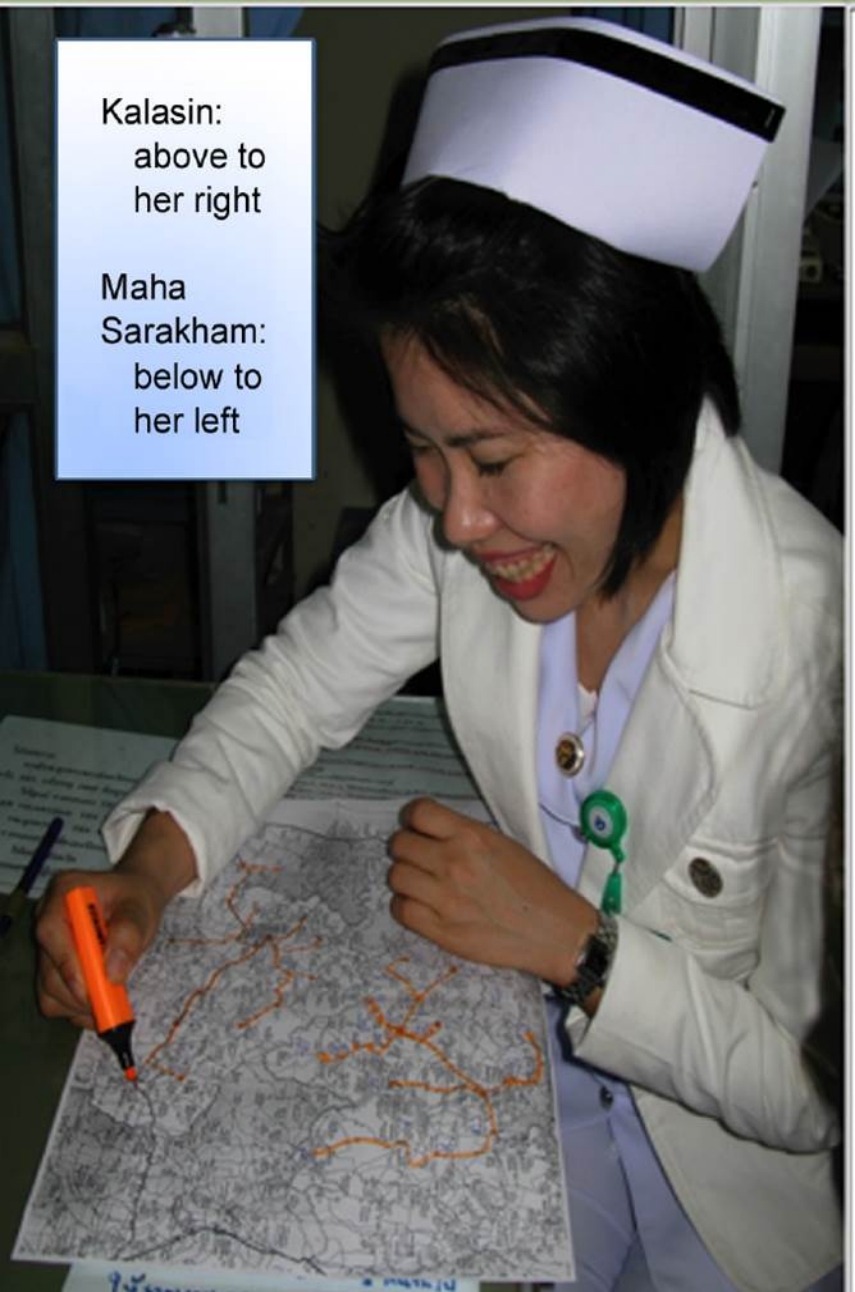
Reference: Curtis CM, et al. Innovations in point-of-care testing for enhanced U.S. disaster caches. *Am J Disaster Med. 2014*;8:181-204.

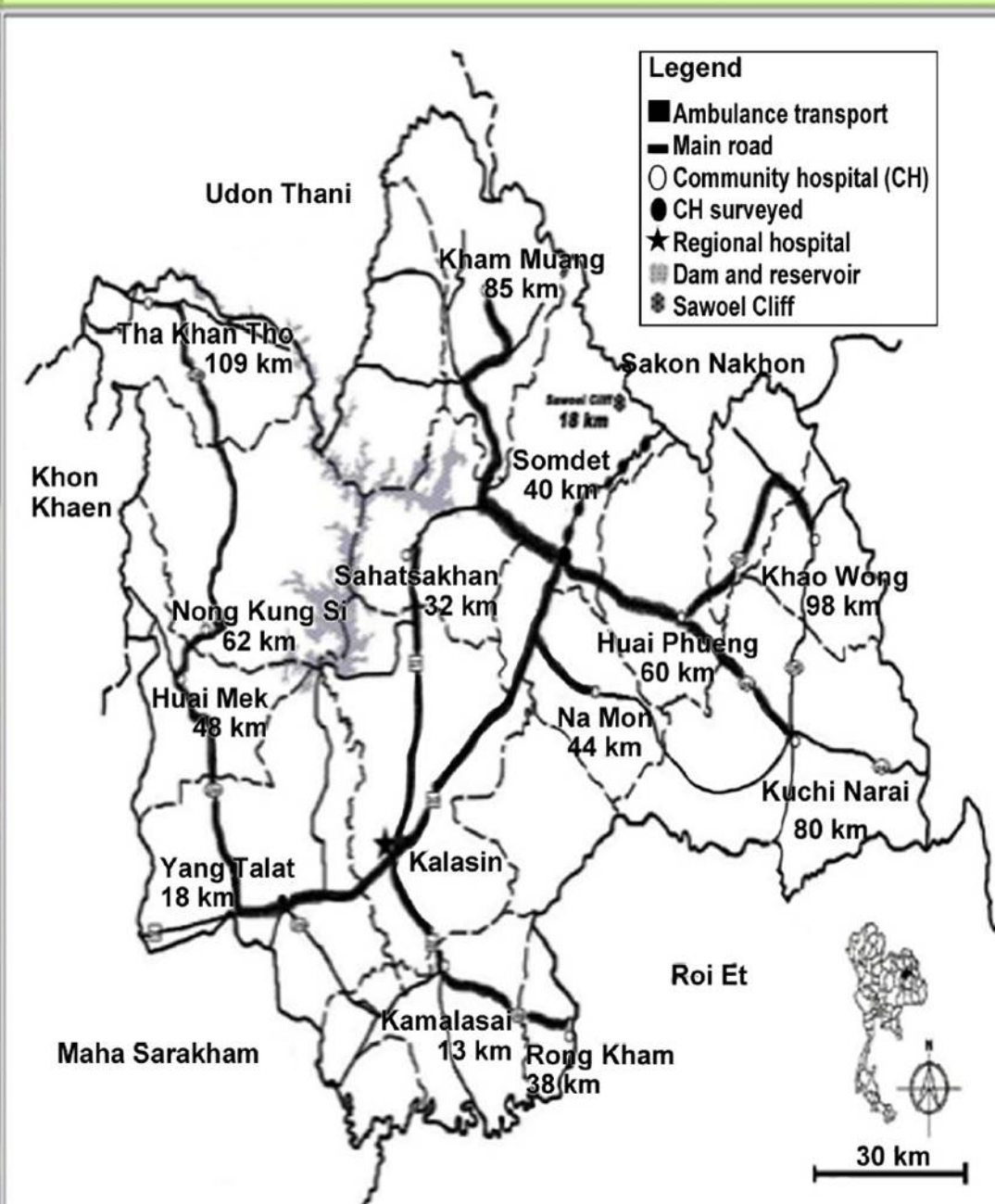


Reference: Kost GJ, Sakaguchi A, Curtis CM, Tran NK, Katip P, Louie RF. Enhancing crisis standards of care using innovative point-of-care testing. *Am J Disaster Med*. 2011;6:351-368.

Drawing Kalasin and Marha Sarakham Province SWN ambulance routes

Critical paths (bold) of Kalasin Province SWN extracted from the ER RN's highlights (orange)





THE SPATIAL CARE PATH™

- ***Definition:*** *The most effective route taken by the patient when receiving definitive care in a small-world network.*

- ***Hypothesis:*** *Integrates prevention and intervention to shift the focus upstream to the patient site early on, in order to save resources, time, and lives, and to stop outbreaks.*

- ***Features:*** *Starts with the patient rather than the institution, empowers primary care, establishes critical access using geographic information systems, positions POCT, and optimizes decision-making with "FAST POC."*

- ***Status:*** *Exploratory research.*

Reference: Kost GJ, Ferguson WJ, Kost LE. Principles of point of care culture, the spatial care path™, and enabling community and global resilience. *e-JIFCC*. 2014;25(2):4-23.

In this Issue: Focusing on POCT

The Journal of the International Federation of Clinical Chemistry and Laboratory Medicine

eJIFCC

Principles of point of care culture, the spatial care path™, and enabling community and global resilience

Gerald J. Kost, MD, PhD, MS, FACB[a,b,c]; William J. Ferguson, BS[a]; Laurie E. Kost, BS, MS[d]

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Running title
Enabling Community and Global Resilience

Key words
Care path, customs, decision-making, empowerment, geographic information systems (GIS), geography, intervention, lifestyle, medical poverty, needs assessment, point-of-care (POC) technologies, POC testing, prevention, public health jurisdictions, small-world network, survey, and value

ABSTRACT

Goals: This article a) defines point of care (POC) culture; b) presents seven underlying fundamental principles; c) describes the importance of needs assessment; d) introduces a new innovation, the spatial care path™; and e) illustrates how POC testing that properly fulfills needs and spatial care paths™ enable community and global resilience.

Observations: Often, POC testing supplants the conventional clinical laboratory, which may be too distant, prohibitively expensive, or simply not available in limited-resource settings. New POC technologies "fit" future medical problem solving. Screening and testing directly in the home or primary care facilitate rapid diagnosis, monitoring, and treatment. In contrast to the past where attention has been placed on emergency departments, hospitals, and referral centers, the spatial care path™ starts with the patient and guides him or her through an efficient strategy of care in small-world networks (SWNs) defined by local geography and topology, long-standing customs, public health jurisdictions, and geographic information systems (GIS).

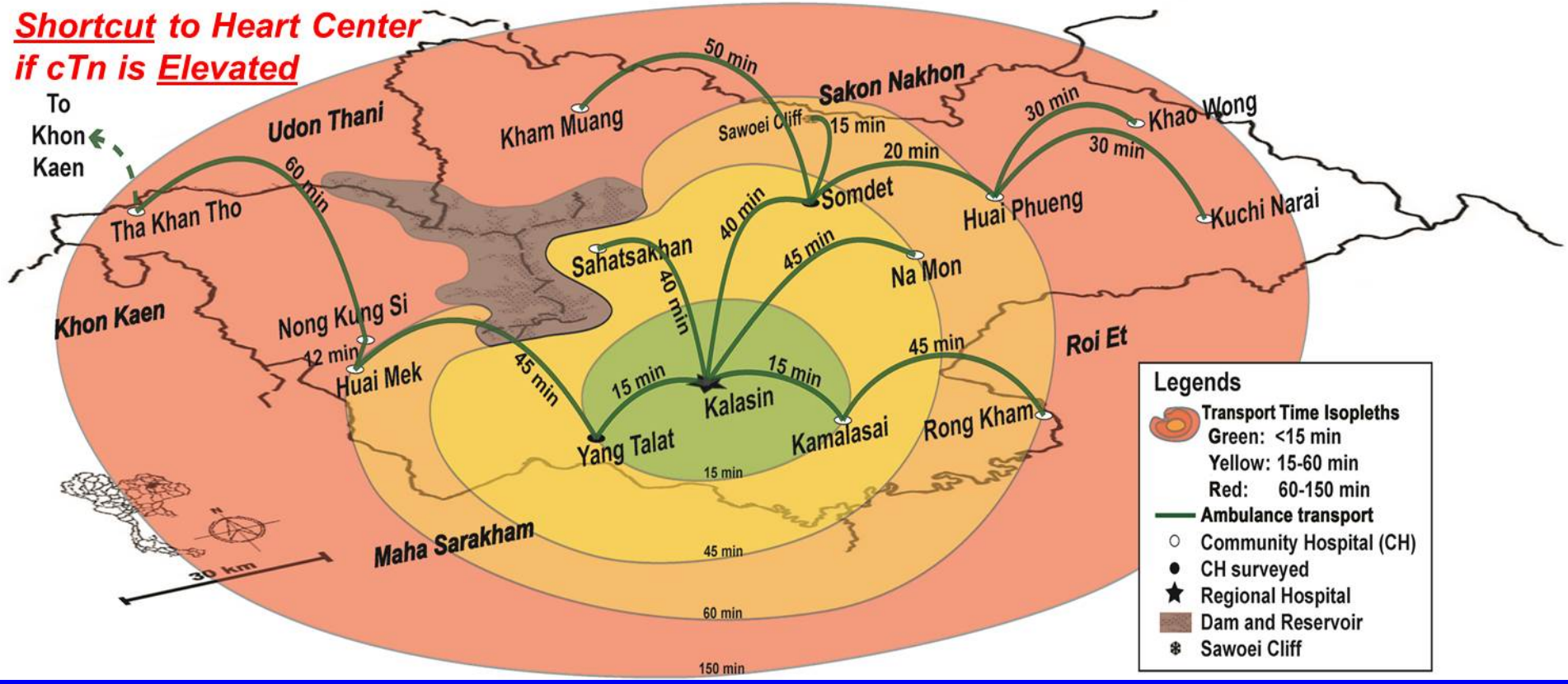
Conclusions: POC testing needs in limited-resource settings are striking. Fulfillment is best guided by thorough understanding of POC culture. Quick feedback and fast decision-making

PUBLISHED AUGUST 2014;25(2):4-23

Online Access:
http://www.ifcc.org/media/260912/eJIFCC%20August%202014.pdf

Transforming the Physical Domain to the Temporal Domain in Small-World Network Spatial Care Paths™

Acute Coronary Syndromes



Reference: Kost GJ. Theory, principles, and practice of optimizing point-of-care small-world networks. *Point of Care*. 2012;11:96-101.

. Am J Disaster Med. 2015 Spring;10(2):121-43. doi: 10.5055/ajdm.2015.0196.

The Ebola Spatial Care Path™: Accelerating point-of-care diagnosis, decision making, and community resilience in outbreaks.

Kost GJ[1], Ferguson WJ[2], Hoe J[2], Truong AT[2], Banpavichit A[3], Kongpila S[4].

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- [2]POCT•CTR, School of Medicine, University of California, Davis, Davis, California.
- [3]Managing Director, Owner, Connect Diagnostics, Bangkok, Thailand.
- [4]Lab Leader Company, Ltd., Bangkok, Thailand.

Abstract

OBJECTIVES:

To present a vision where point-ofcare testing (POCT) accelerates an Ebola Spatial Care Path™ (SCP) and future molecular diagnostics enable facilitated-access self-testing (FAST POC); to design an alternate care facility (ACF) for the SCP; to innovate an Ebola diagnostic center (DC); and to propel rapid POCT to the frontline to create resilience that stops future outbreaks.

DESIGN:

PubMed, literature, and web searches. Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Medicine Without Frontiers, and World Health Organization (WHO) document analyses. Investigations in China, the Philippines, Thailand, and the United States. Review of SE Asia, US, and West Africa isolation-treatment centers. Innovation of a SCP, ACF, and DC suitable for American and other communities.

OUTCOMES:

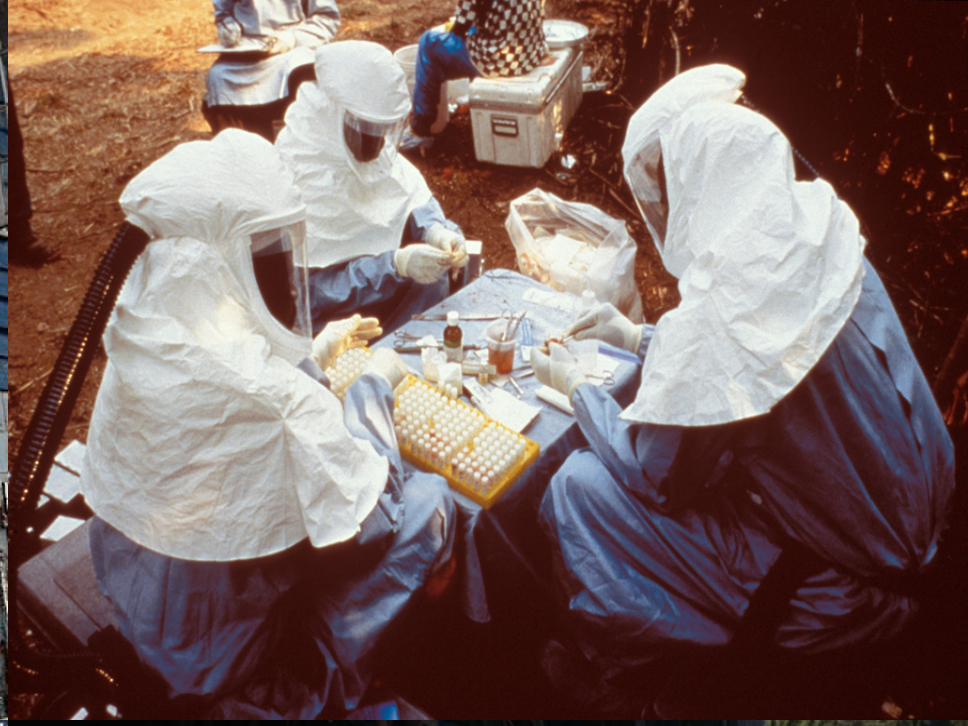
The authors designed an ACF and DC to integrate SCP principles for urgent Ebola care. FDA emergency use authorizations for Ebola molecular diagnostics were discovered, but no portable, handheld, or selfcontained molecular POC instruments are yet available, although feasible. The WHO initiated design criteria and an acceptance protocol for testing. Financial investment in POCT will downsize Ebola outbreaks.

CONCLUSIONS:

POCT is facilitating global health. Now, global health problems are elevating POCT to new levels of importance for accelerating diagnosis and evidence-based decision making during disease outbreaks. Authorities concur that rapid diagnosis has potential to stop disease spread. With embedded POCT, strategic SCPs planned by communities fulfill CDC recommendations. POC devices should consolidate multiplex test clusters supporting patients with Ebola in isolation. The ultimate future solution is FAST POC. New technologies offer minimally significant risks. Diagnostic centers in ACFs and transportable formats also will optimize Ebola SCPs.

PMID: 26312494 [PubMed - in process]


Irish Aid
EBOLA
Signs and Symptoms
FEVER
BLOODY DIARRHOEA
BLEEDING
VOMITING BLOOD
MUSCLE OR JOINT PAIN
SKIN RASH
If You Have Fever, Diarrhoea and Vomiting With or Without Bleeding
GO IMMEDIATELY TO THE NEAREST HEALTH FACILITY
For more information call 117 (Call free)
GOAL




C.N.P.

Ebola Preparedness and Resilience

First, let's recognize that we are not yet prepared!
…and what of others, MERS CoV or new highly infectious threats?

- **POCT to detect threats early, isolate effectively, & stop outbreaks**
- **Portable molecular diagnostics with ultrahigh sensitivity and specificity**
- **"FAST-POC" (facilitated-access self-testing) to avoid exposure of the healthcare workforce**
- **Accelerated availability of "EUA" devices (emergency use authorization, US FDA approval)**
- **Harmonized strategies for communities at risk**
- **National POCT policy and guidelines for foundation and integrated "point of care culture"**

Developing a Spatial Care Path™ for Ebola

Enzootic Cycle

New evidence strongly implicates bats as the reservoir hosts for ebolaviruses, though the means of local enzootic maintainance and transmission of the virus within bat populations remain unknown.

Ebolaviruses:

Ebola virus (formerly Zaire virus)
Sudan virus
Taï Forest virus
Bundibugyo virus
Reston virus (non-human)

Epizootic Cycle

Epizootics caused by ebolaviruses appear sporadically, producing high mortality among non-human primates and duikers and may precede human outbreaks. Epidemics caused by ebolaviruses produce acute disease among humans, with the exception of Reston virus which does not produce detectable disease in humans. Little is known about how the virus first passes to humans, triggering waves of human-to-human transmission, and an epidemic.

Human-to-human transmission is a predominant feature of epidemics.

Following initial human infection through contact with an infected bat or other wild animal, human-to-human transmission often occurs.

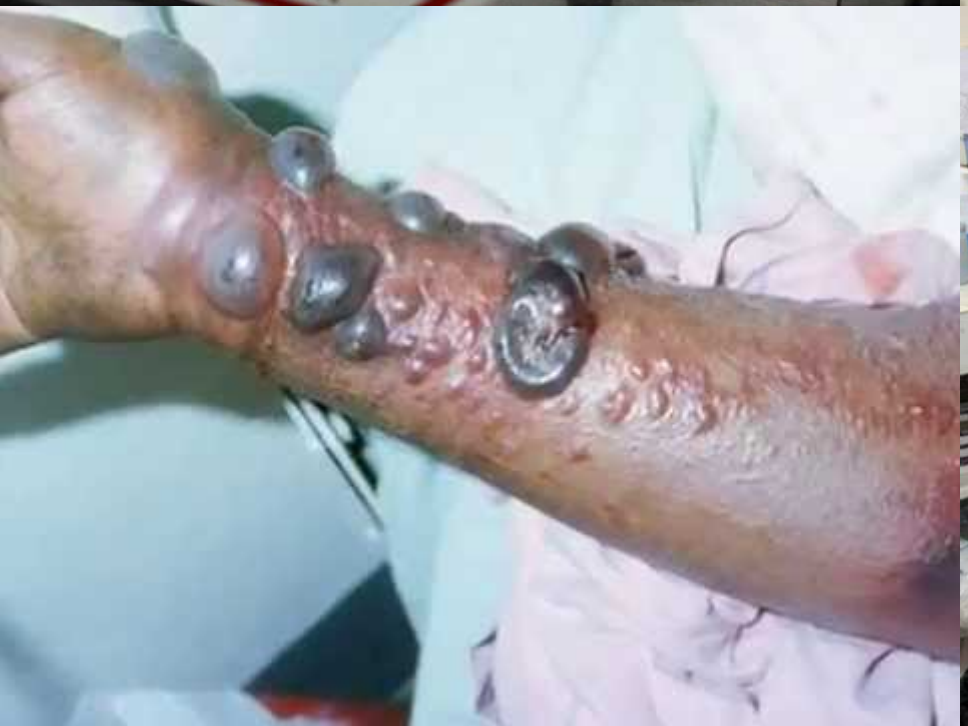
CDC

Laboratory Diagnosis of Ebola—Too Slow!

TIMELINE OF INFECTION	DIAGNOSTIC TESTS AVAILABLE
Within a few days after symptoms begin	Antigen-capture enzyme-linked immunosorbent assay (ELISA) test
	IgM ELISA
	Polymerase chain reaction (PCR)
	Virus isolation
Later in disease course or after recovery	IgM and IgG antibodies
	Immunohistochemistry test
	PCR
Retrospectively in deceased patients	Virus isolation

Source: Centers for Disease Control. http://www.cdc.gov/vhf/ebola/diagnosis/ Accessed October 18, 2014

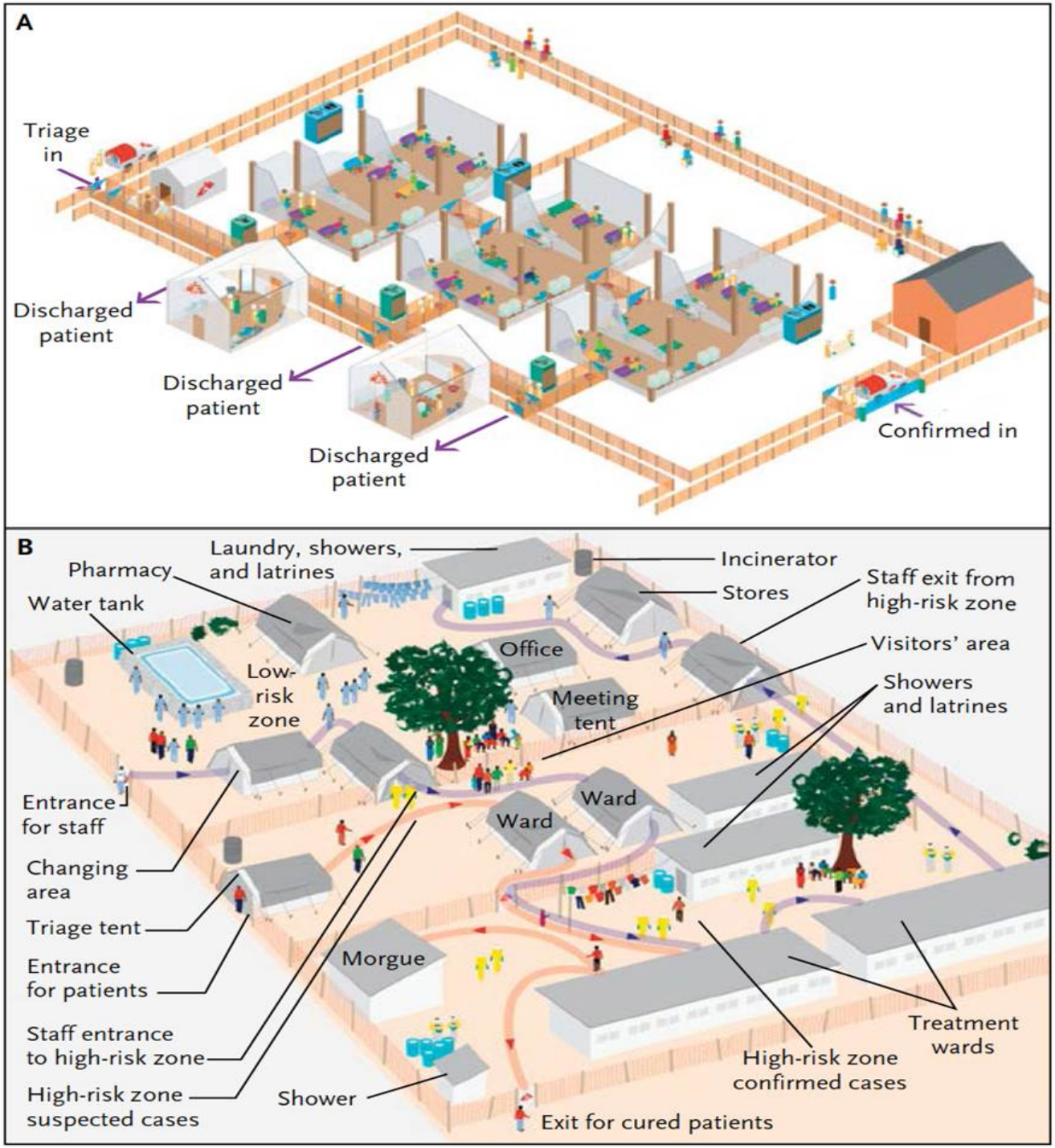

STOP
PERSONAL
PROTECTIVE
EQUIPMENT
REQUIRED
BEYOND THIS
POINT



Ebola Containment

Top (A)
High Risk Zone

Bottom (B)
A Complete Center



From Chertow DS et al. Ebola Virus disease in West Africa—Clinical Manifestations and Management. *New England Journal of Medicine*. 2014; November 5.

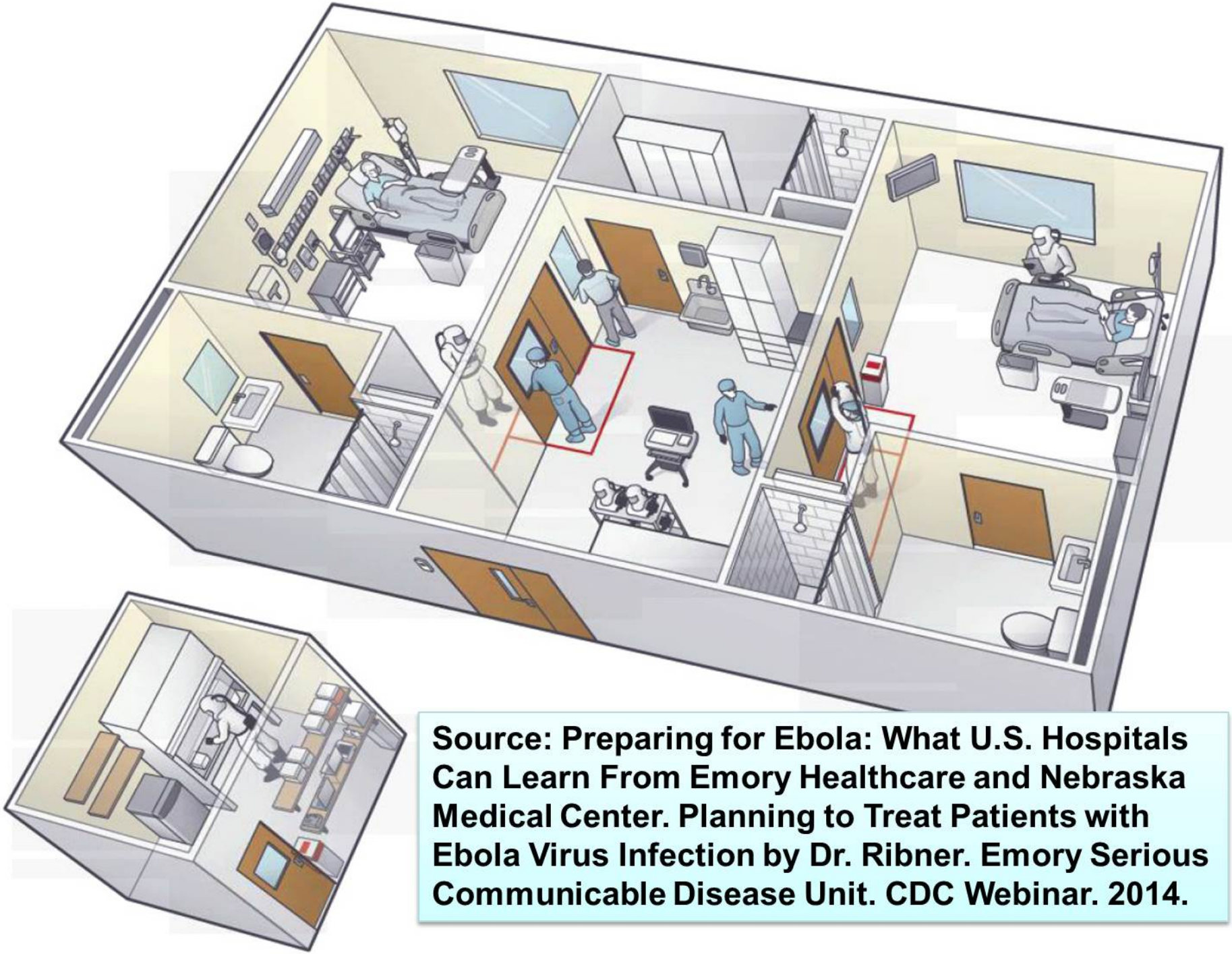
Move POC testing upstream in the spatial care path.™ Detect the disease before the patient spreads it!

World Health Organization

"Target Product Profile for *Zaire Ebola virus rapid, simple test* to be used in the control of the Ebola outbreak in West Africa"

Source: http://www.who.int/medicines/publications/target-product-profile.pdf?ua=1

KEY FEATURES	DESIRED	ACCEPTABLE
PRIORITY FEATURES		
Target population	*Warning!* Patients presenting with fever to health care facilities for assessment.	
Target use setting	Decentralized health care facilities with no laboratories infrastructure available	Decentralized health care facilities with minimum laboratory infrastructures available.
Intended Use	In Ebola outbreak setting, distinguish between symptomatic patients with acute Ebola virus infection and non-Ebola virus infection without the need for confirmatory testing	In Ebola outbreak setting, distinguish between symptomatic patients with acute Ebola virus infection and non-Ebola virus infection with the need for confirmatory testing
Clinical sensitivity[a, b]	> 98%	>95%
Analytical specificity	>99%	>99%
Type of analysis	Qualitative or Quantitative	Qualitative
Sample type	• Capillary whole blood from finger stick once/if the use of this type of samples has been validated. • Other less invasive sample types (e.g.., saliva, buccal) once/if their use has also been validated	Whole blood from phlebotomy, in particular if collection is simple and automated to reduce biosafety requirements
TEST PROCEDURE		
Number of steps to be performed by operator (use of different reagents/incubation steps)	< 3 0 timed steps	<10 1 timed step
Biosafety[c]	No additional biosafety in addition to Personal Protective Equipment [c]	No additional biosafety in addition to Personal Protective Equipment [c]
Need for operator to transfer a precise volume of sample	No	Acceptable if adequate disposable blood transfer device is provided
Time to result	< 30 minutes	< 3 hours
Internal control	included	included



Source: Preparing for Ebola: What U.S. Hospitals Can Learn From Emory Healthcare and Nebraska Medical Center. Planning to Treat Patients with Ebola Virus Infection by Dr. Ribner. Emory Serious Communicable Disease Unit. CDC Webinar. 2014.

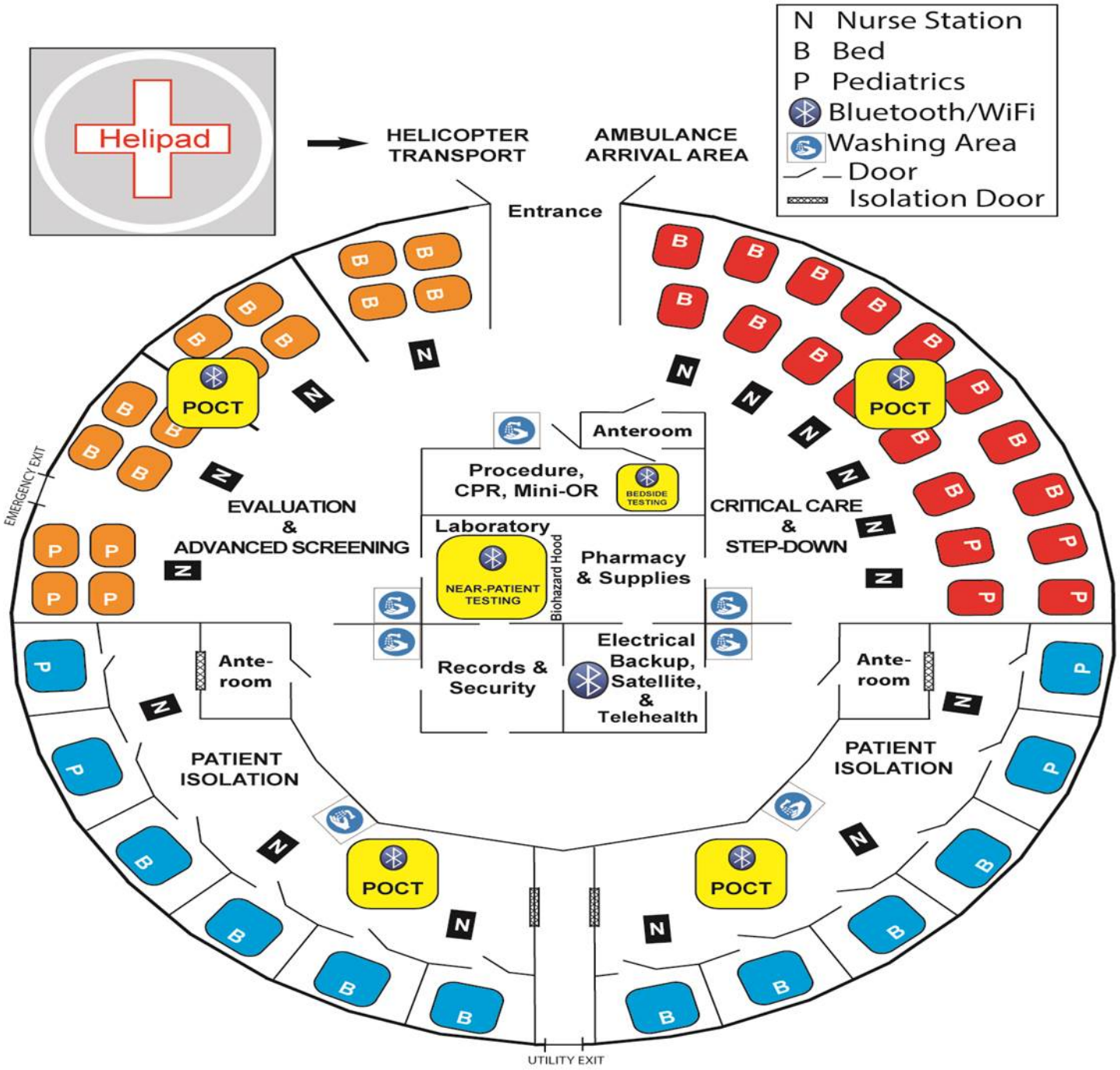
Point-of-Care Tests Established in Ebola Isolation Areas

Ebola proved the absolute need for POCT!

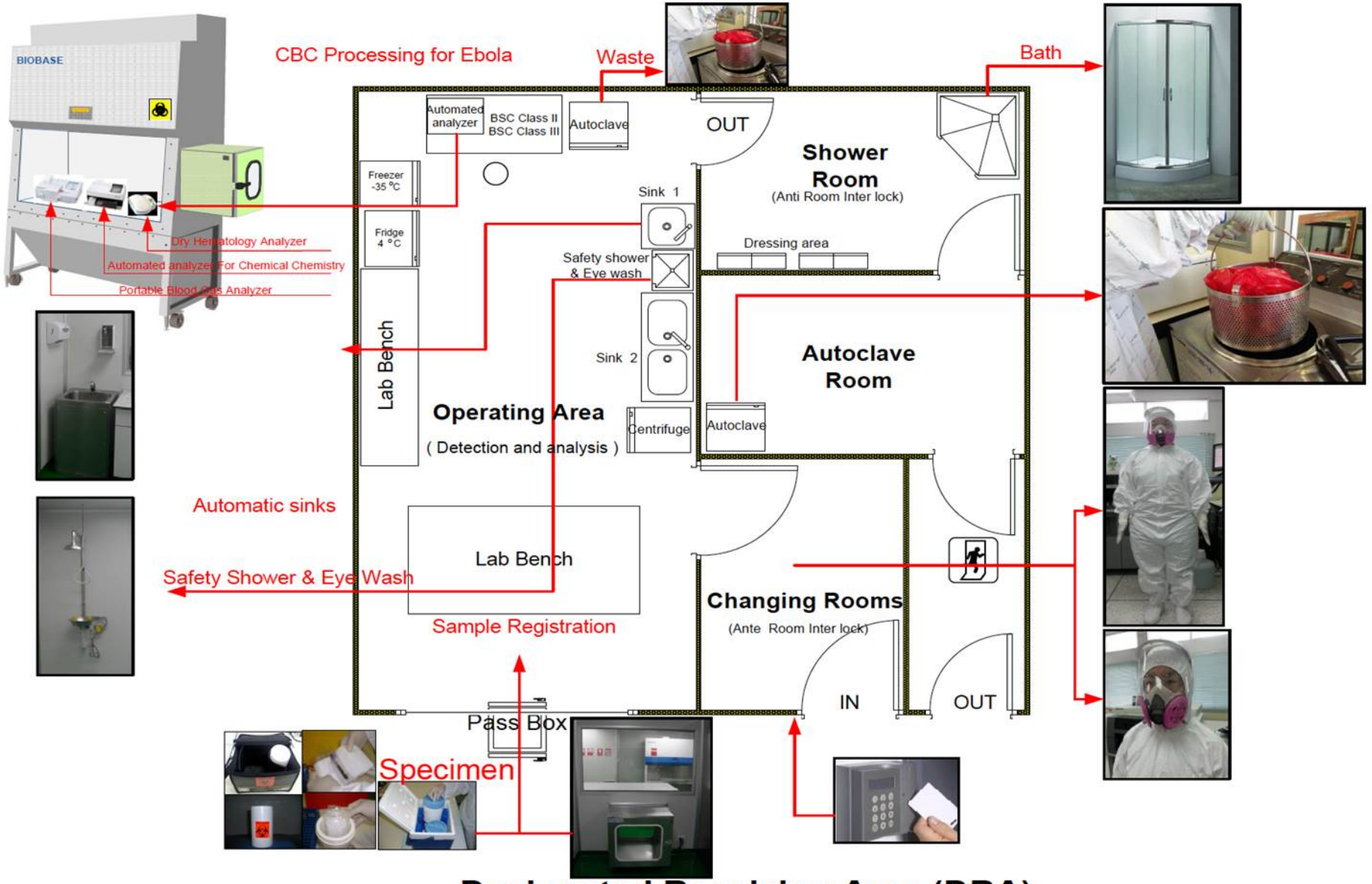
A. Emory University Hospital Specialized Isolation Area[9]

Manufacturer Website	Instrument	Test(s)
Abaxis www.abaxis.com	Piccolo Express	Chemistry profiles, Magnesium, Phosphate, liver enzyme assays, others available[a]
Instrumentation Laboratory www.instrumentationlaboratory.com	GEM Premier 4000	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Glu, Lac, Hct, THb, CO-Oximetry, TBil
Siemens www.healthcare.siemens.com	CLINITEK Status automated urinalysis	Albumin, Bilirubin, Cr, Glu, Ketone, Leukocytes, Nitrite, pH, Protein, Specific Gravity, Urobilinogen, others available[b]
Hoffman-La Roche www.coaguchek.com	CoaguChek	PT/INR[c]
Sysmex www.sysmex.com	pocH-100i	CBC: WBC (3-part differential), RBC, Hb, Hct, MCV, MCH, MCHC, Platelets[d]
Alere www.alere.com	BinaxNOW	Malaria
BioFire Diagnostics www.biofiredx.com	FilmArray	Infectious diseases including Ebola[e] (see **Table 1**)

Alternate Care Facility for Ebola Triage and Care



Diagnostic Center



DE GRUYTER Clin Chem Lab Med 2015; 53(12): 1903–1910

Mini Review

Late Breaking News!

Belen Fernandez-Puntero*, Ruben Gomez-Rioja, Maria Jose Alcaide, Paloma Oliver, Pilar Fernandez-Calle, Jose Manuel Iturzaeta and Antonio Buno

The Laboratory Medicine and the care of patients infected by the Ebola virus. Experience in a reference hospital of Madrid, Spain

Abstract

The ongoing Ebola virus outbreak in several countries in West Africa was considered by the World Health Organisation (WHO) as a public health emergency of international concern. Healthcare providers must be prepared by organising specific procedures in our hospitals based on recommendations from national and international healthcare organisations. Two aims should be considered: appropriate medical care for patients with suspected or confirmed disease must be ensured, as must measures to prevent transmission to healthcare workers. The clinical laboratory plays an important role and must define and establish its own procedures in accordance with clinicians and integrated into those of the institution, starting with the definition of the organisation model in the laboratory to achieve those goals. In this review we present our experience based on the care of three patients with confirmed cases. We hope it will help other colleagues to plan for Ebola.

Table 1: Containers, analysers (provider) and tests.

Care for the first patient			Care for subsequent patients		
Container	**Device**	**Tests**	**Container**	**Device**	**Tests**
1 Tube of dipotassium EDTA	PocH-100*i* (Sysmex-Roche, Madrid, Spain)	Differential blood count 3 diff	1 Tube dipotassium EDTA	PocH-100*i* (Sysmex-Roche, Madrid,Spain)	Differential blood count 3 diff
	SPOTCHEM-EZ (Arkray-Menarini, Madrid, Spain)	Glucose Cholesterol Total proteins Creatinine BUN Total bilirubin AST ALT	1 Tube lithium heparin	SPOTCHEM-EZ (Arkray-Menarini, Madrid, Spain)	Total proteins Albumin Creatinine BUN Uric acid Total bilirubin AST ALT LD CK Total calcium Magnesium Inorganic phosphorus
1 Syringe lithium heparin	SPOTCHEM-EL (Arkray-Menarini, Madrid, Spain) NPT-7 (Radiometer, Madrid, Spain)	Sodium, Potassium, Chlorine ions pH $PaCO_2$ PaO_2 Oxygen saturation Cooximetry Bicarbonate Excess of base Total CO_2 concentration	1 Syringe lithium heparin	EPOCAL (Alere, Madrid, Spain)	Sodium and Potassium ions Glucose Ionized calcium Lactate pH $PaCO_2$ PaO_2 Oxygen saturation Bicarbonate Excess of base Total CO_2 concentration
1 Drop whole blood	COAGUCHECK (Roche, Madrid, Spain)	INR	1 Syringe without anticoagulant with whole blood	COAGUCHECK (Roche, Madrid, Spain)	INR

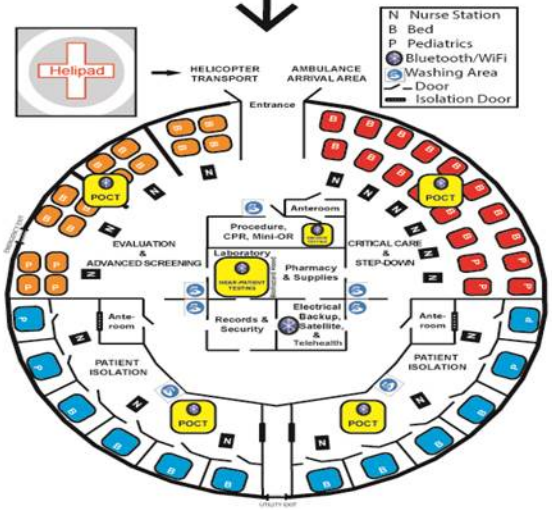
SPATIAL CARE PATH™

HYBRID SOLUTION

SYMPTOMATIC PATIENT

RAPID MOLECULAR TESTING

TN, *FN(t)*



ALTERNATE CARE FACILITY

- Dynamic Segregation
- POC Coordinator
- Fully Equipped POCT
- Telehealth

HIGHER EFFICIENCY
LOWER RISK

OPTIMIZED POC SOLUTION

COMMUNITY RESILIENCE

EXPOSED PATIENT

CLINICAL EVALUATION & DIAGNOSTIC TESTING

POC WBC, DIFFERENTIAL & PLATELET COUNT
INR, aPTT, Bleeding Time, ALT, & AST

LIMITED QUARANTINE
VACCINATION

HIGHLY INFECTIOUS DISEASE BEDS WITH ANTEROOM

BLOOD SAMPLE PROCESSED IN ISOLATION UNIT &/OR TRANSPORTED TO REFERRAL LAB:
-CDC
-PUBLIC HEALTH

SLOWER RESPONSE
GREATER EXPENSE

INTEGRATED PLANNING

SWN

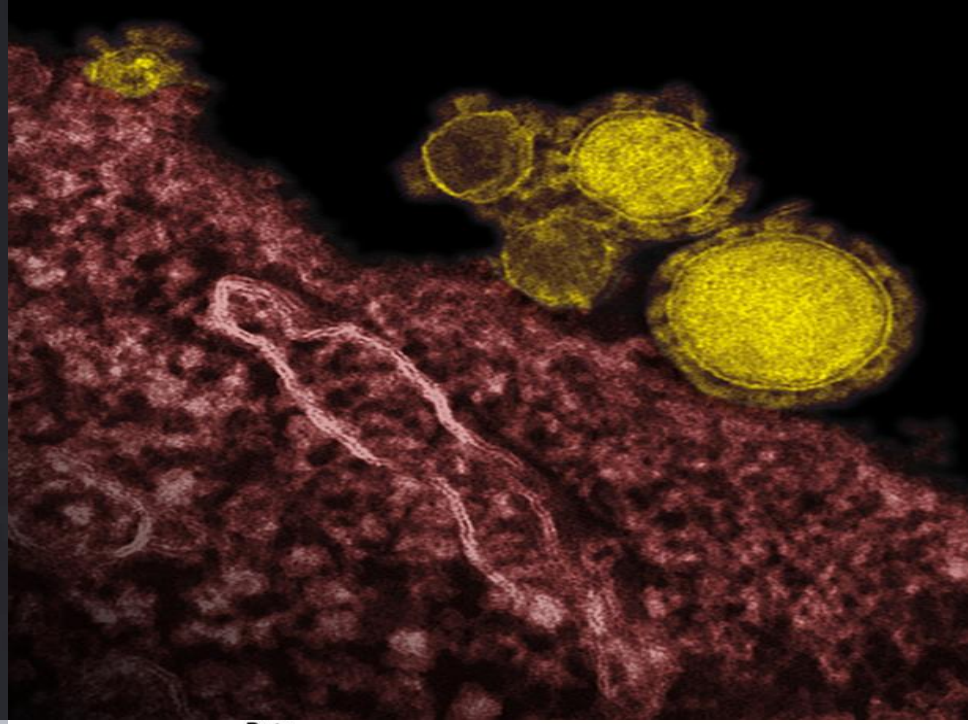
CDC REQUIREMENTS FOR EBOLA CENTERS

NEW 2015

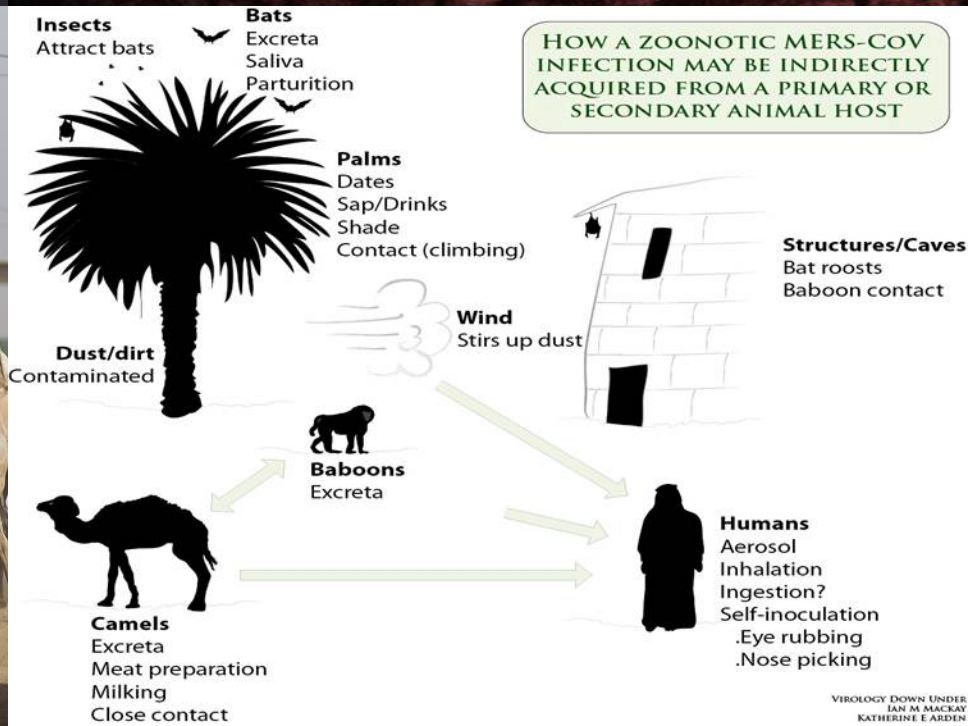
- Accept patients within eight hours of being notified,
- Have the capacity to treat at least two Ebola patients at the same time,
- Have respiratory infectious disease isolation capacity or negative pressure rooms for at least 10 patients,
- Conduct quarterly trainings and exercises,
- Receive an annual readiness assessment from the soon-to-be-established National Ebola Training and Education Center, composed of experts from health care facilities that have safely and successfully cared for patients with Ebola in the U.S., and funded by ASPR and the Centers for Disease Control and Prevention, to ensure clinical staff is adequately prepared and trained to safely treat patients with Ebola and other infectious diseases,
- Be able to treat pediatric patients with Ebola or other infectious diseases or partner with a neighboring facility to do so, and,
- Be able to safely handle Ebola-contaminated or other highly contaminated infectious waste.

Does not require POC resources or strategies.
No harmonized POC testing, molecular diagnostics, or early detection.
Neglects integrated community resilience and optimized geospatial care (no SCP).

Source: ASPR Press Office. HHS selects nine regional Ebola and other special pathogen treatment centers. June 12, 2015. HSS.gov or http://www.hhs.gov/news




Camels vs. Humans

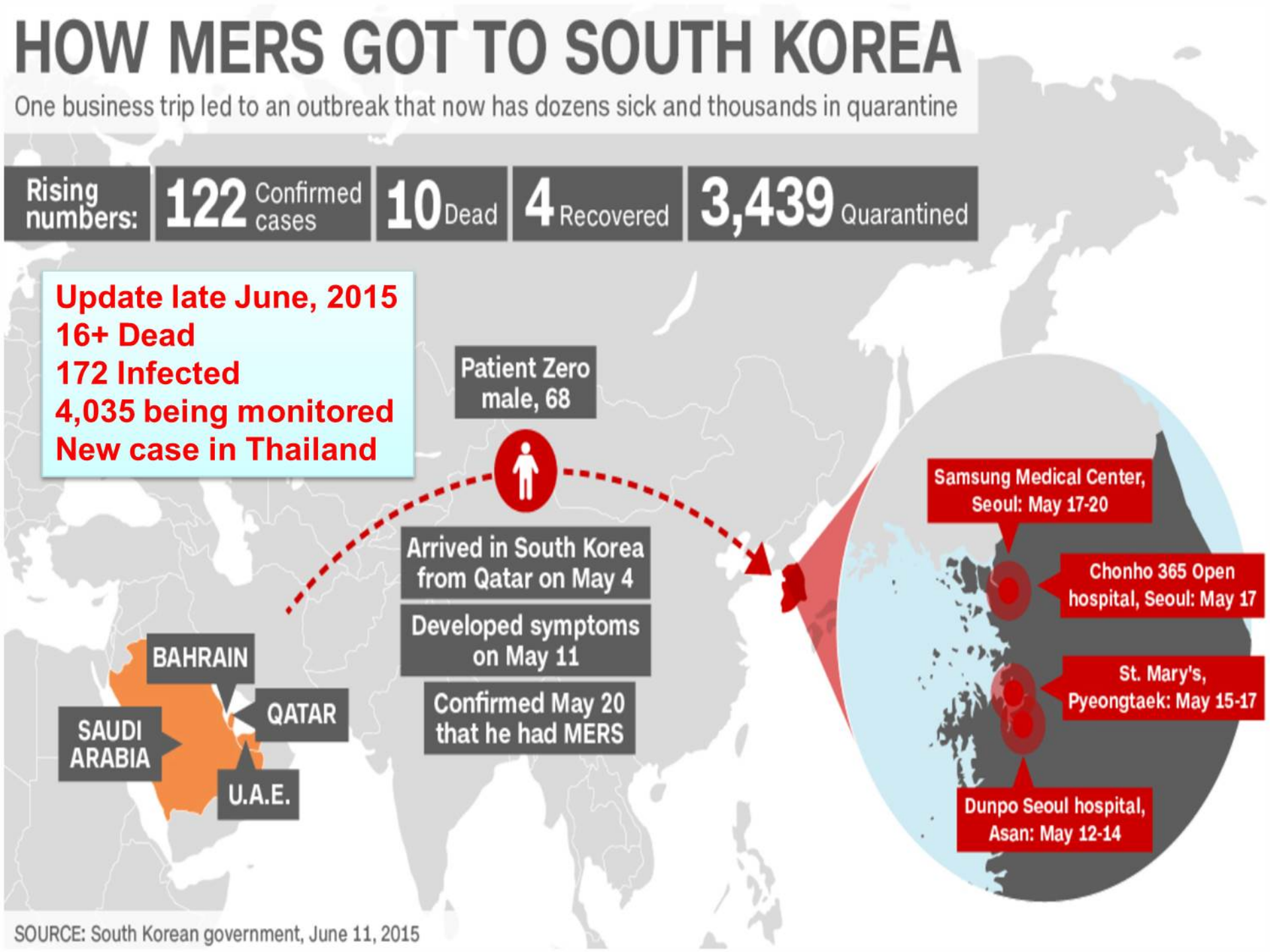

HOW A ZOONOTIC MERS-CoV INFECTION MAY BE INDIRECTLY ACQUIRED FROM A PRIMARY OR SECONDARY ANIMAL HOST
Insects
Attract bats
Bats
Excreta
Saliva
Parturition
Palms
Dates
Sap/Drinks
Shade
Contact (climbing)
Structures/Caves
Bat roosts
Baboon contact
Wind
Stirs up dust
Dust/dirt
Contaminated
Baboons
Excreta
Camels
Excreta
Meat preparation
Milking
Close contact
Humans
Aerosol
Inhalation
Ingestion?
Self-inoculation
.Eye rubbing
.Nose picking
VIROLOGY DOWN UNDER
IAN M MACKAY
KATHERINE E ARDEN

HOW MERS GOT TO SOUTH KOREA

One business trip led to an outbreak that now has dozens sick and thousands in quarantine

Rising numbers:	122 Confirmed cases	10 Dead	4 Recovered	3,439 Quarantined

Update late June, 2015
16+ Dead
172 Infected
4,035 being monitored
New case in Thailand



SOURCE: South Korean government, June 11, 2015


1.000~
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설악건강원

EXPERT REVIEWS

Molecular detection and point-of-care testing in Ebola virus disease and other threats: a new global public health framework to stop outbreaks

Expert Rev. Mol. Diagn. 15(10), 000–000 (2015)

Gerald J Kost*, William Ferguson, Anh-Thu Truong, Jackie Hoe, Daisy Prom, Arirat Banpavichit and Surin Kongpila

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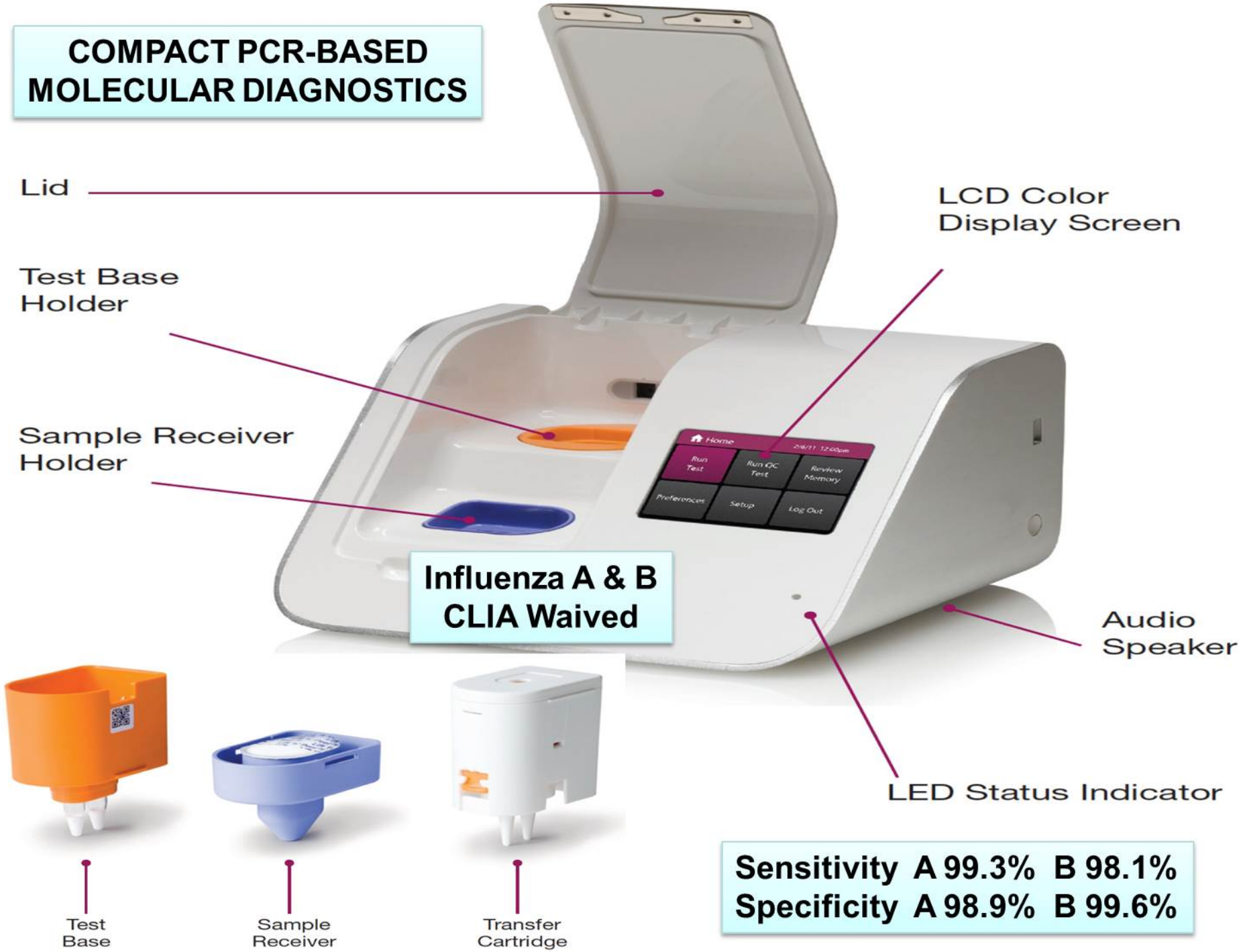
Ultrahigh sensitivity and specificity assays that detect Ebola virus disease or other highly contagious and deadly diseases quickly and successfully upstream in Spatial Care Paths™ can stop outbreaks from escalating into devastating epidemics ravaging communities locally and countries globally. Even had the WHO and CDC responded more quickly and not misjudged the dissemination of Ebola in West Africa and other world regions, mobile rapid diagnostics were, and still are, not readily available for immediate and definitive diagnosis, a stunning strategic flaw that needs correcting worldwide. This article strategizes point-of-care testing for diagnosis, triage, monitoring, recovery and stopping outbreaks in the USA and other countries; reviews Ebola molecular diagnostics, summarizes USA. FDA emergency use authorizations and documents why they should not be stop-gaps; and reduces community risk from internal and external infectious disease threats by enabling public health at points of need.

Table 3. The rapid evolution of diagnostics for Ebola virus disease.

Instrument(s) &/or Assay/Kit Manufacturer	Principle	Sample(s)	Time to Results	FDA Status
Xpert Ebola Assay Cepheid	rRT-PCR Cartridge-based	Blood	2 h	EUA 3/23/15
Corgenix ReEBOV & Fio Corp†	Lateral flow Ag immunoassay, Deki reader, smartphone data capture, & case tracking	Blood or plasma	15 min	EUA 3/16/15 [eligible for WHO procurement]
LIghtMix Roche cobas z480	rRT-PCR	Blood	Over 3 h	EUA 12/23/14
QIAamp Viral Kit RealStar Filovirus: ABI Prism 7500 SDS LightCycler 480 II CFX96/Dx RT Sys	rRT-PCR (Kit 1.0)	Blood, plasma	Varies with instrument	EUA 11/26/14 [eligible for WHO‡ procurement]
BioFire Defense Biothreat-E/NGDS bioMerieux§ [in 300 hospitals]	Film Array EZV Auto'd. rRT-PCR	Blood, urine (if matched to blood)	1 h	EUA 10/25/14 3/2/15 (RI)
MagMax Pathogen Kit, Dynal Bead Re. ABI 7500 BioRad CFX96	CDC NP rRT-PCR VP40 rRT-PCR	Blood, plasma, serum, urine (if matched)	NS	EUA 10/10/14 3/2/15 (RI)
ABI 7500 LightCycler 480 JBAIDS	DOD EZ1 rRT-PCR TaqMan Assay	Inactivated whole blood & plasma	Varies with instrument	EUA 10/10/14
Nanomix [Corgenix & Tulane University]	Carbon nanotube biosensor¶ Handheld multiplex cartridge-based	Pinprick capillary blood	10 min	No EUA# (see above)
Lucigen AmpliFire [Douglas Sci., UTMB, CDC]	LAMP (isothermal) 1-step, battery-operated, portable††	RNA extract [plan 50 µL POC fingerstick capillary blood]	40 min	No EUA#
Biomarkers USAMRIID/ECBC/TFS	Mass spectrometry	In development	NS	No EUA#
OraQuick‡‡ Orasure	CLF Ag assay [EZV, SEV, & BEV not differentiated]	In development: saliva sample	Est. 20 min	EUA# 7/31/15 [venous WB & fingerstick WB; not for screening, e.g., in airports; not for contact tracing]

COMPACT PCR-BASED MOLECULAR DIAGNOSTICS



Sensitivity A 99.3% B 98.1%
Specificity A 98.9% B 99.6%

CONCEPT SOLUTION
USING "*FAST POC™*" TO STOP OUTBREAKS!

Definition: *Facilitated-access Self-testing Point of Care*

The patient obtains his or her own (capillary blood, saliva, urine, or other) sample with an automatic retractable lancet or suitably simple sampling device built into a self-aspirating and self-contained microcassette, microcuvette, or cartridge, which then seals for automatic testing and automated processing by a POC instrument, while another person, the "facilitator," instructs and guides hands off, so there is extremely limited or no exposure to infectious agents.


Next Step
Insert the FAST strip with your sample into the reagent cassette.

A

Influenza A & B (CLIA Waived)
Sensitivity A 100% B 100%
Specificity A 96.8% B 94.1%

B

20 min PCR assay

C

Sample

Scan

Start

Global Point of Care

Strategies for Disasters, Emergencies, and Public Health Resilience

Edited by

Gerald J. Kost

&

Corbin M. Curtis

AACCPress

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UNDERSTANDING OF POINT OF CARE CULTURE IMPROVES RESILIENCE AND STANDARDS OF CARE IN LIMITED-RESOURCE COUNTRIES

GERALD J. KOST, YIMENG ZHOU, AND PRATHEEP KATIP

OVERVIEW

This chapter (a) defines point of care (POC) culture and reviews the historical impact of cultural aspects of medical care; (b) analyzes the underlying principles of POC culture in order to produce a future vision for POC testing (POCT); (c) describes how to characterize POC culture using formal subject surveys; (d) assesses objective and practical methods for implementing emerging POC technologies while simultaneously targeting value; (e) investigates four country settings where cultural attributes, including education, demography, eating habits, geography, politics, religion, and social science affect patient lifestyles, medical care, and health outcomes; and (f) with the aid of survey evidence showing subject preferences, prioritizes clever point of care, such as fingertip pulse oximeters and noninvasive skin autofluorescence (SAF) screening of prediabetes risk, in value propositions for nations seeking resilience for huge populations at risk. We investigated: (a) the status of POC culture in China and three ASEAN member states: Cambodia, Indonesia, and Thailand; (b) cultural factors based on preliminary survey results; and (c) the ability of new POC technologies to "fit" future medical problem solving, with emphasis on prediabetes and diabetes, for which we created a POCT-driven care path. Screening and testing directly in primary care facilitate unique rapid diagnosis, monitoring, and treatment. Often, POCT supplants the conventional clinical laboratory, which may be too distant, prohibitively expensive, or simply not available in limited-resource settings. Needs for POCT in these settings are striking, but fulfillment should be guided by thorough understanding of POC culture. Quick feedback and fast decision making by patients and physicians alike yield significant value that motivates necessary changes in patient lifestyles and physician interactions. Therefore, culturally sensitive technology assimilation ranks highly when addressing leadership challenges in nations adapting to increasing populations of both young and old persons, despite scarcity of resources. Global harmonization of POC performance and astute cultural awareness accelerate favorable outcomes by improving the quality, usefulness, speed, and effectiveness of medical decision making. Worldwide outreach and carefully designed POC strategies in small-world networks (SWNs) enhance standards of care, including crisis standards of care for complex emergencies, natural disasters, and public health pandemics. At the same time, these strategies address evolving "newdemics" that burden nations economically. Despite episodic unexpected chaos from weather disasters and other natural calamities, predictable medical problems, such as obesity and prediabetes, should be addressed now at the point of need using point of care in proper cultural context with sound value propositions, while there is still time to avoid adverse and expensive consequences.

DEFINITIONS AND SCOPE

Broadly interpreted, culture, per se, has several practical definitions, including the beliefs, customs, and arts of a particular society, group, place, or time; a society that has its own ways of life; and a way of thinking, behaving, or working that exists in a place or organization. Point of care culture is medical empowerment of the individual and family nucleus integrated with norms, behaviors, beliefs, attitudes, expectations, POC technology, and outcomes *(1)*. Point of care culture crosses the standard definitional dimensions of culture, because health is at the core of human existence, and people expect society to assure their good health. Expectations are strong beliefs that something will happen in the future. New technologies weigh heavily on expectations, and therefore, expectations should be assessed through frequent surveys designed to improve health with POCT.

POCT is medical testing at or near the site of care *(2)*. It includes in vitro testing with handheld, portable, and transportable instruments, as well as self-monitoring and noninvasive scanning. A newdemic is a simultaneous set of unexpected and disruptive problems that affect the health of large numbers of individuals in a crowded world *(3)*. A SWN is a loosely tied

Research in limited-resource and other settings. POC culture is medical empowerment of the individual and family nucleus integrated with norms, behaviors, beliefs, attitudes, expectations, POC technology, and outcomes—the final

WHAT WE HAVE LEARNED!

- ***Needs assessment defines the role of POCT in pandemics, complex emergencies, disasters, and outbreaks.***

- ***Environmental stresses affect test results and must be avoided, so that POCT can be effective for decision-making in urgent care, emergencies, & crises (Ebola, MERS CoV).***

- ***Disaster caches should be designed and harmonized for collaborative use throughout the world, and for pandemics.***

- ***Spatial Care Paths™ start with the patient, position POCT optimally, and accelerate care, while ones "tunes" cultural acceptance. Then, national POCT policy and guidelines and fiscal planning will enhance and sustain community resilience, keys to stopping outbreaks.***

NATIONAL POLICY & GUIDELINES

- **Introduced at a National POC Testing Forum in Kuala Lumpur,** Malaysia, **July, 2012**

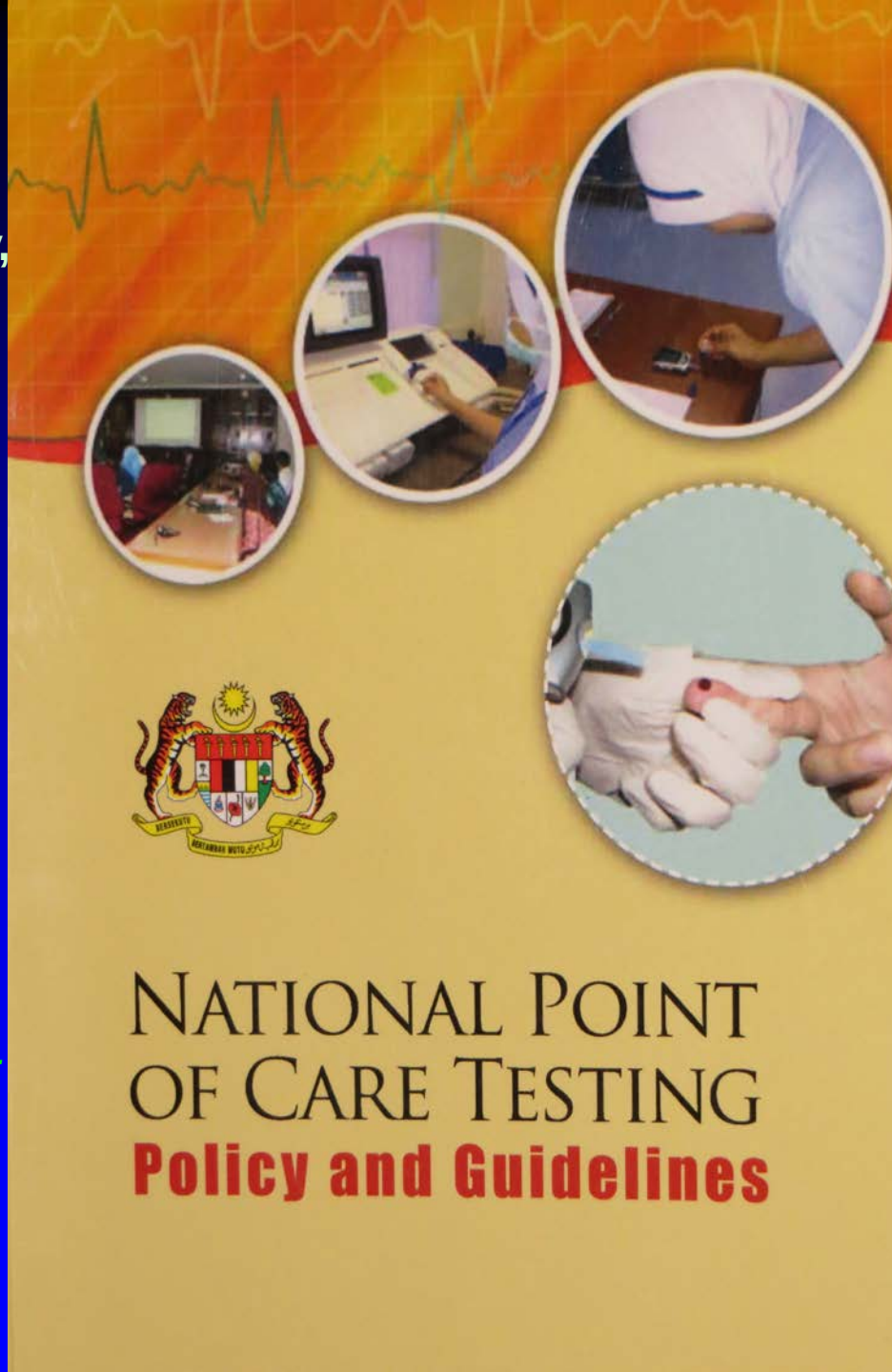
- **Uniquely combines policy *and* guidelines in one document**

- **Endorsed by the Ministry of Health**

- **One of the first nationally harmonized approaches to point-of-care testing**

- **Needs extension for disaster management and Ebola preparedness**

PHILIPPINES CHALLENGE! To produce national POCT policy and guidelines that will increase funding, enhance quality, harmonize POC, & improve outcomes! A step toward "Sustaining Quality through Global Standards."



Progress in Asia

China—

A new 2015 book (right) by Professor Liu et al., Editors, Wuhan (with Dr. Kost, Honorary Editor)

A new concept:

"Point of Careology"!

Other countries—

Developing policy and guidelines, e.g., in Thailand

More Late Breaking News!

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