GLOBAL POINT OF CARE: STRATEGIES FOR DISASTER, EMERGENCY, AND PUBLIC HEALTH RESILIENCE—USING "FAST POC" TO STOP EBOLA & MERS CoV OUTBREAKS

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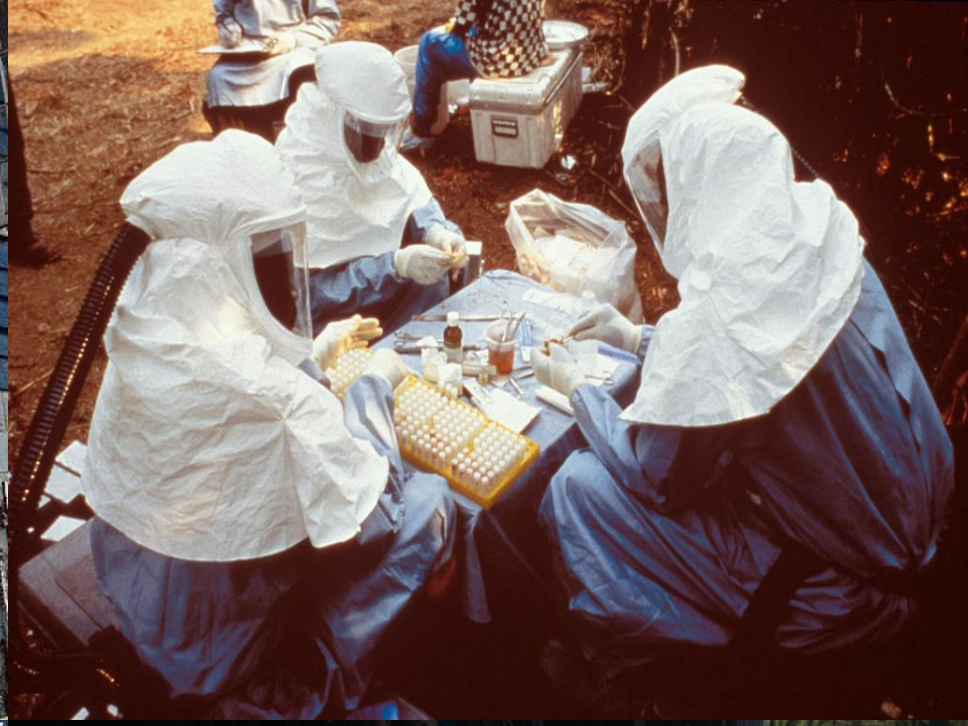
[Disclaimer: Research results may be preliminary. Final conclusions may differ. Please consult published papers. Device use must comply with regulatory & legal requirements.]

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

Point-of-Care Testing Center
for Teaching and Research


Irish Aid
EBOLA
Signs and Symptoms
FEVER
BLOODY DIARRHOEA
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



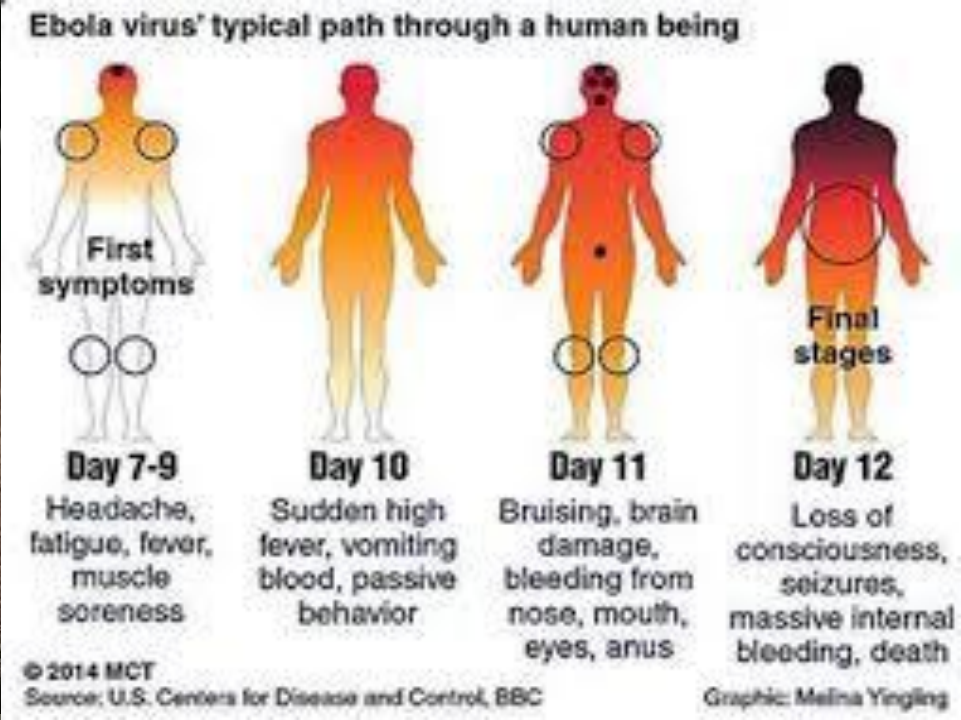

C.N.P.

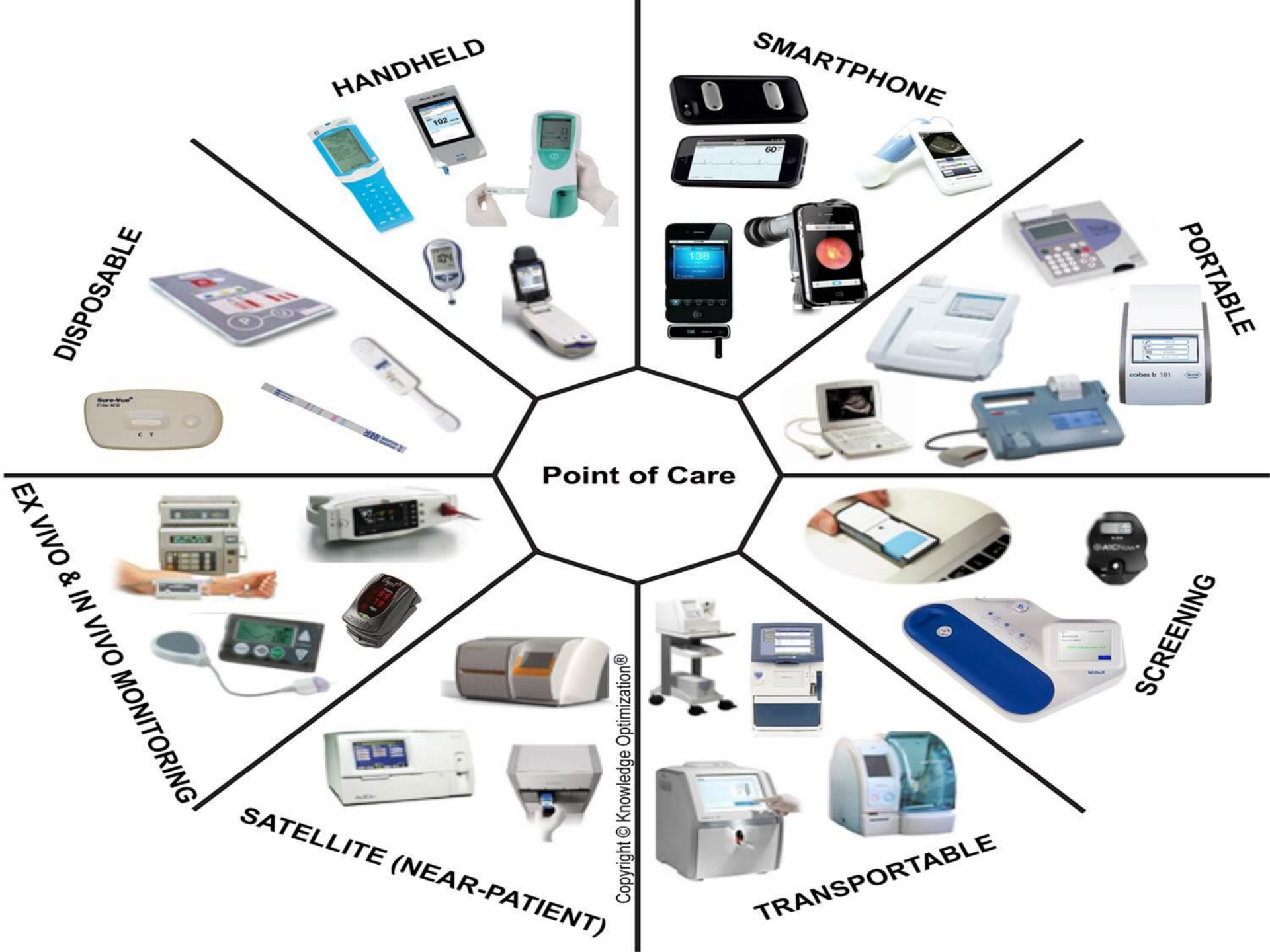

KENZO TRIBOUILLARD/AFP/GETTY IMAGES
SAFETY

Fear is what you imagine.
Danger is real.
Courage to act is everything!

"Newdemics" Publication Set—2015

AMERICAN JOURNAL OF DISASTER MEDICINE
CLINICAL LABORATORY INTERNATIONAL
EXPERT REVIEWS IN MOLECULAR DIAGNOSTICS
WHITEHAT COMMUNICATIONS WEBINARS


Ebola virus' typical path through a human being
First symptoms
Final stages
Day 7-9
Headache, fatigue, fever, muscle soreness
Day 10
Sudden high fever, vomiting blood, passive behavior
Day 11
Bruising, brain damage, bleeding from nose, mouth, eyes, anus
Day 12
Loss of consciousness, seizures, massive internal bleeding, death
© 2014 MCT
Source: U.S. Centers for Disease and Control, BBC
Graphic: Melina Yingling


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

Strategies for Disasters, Emergencies, and Public Health Resilience

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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.

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.*

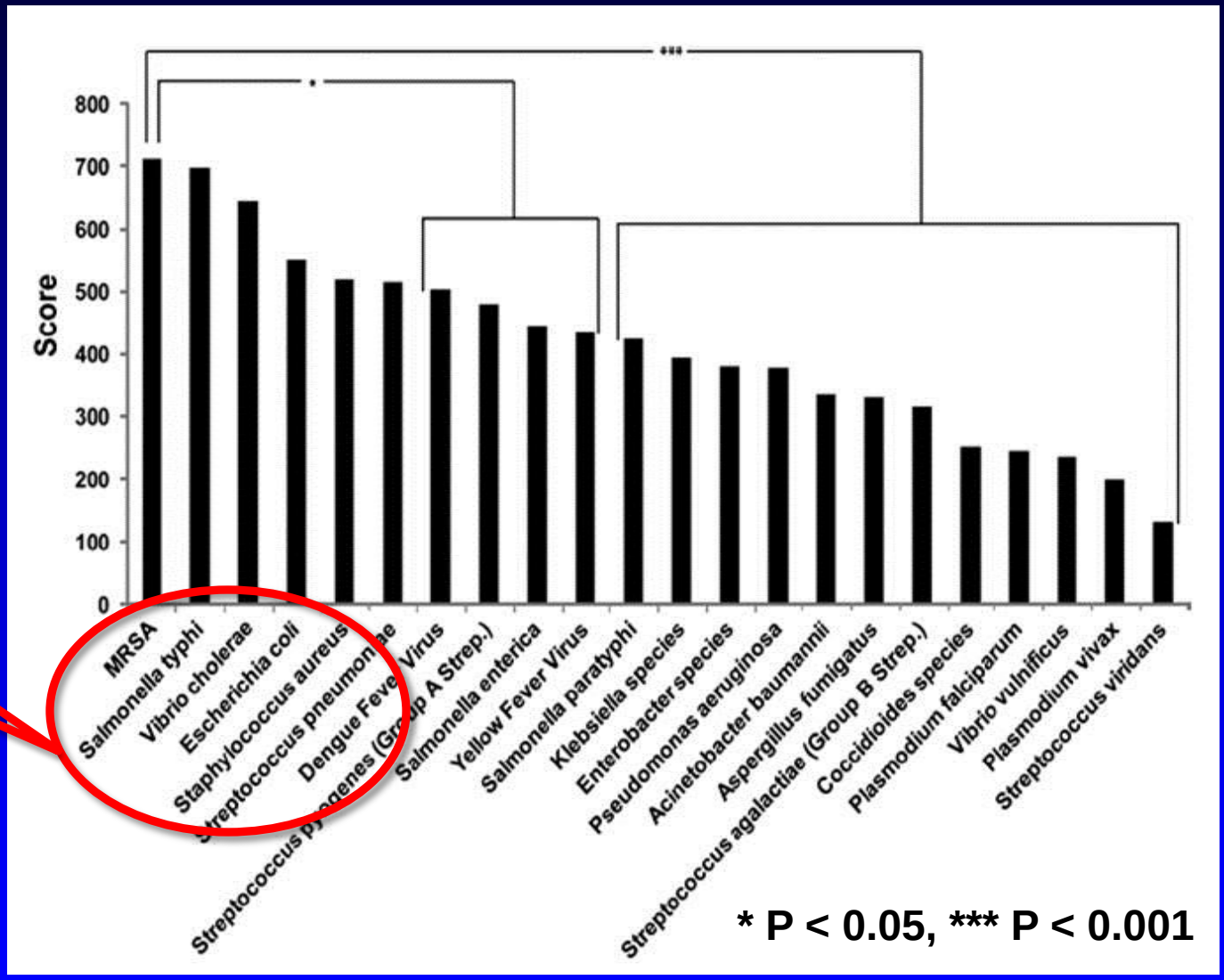
- ***To understand environmental stresses:*** *Environmental stresses affect test results and must be avoided, so that POCT can be effective for decision-making in crises.*

- ***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.*

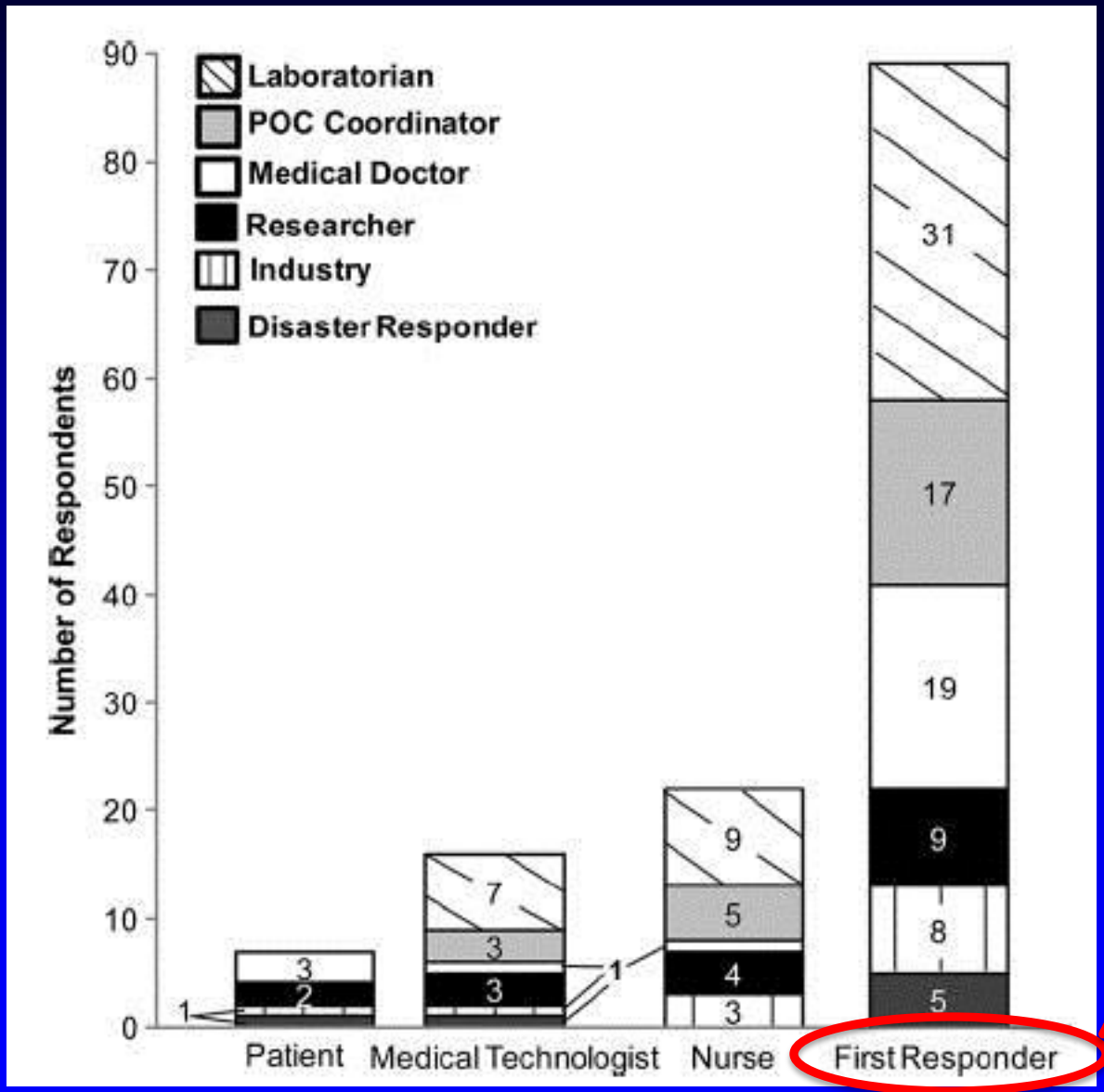
Needs Assessment Results from AACC members

Top five pathogens selected for disaster settings



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 AACC members

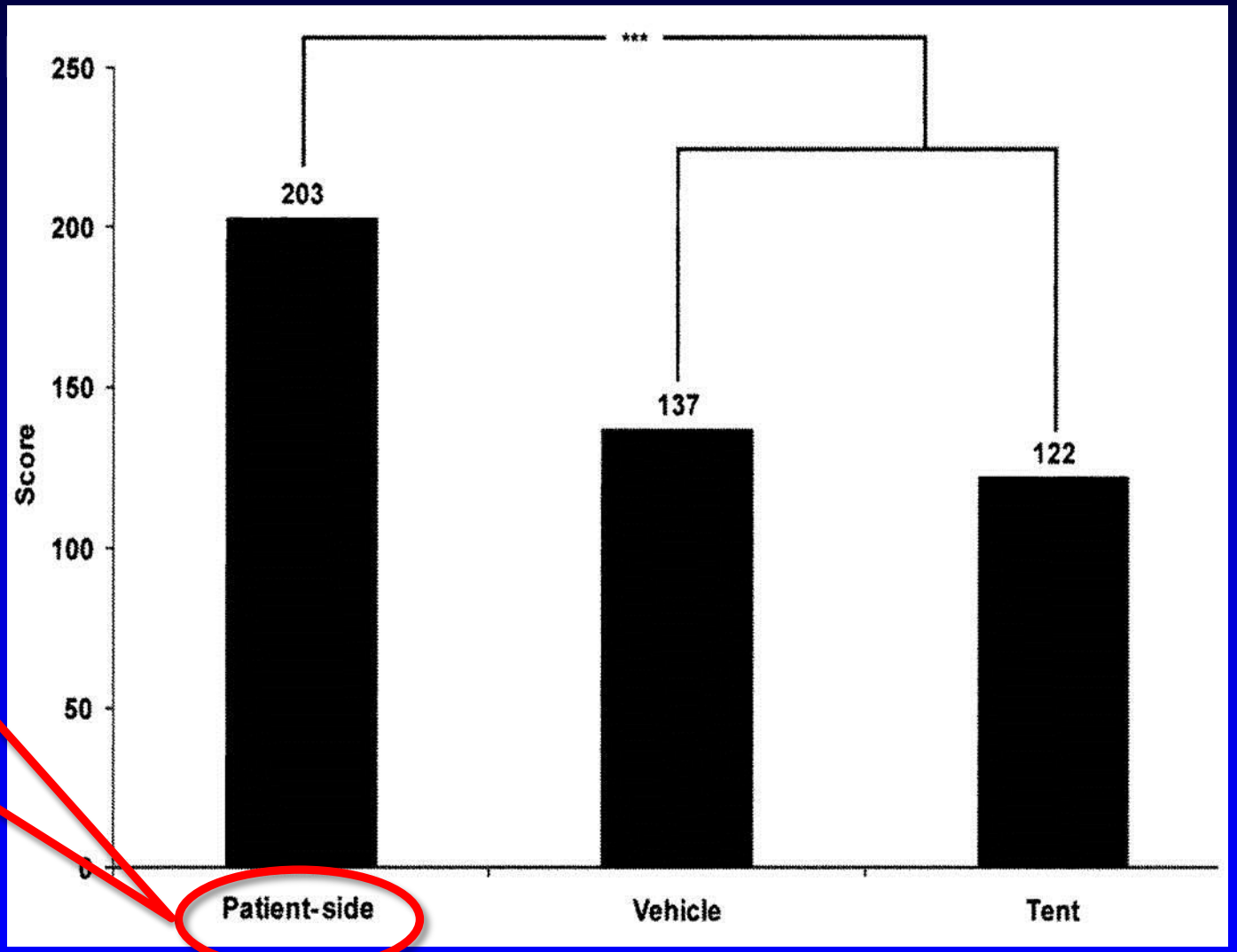


First Responders are the preferred group to perform POC testing in disasters

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

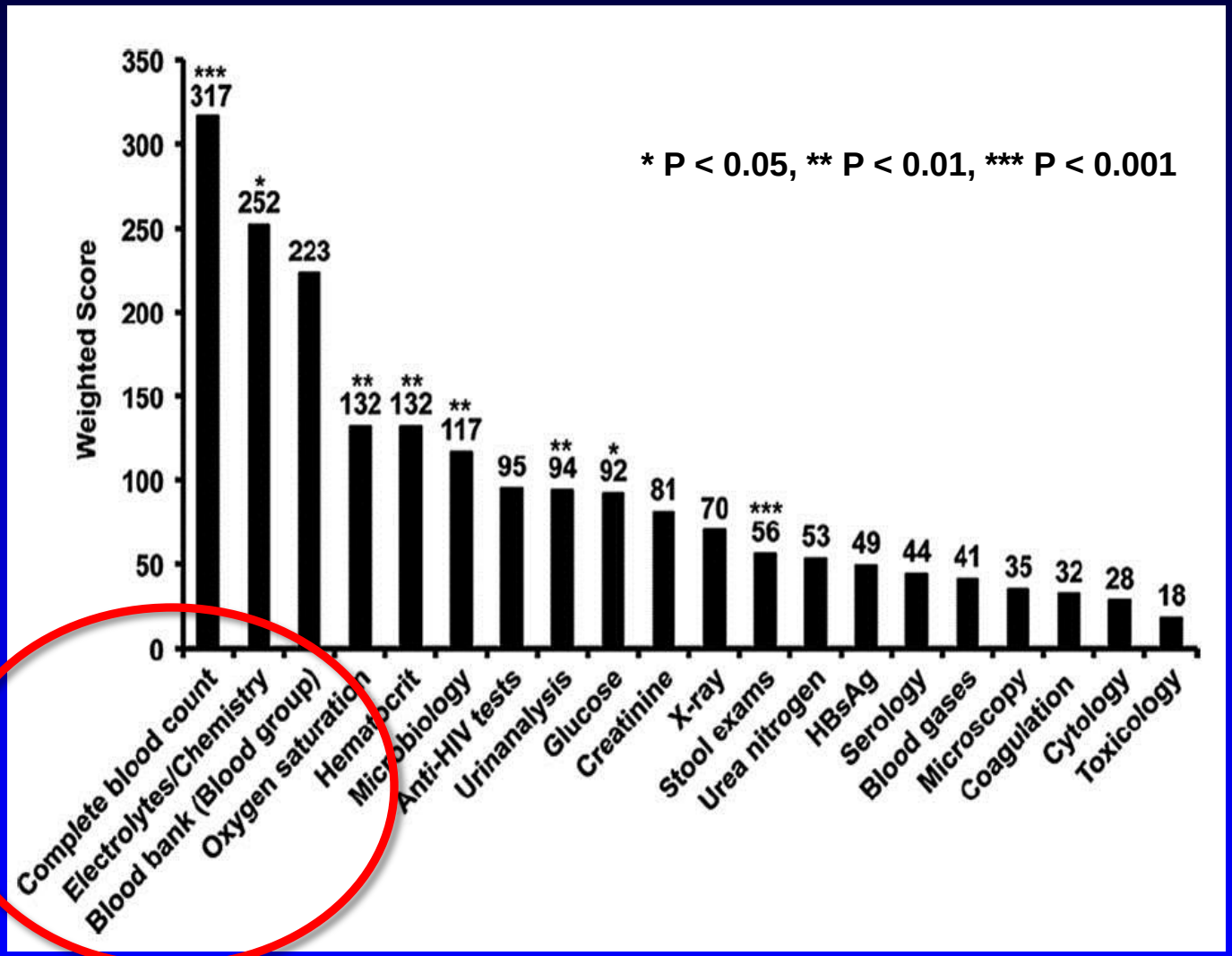


Respondents preferred patient-side testing in the field over testing inside a vehicle or tent.

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)

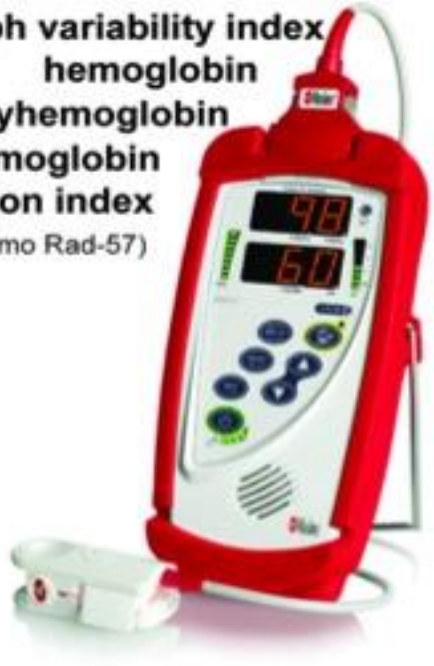
O2 Pulse Oximeters for adult and neonate
(Nellcor OxiMax N-600x)

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
Pathogen Detection Must Flex for Future!

Changing threats: Ebola & MERS CoV— moving targets need flexible POC devices & culturally sound solutions!

TABLE 1. Pathogen Test Menus for Emergency and Disaster Care

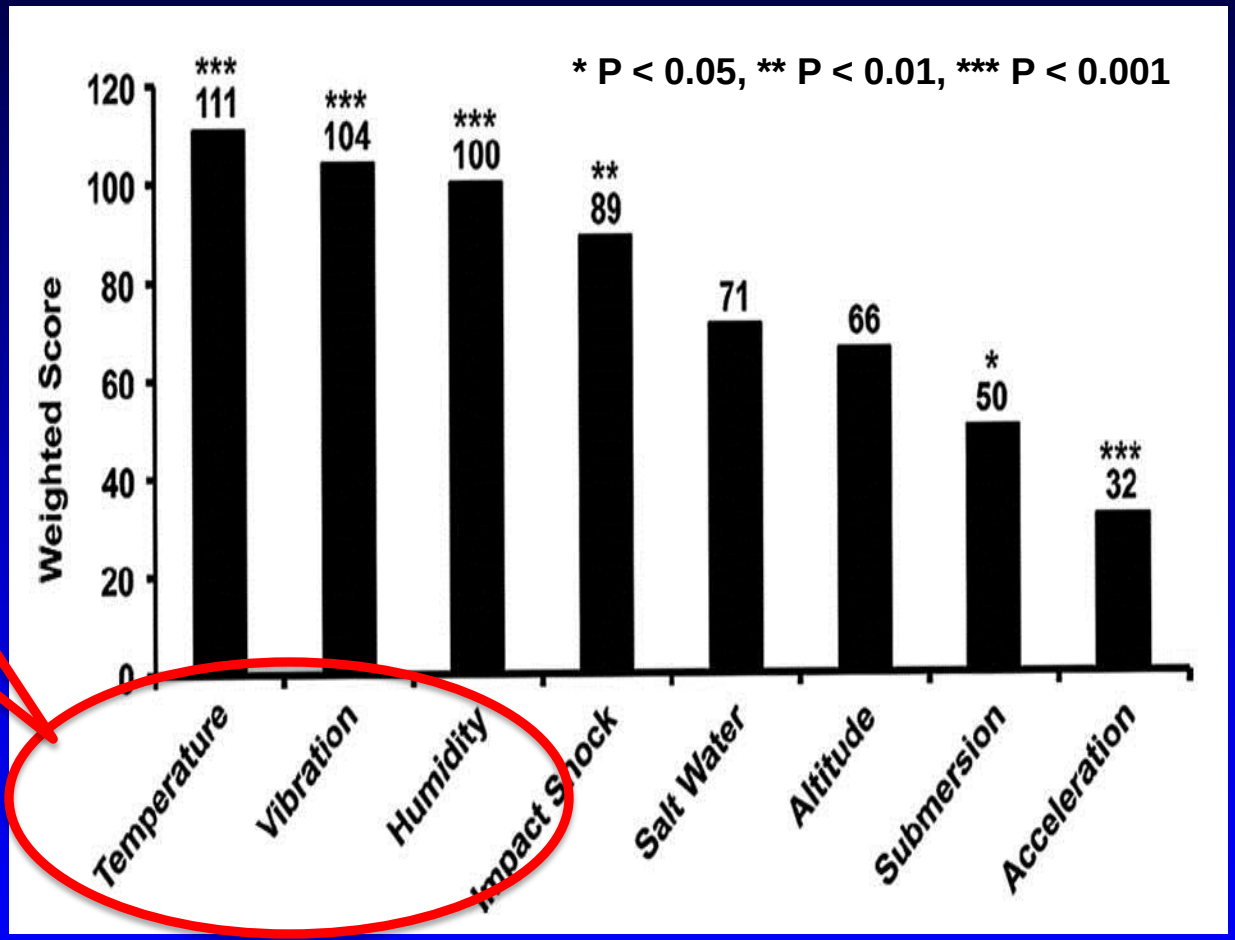
Objective	Weighted Score	Pathogen
(A) Civil disaster infections (n = 24)	53	*S. aureus*
	4[illegible]	*Klebsiella* sp
	41	Dengue fever virus
	36	*Pseudomonas aeruginosa*
	34	Human immunodeficiency virus types 1 and 2
	30	Hepatitis B virus
	28	*Enterobacter* sp
	23	*Vibrio cholerae*
	23	*Plasmodium vivax*
	20	*Plasmodium falciparum*
	18	*Streptococcus pyogenes*
(B) Respiratory pandemics (n = 24)	60	SARS
	[illegible]0	Avian influenza (H5N1)
	[illegible]5	Respiratory syncytial virus
	43	*S. pneumoniae*
	42	Influenza A/B virus
	41	*Mycobacterium tuberculosis*
	37	*Haemophilus influenzae*
	35	*Mycoplasma pneumoniae*
	34	*S. aureus*
	33	*Klebsiella* sp
	26	Pandemic (H1N1) 2009 influenza

Objective	Weighted Score	Pathogen
(C) Bloodstream infections (n = 24)	95	*S. pneumoniae*
	85	*S. aureus*
	75	*Escherichia coli*
	72	*Pseudomonas aeruginosa*
	65	*Streptococcus* sp
	52	*Klebsiella* sp
	48	Methicillin-resistant *S. aureus*
	43	*Enterobacter* sp
	31	*Acinetobacter baumannii*
	30	Coagulase-negative *Staphylococcus*
(D) Emergency blood donor screening (n = 24)	155	Hepatitis B virus
	[illegible]50	Human immunodeficiency virus types 1 and 2
	138	Hepatitis C virus
	68	Epstein-Barr virus
	61	Dengue fever virus
	57	*Cytomegalovirus*
	49	Parvovirus B19
	49	Chikungunya virus
	43	Human T-cell lymphotropic virus 1 and 2 (HTLV 1 and 2)

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.

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, 2005

Haiti Earthquake, 2010

Christchurch, New Zealand, 2011

Japan Earthquake / Tsunami, 2011

Global Point of Care

Strategies for Disasters, Emergencies, and Public Health Resilience

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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.

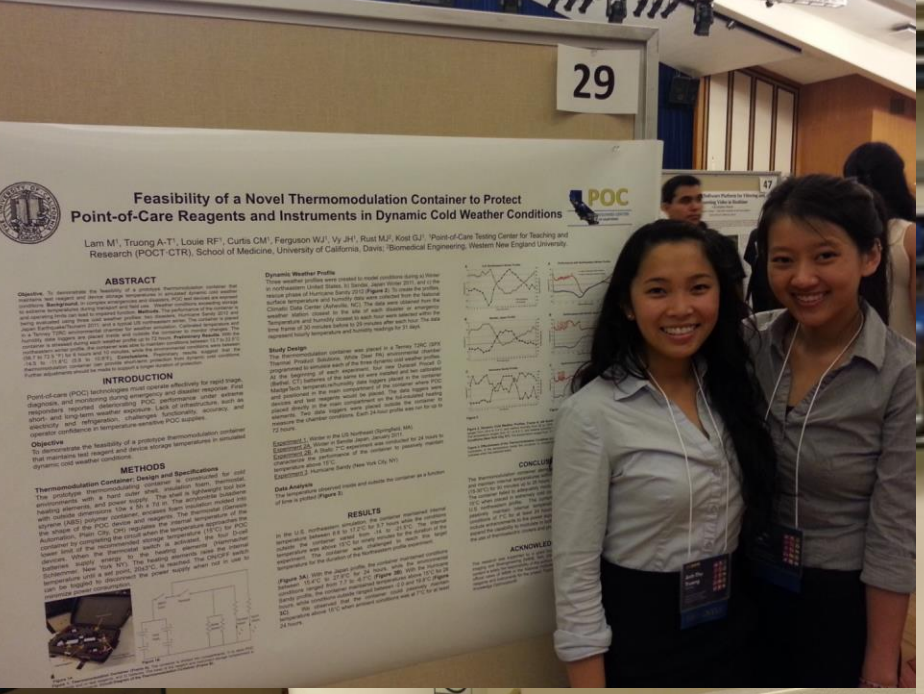
To ensure accurate and safe use, POCT needs to deliver excellent performance in any environment in which it is used *(6)*. Erroneous results can cause serious harm and alter clinical decision making, such as improper insulin dosage *(7)*. Emergency and disaster responders equipped with POC technologies 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.

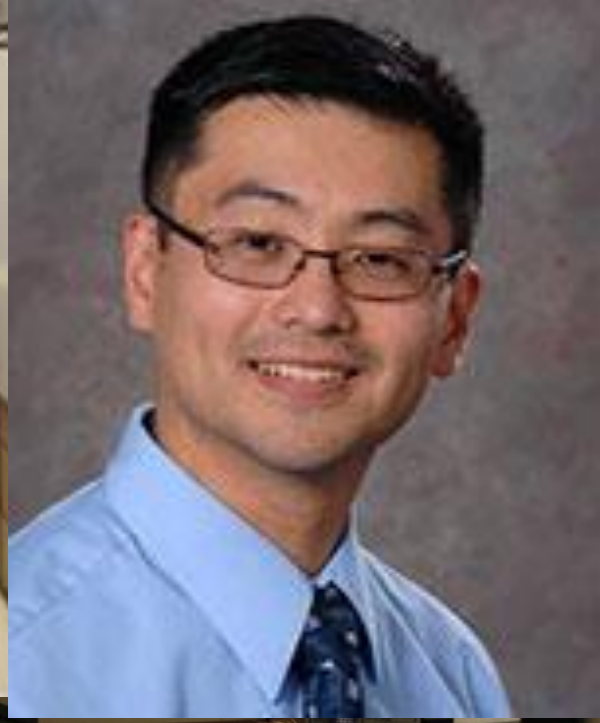
Tables 23-2, and 23-3 *(8)* summarize the storage and operating specifications of select POC devices. Test reagents typically are refrigerated or stored in ambient conditions between 15–30 °C (59–86 °F). Reagents requiring refrigeration can be stored at ambient conditions (e.g., room temperature), but 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).

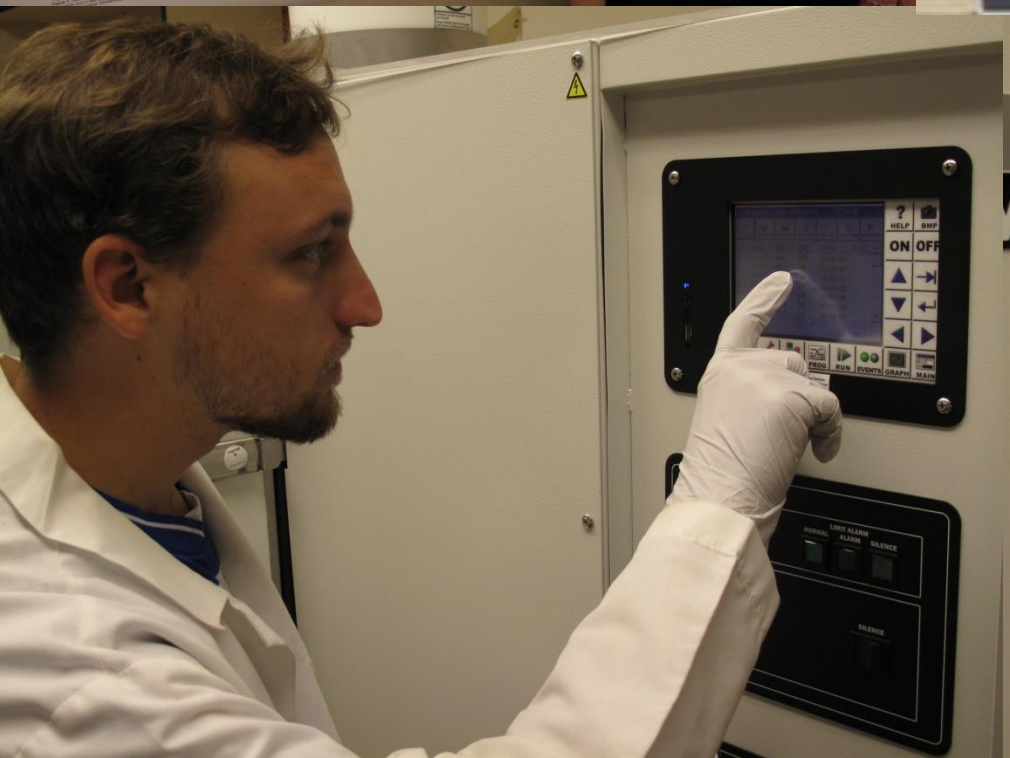
Mean Kinetic Temperature.

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)*:

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


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

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ORIGINAL RESEARCH

Dynamic Temperature and Humidity Environmental Profiles: Impact for Future Emergency and Disaster Preparedness and Response

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Conflicts of interest and funding: This research was supported by a grant from the National Institute of Biomedical Imaging and Bioengineering, NIH (U54EB007959, Principal Investigator: Dr. Gerald Kost). Partial support for Dr. Kyaw Tha Paw U came from National Science Foundation award EF#1137306 to MIT, subaward #5710003122 to UC Davis.

Keywords: mean kinetic temperature; point-of-care; weather profiles

Abbreviations:
BNP: B-type natriuretic peptide
Ca^{2+}: calcium
CK-MB: creatine-kinase MB isoform
CTnI: cardiac troponin I
K^+: potassium
MKT: mean kinetic temperature
MYO: myoglobin
Na^+: sodium
PCO_2: partial pressure of carbon dioxide
PO_2: partial pressure of oxygen
POC: point of care

Abstract

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

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

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

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

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

Ferguson WJ, Louie RF, Tang CS, Paw U KT, Kost GJ. Dynamic temperature and humidity environmental profiles: impact for future emergency and disaster preparedness and response. *Prehosp Disaster Med.* 2014;29(1):4-12.

Online publication: January 2, 2014

doi:10.1017/S1049023X13009199

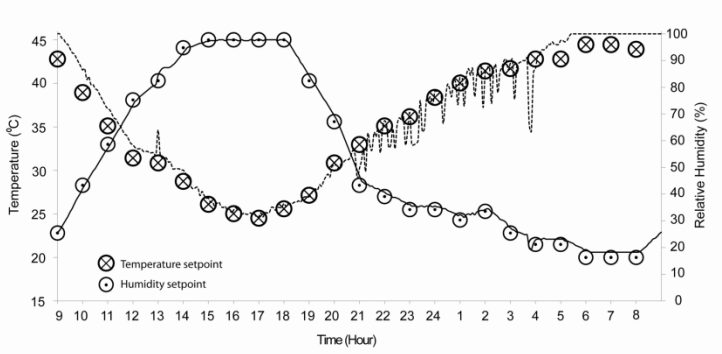
Received: April 3, 2013
Accepted: July 1, 2013

Ferguson WJ, et al. *Prehosp Disaster Med.* 2014;29:4-12.

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.

ORIGINAL RESEARCH

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

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

ABSTRACT

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

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

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

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

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

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

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

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

METHODS

Point-of-Care Systems and Reagents

GMS1 is a glucose oxidase-based electrochemical meter system, and GMS2 is a glucose dehydrogenase-based meter system. Glucose meters and aqueous quality control solutions (QC) were stored and operated within manufacturer's specifications, at room temperature (19.7 ± 0.6°C, range 18.8 to 23.0°C) and at relative humidity (46.4 ± 12.8%, range 21% to 77%). A subset of single-use disposable reagent test strips from each GMS was stressed with an environmental testing chamber (Tenney T2RC, Thermal Products Solution) that was programmed to simulate conditions during Hurricane Katrina. Stressed strips were tested immediately after removal from the chamber in pairs with control (unstressed) strips. Control strips were stored at room temperature.

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

Environmental Profile

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

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

Dynamic Temperature and Humidity Stress

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

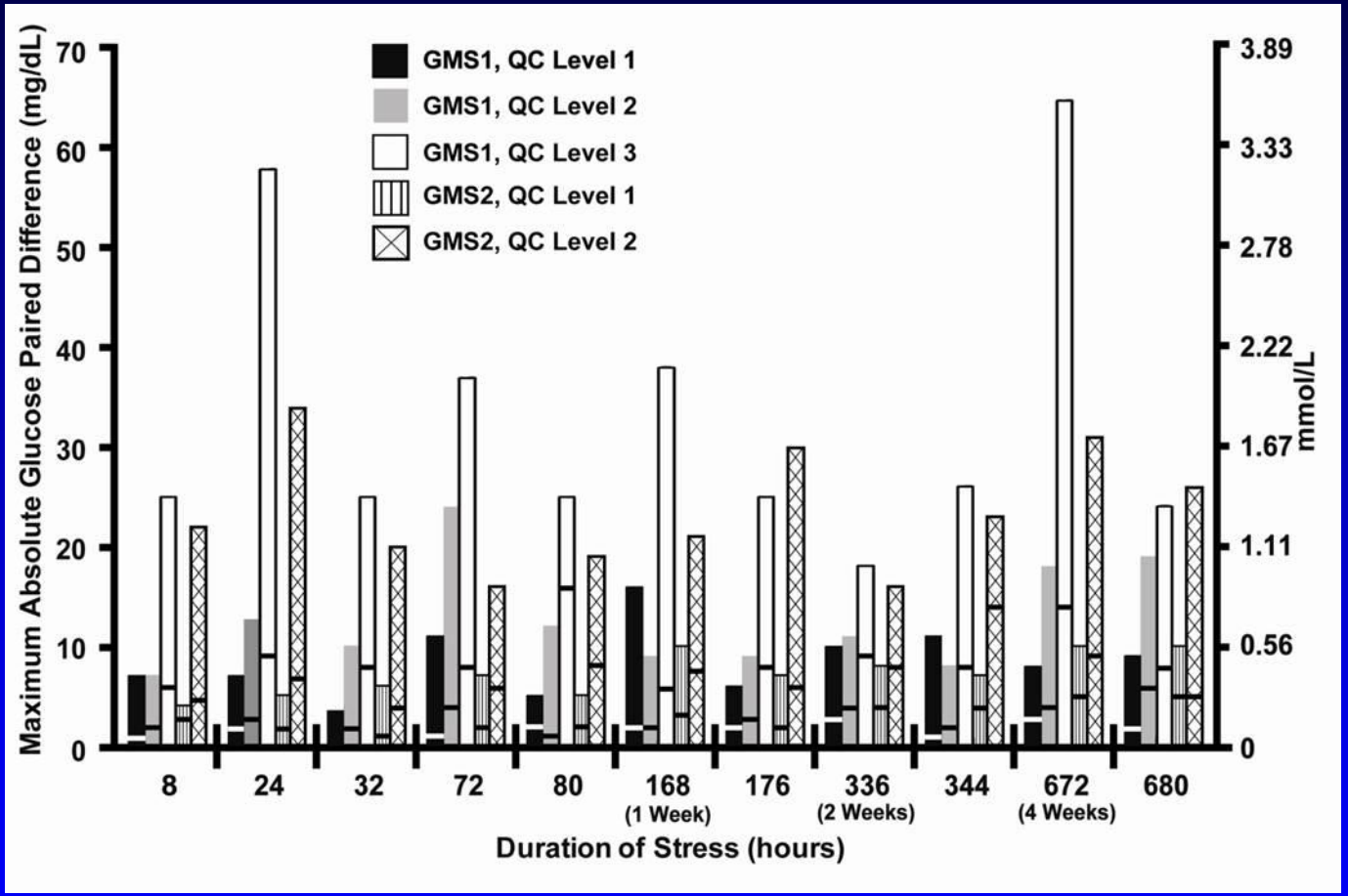
- **Methods**—Glucose test strips were exposed to conditions simulating the temperature and humidity experienced in New Orleans following the Hurricane Katrina disaster for a duration of ~4 weeks

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

- **Results**—The duration of stress affected the performance of the glucose meter systems. One system provided lower measurements and the other elevated when stressed. As demonstrated on one system, the stress effects on test performance is cumulative with pronounce effect after 32 hours of exposure.

Maximum Absolute Paired Differences Between Stress & Control Glucose Test Strips

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



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

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
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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.

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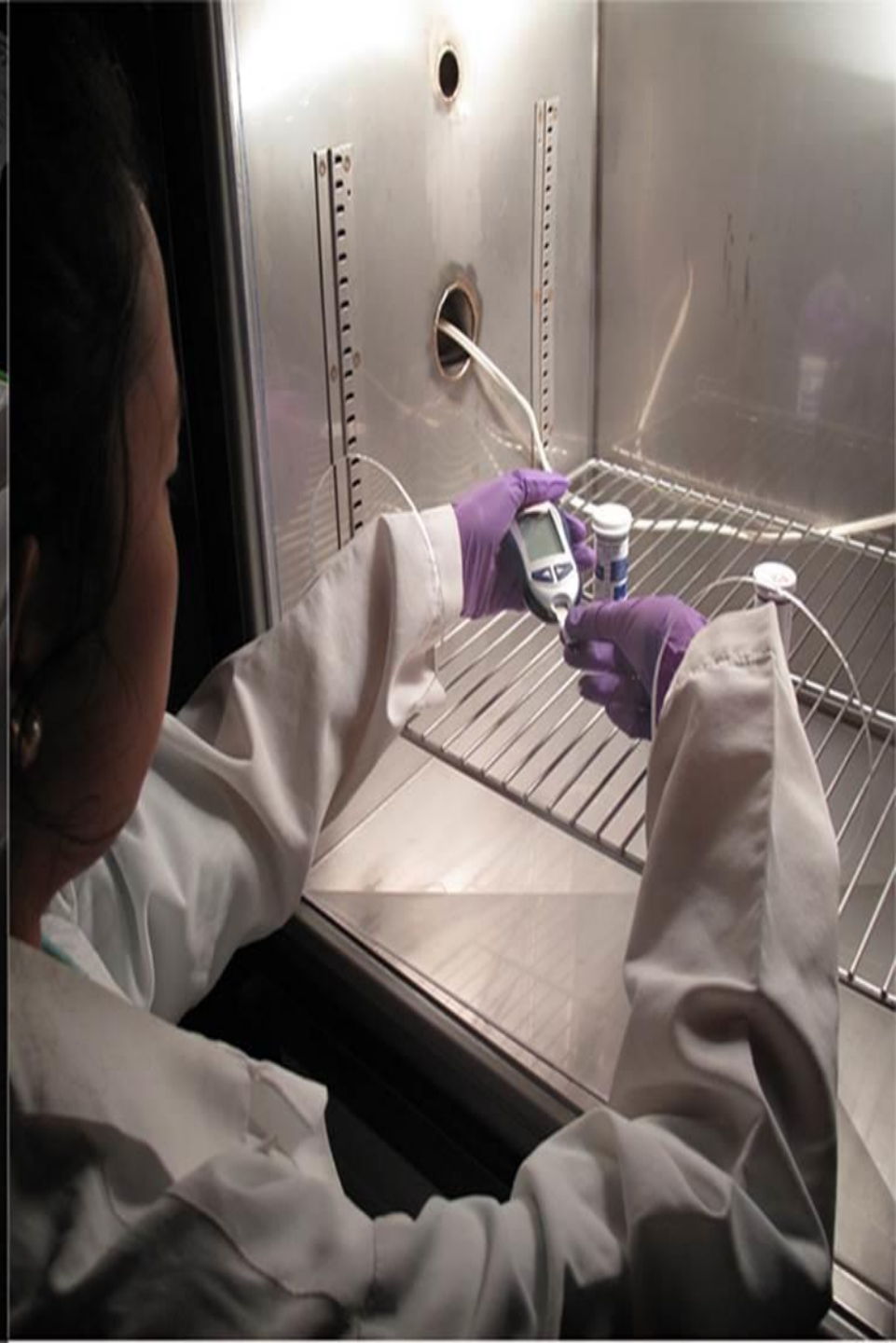
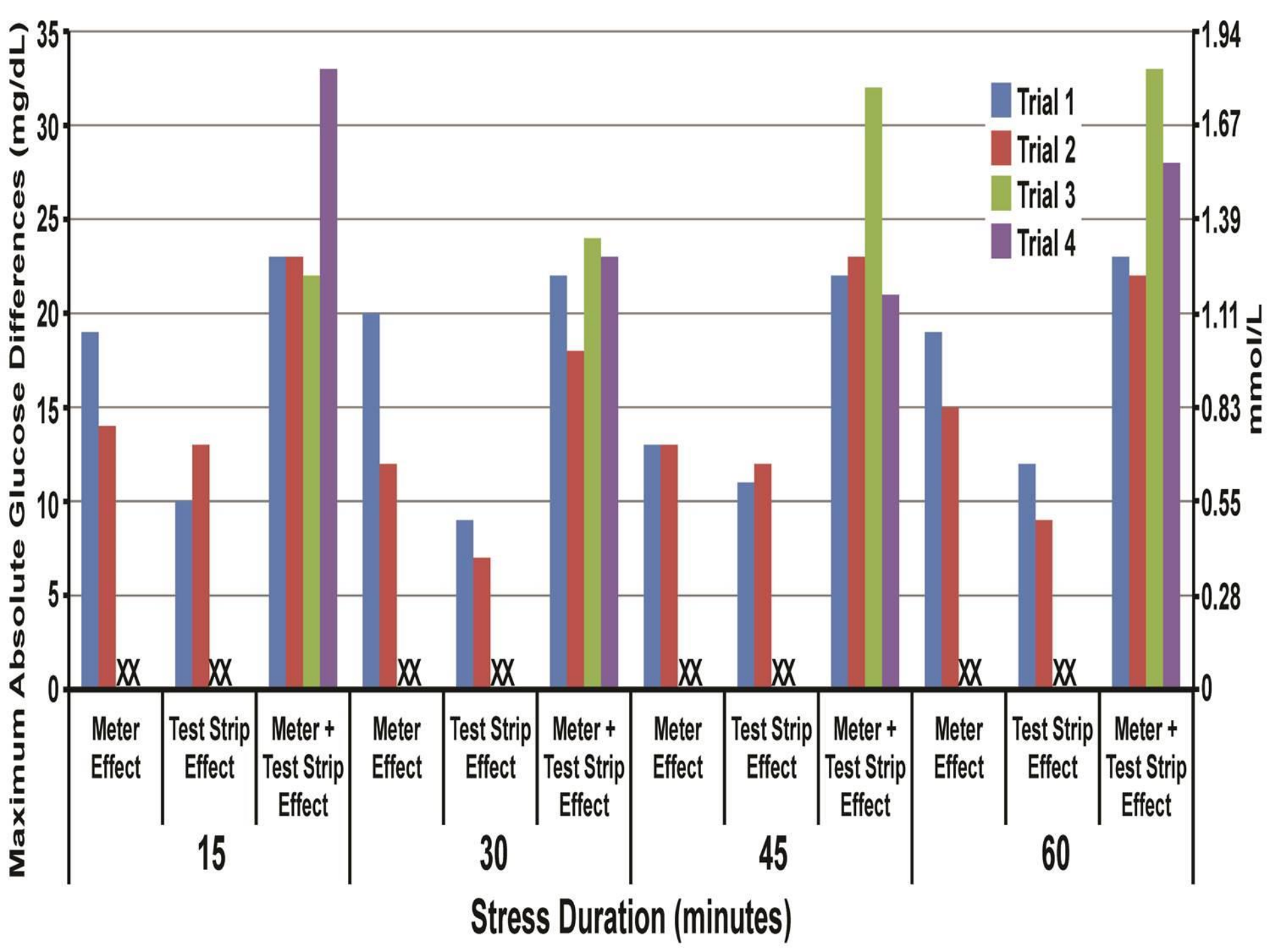



Maximum Absolute Glucose Differences (mg/dL)
35
30
25
20
15
10
5
0
1.94
1.67
1.39
1.11
0.83
0.55
0.28
0
mmol/L
Trial 1
Trial 2
Trial 3
Trial 4
XX
Meter Effect
Test Strip Effect
Meter + Test Strip Effect
15
30
45
60
Stress Duration (minutes)

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 ($p < 0.05$).*

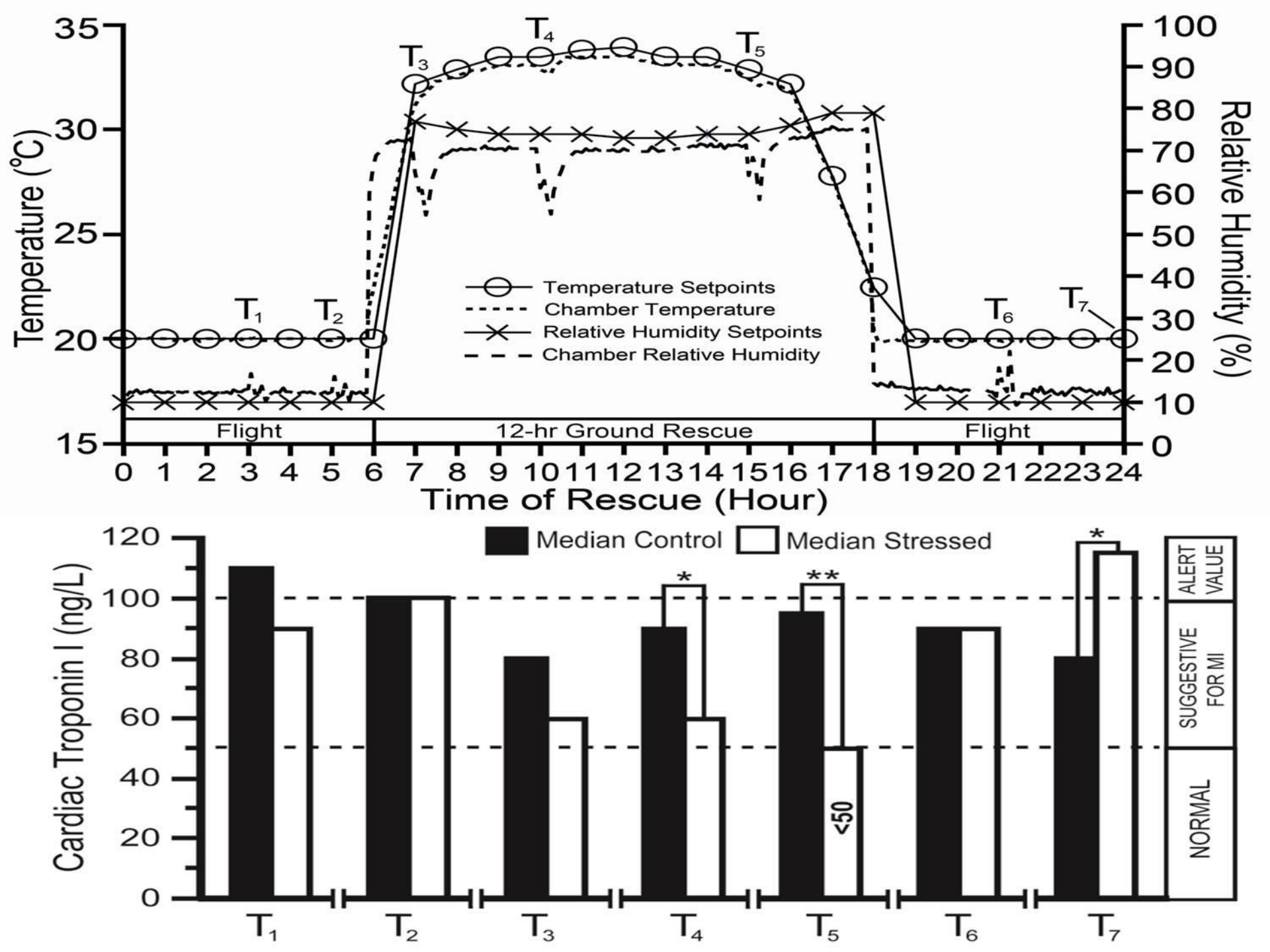
Conclusion: *Despite modest, short-term temperature elevation, environmental stresses led to erroneous results. False negative cTnI and BNP results potentially could miss acute myocardial infarction and congestive heart failure, confounded treatment, and increased mortality and morbidity. Therefore,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

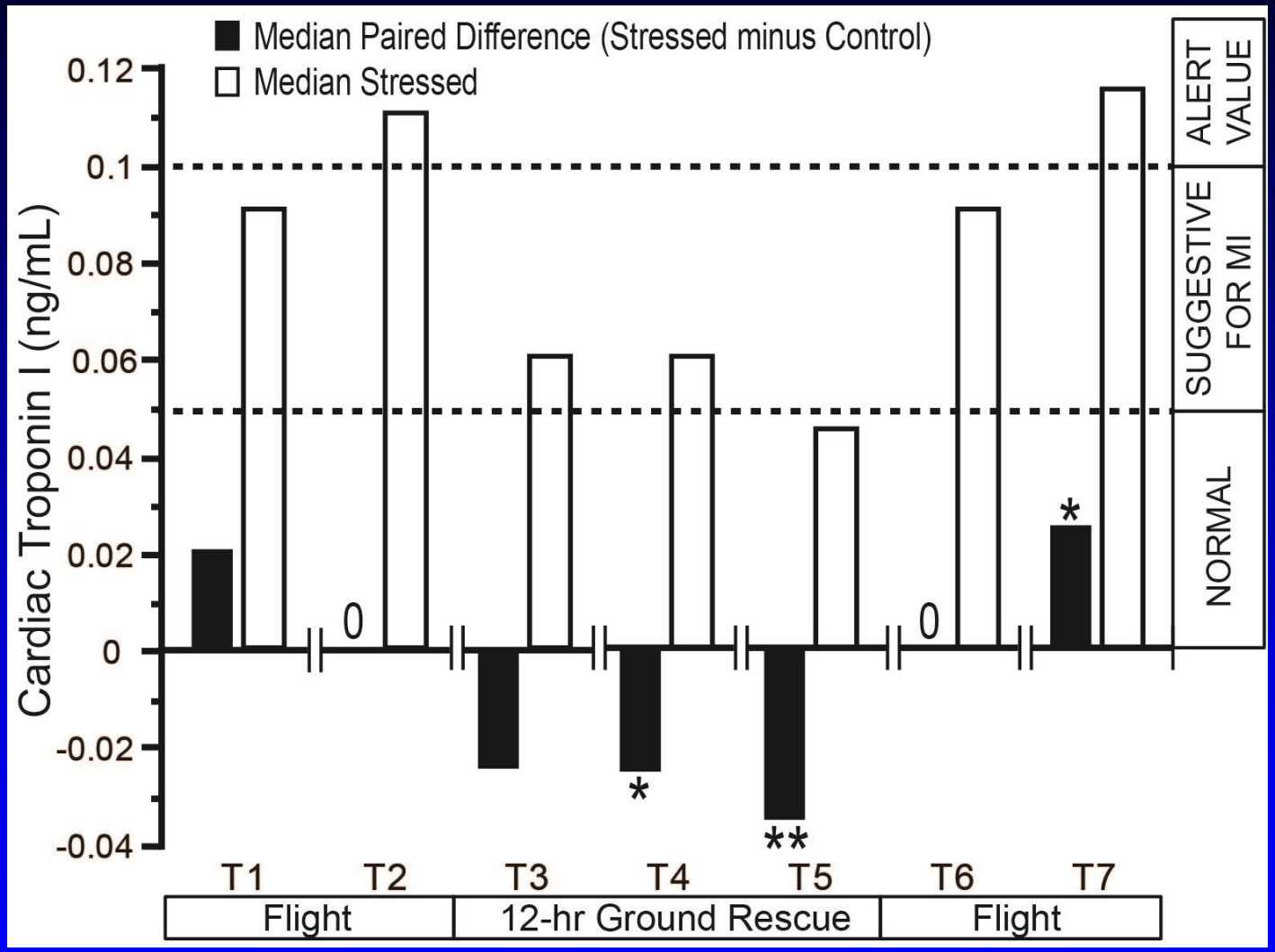

Temperature (°C)
Relative Humidity (%)
Time of Rescue (Hour)
Temperature Setpoints
Chamber Temperature
Relative Humidity Setpoints
Chamber Relative Humidity
Flight
12-hr Ground Rescue
Flight
T1
T2
T3
T4
T5
T6
T7
Median Control
Median Stressed
Cardiac Troponin I (ng/L)
ALERT VALUE
SUGGESTIVE FOR MI
NORMAL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

Effects of Stress on cTn I Test Results

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

- At T_5, 20% (2/10) results were highly discrepant: stress <0.05, control ≥0.10 ng/mL

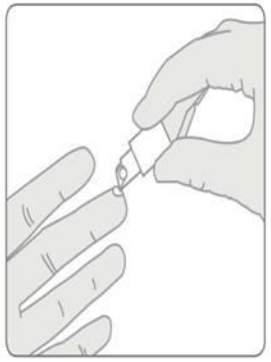
- Median stressed cTnI at T_5 was <0.05 ng/mL



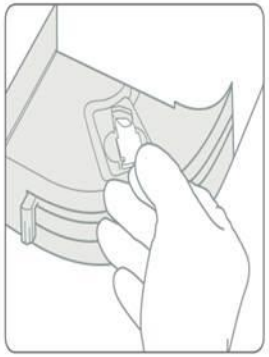
- During the return flight, stressed cards reported falsely elevated cTnI >0.1 ng/mL at T_7, which in our emergency department “alerts” possible AMI.

Louie RF, et al. *Am J Disaster Med.* 2013;8:205-212.

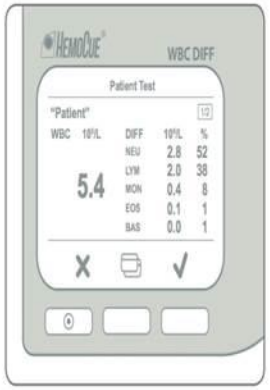
WBC & 5-PART DIFFERENTIAL— ENVIRONMENTAL STRESS VALIDATION IN PROGRESS



1 Fill microcuvette.

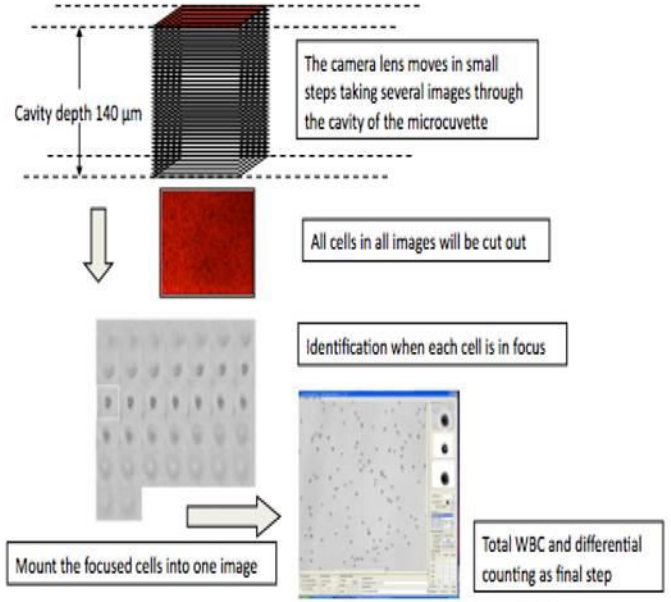


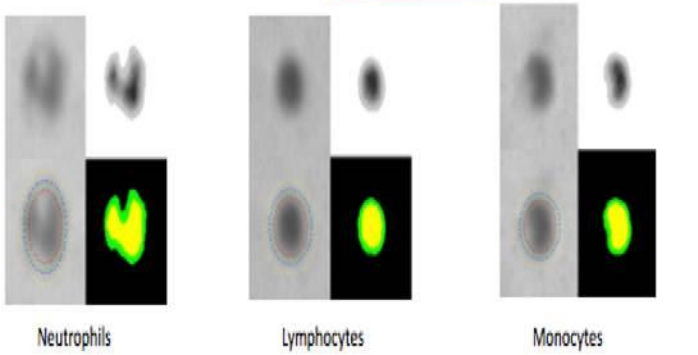
2 Place microcuvette into analyzer.

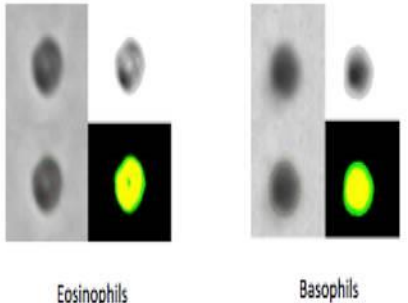


3 View results.

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







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

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.

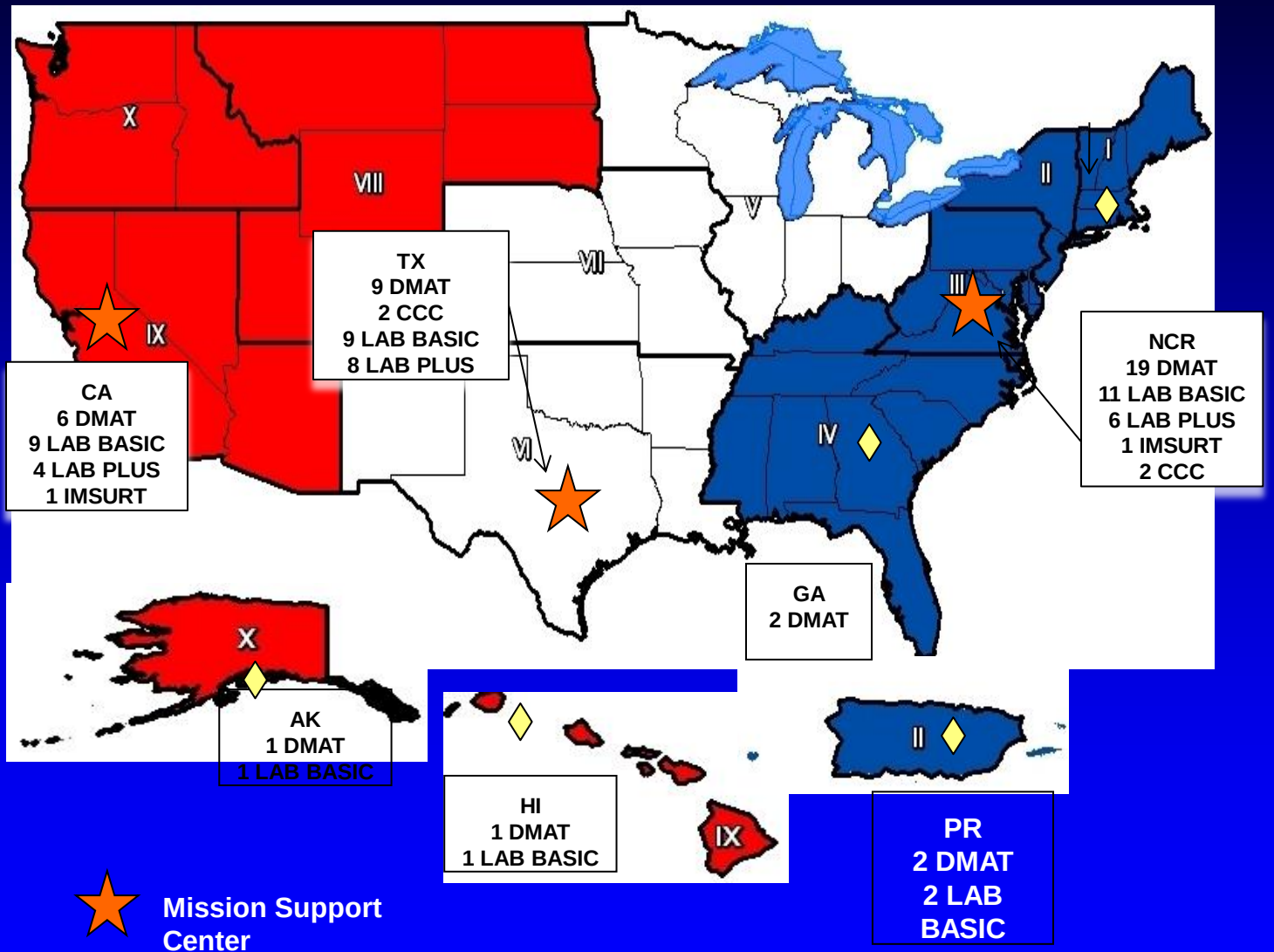
This study was supported by the Point-of-Care Testing Center for Teaching and Research (POCT•CTR) and by a National Institute for Biomedical Imaging and Bioengineering (NIBIB) Point-of-Care Technologies Center grant (Dr. Kost, PI, NIH U54 EB007959). The content is solely the responsibility of the authors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

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

*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

Coming:
Orasure Ebola POC Test

CoaguChek® XS Plus System for PT/INR

Hemoccult®-Immunochemical Fecal Occult Blood Test

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

QuickVue® Influenza Test

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

QuickVue® Influenza Test

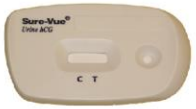
Triage® Drugs of Abuse Test Card

CoaguChek® XS Plus System for PT/INR

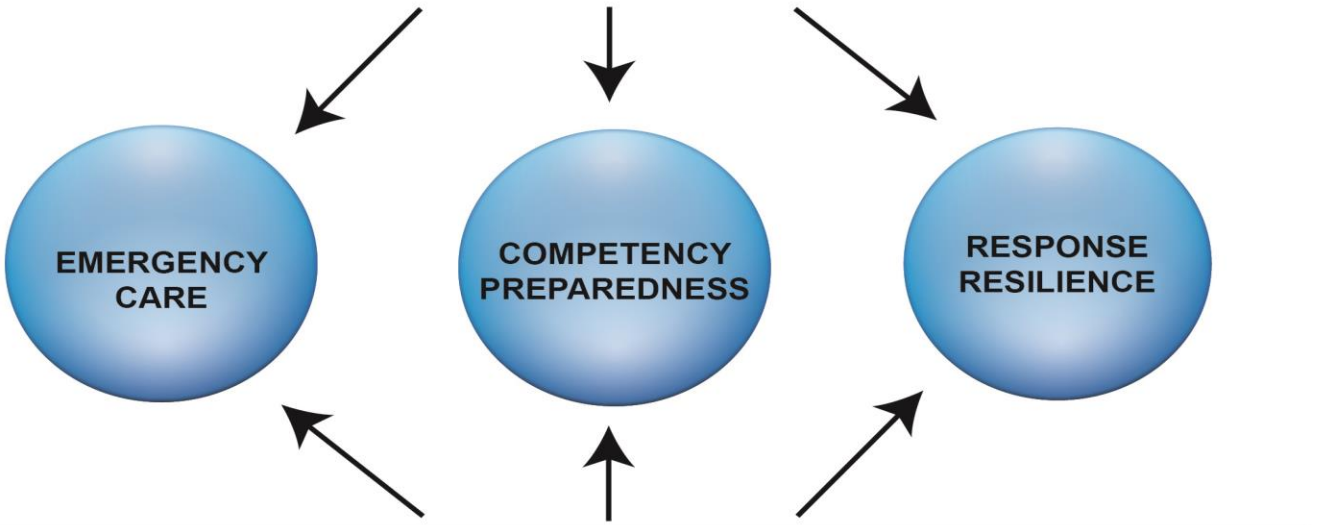
Rapid tests for Strep Throat, Mono and D-dimer

Hemoccult®-Immunochemical Fecal Occult Blood Test

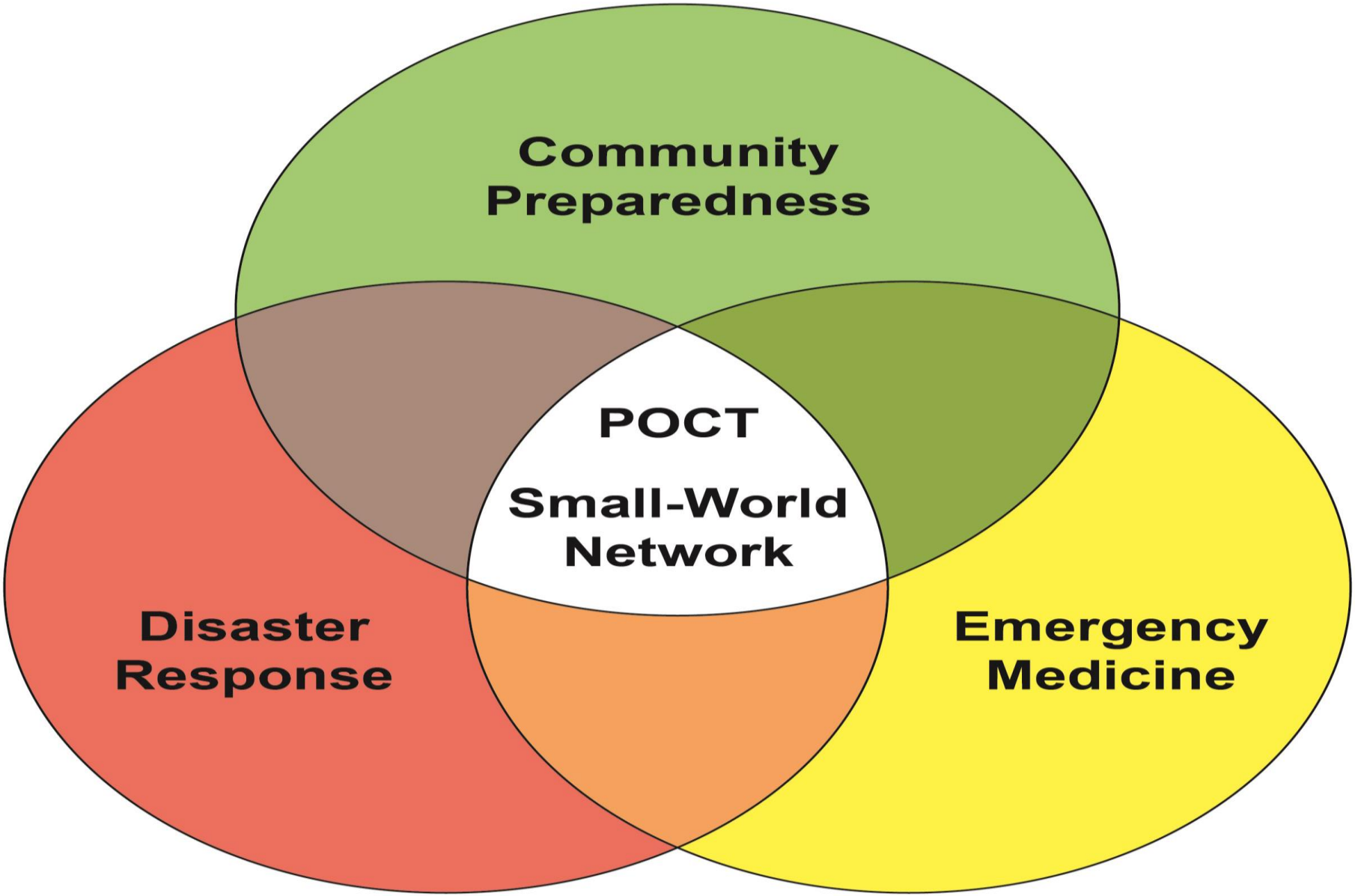
ABORhCard® Blood Typing Test Card



Sure-Vue® Urine hCG Cartridge



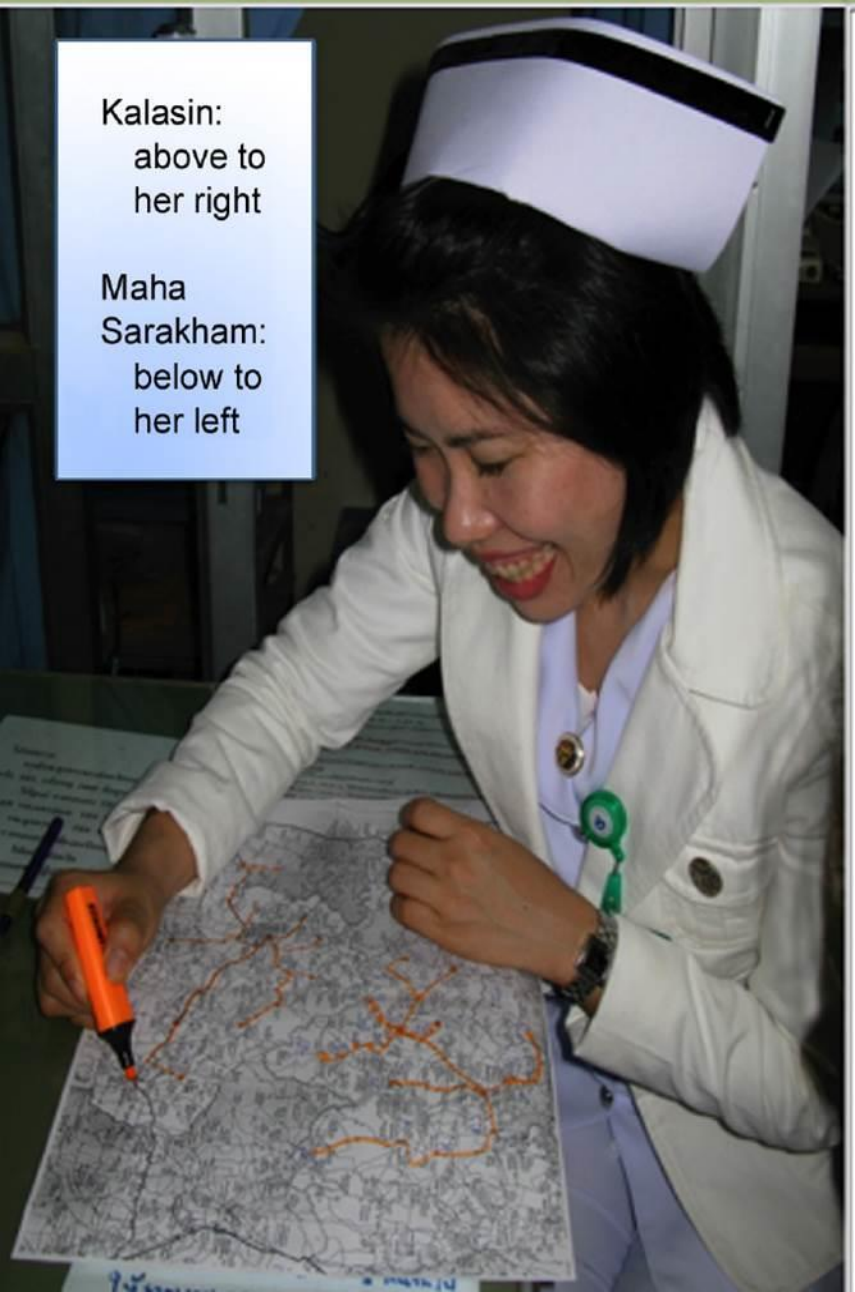
Reference: Curtis CM, et al. Innovations in point-of-care testing for enhanced U.S. disaster caches. *Am J Disaster Med. 2014*;8:181-204.

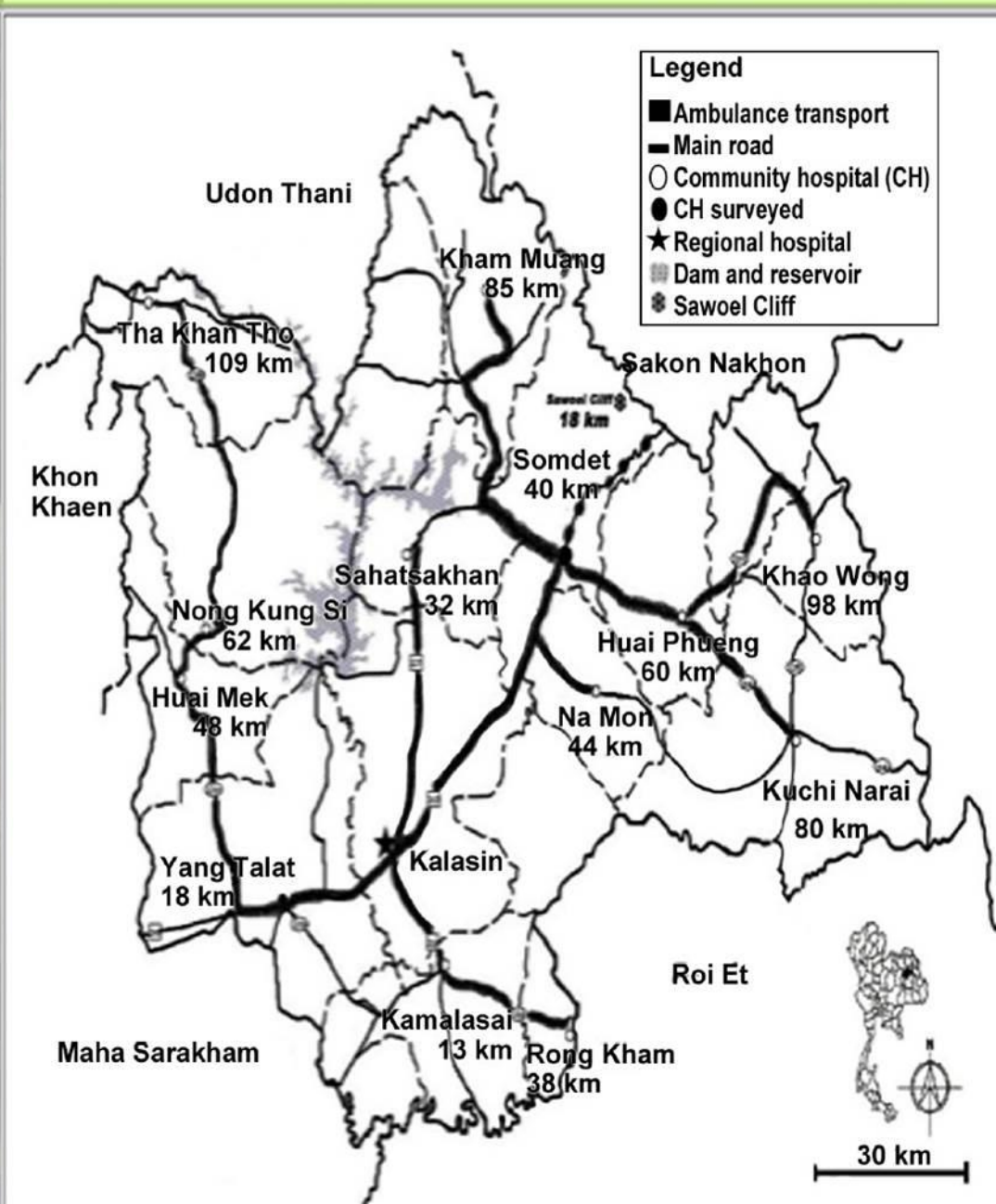


Reference: Kost GJ, Sakaguchi A, Curtis CM, Tran NK, Katip P, Louie RF. Enhancing crisis standards of care using innovative point-of-care testing. *Am J Disaster Med*. 2011;6:351-368.

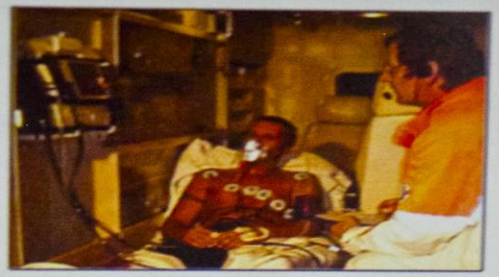
Drawing Kalasin and Marha Sarakham Province SWN ambulance routes

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

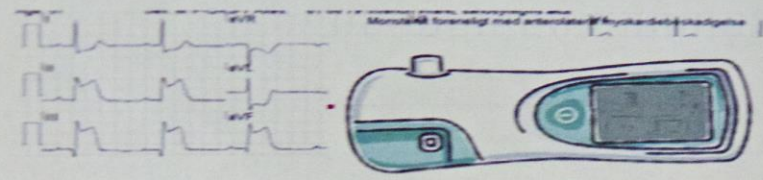




Prehospital Spatial Care Path™ for Acute Myocardial Infarction



1. The patient alerts emergency medical services.



2. An ECG is recorded and a blood test performed if there is suspicion of an acute myocardial infarction.

3. The results are transmitted wirelesly to the cardiologist on call.

4. The ambulance is directed to the invasive center or nearest coronary care unit, depending on the diagnosis.

Step 1. The patient alerts emergency services while at home or about.

Step 2. An ECG is recorded and a cardiac troponin T (or I) test is performed if there is suspicion of AMI.

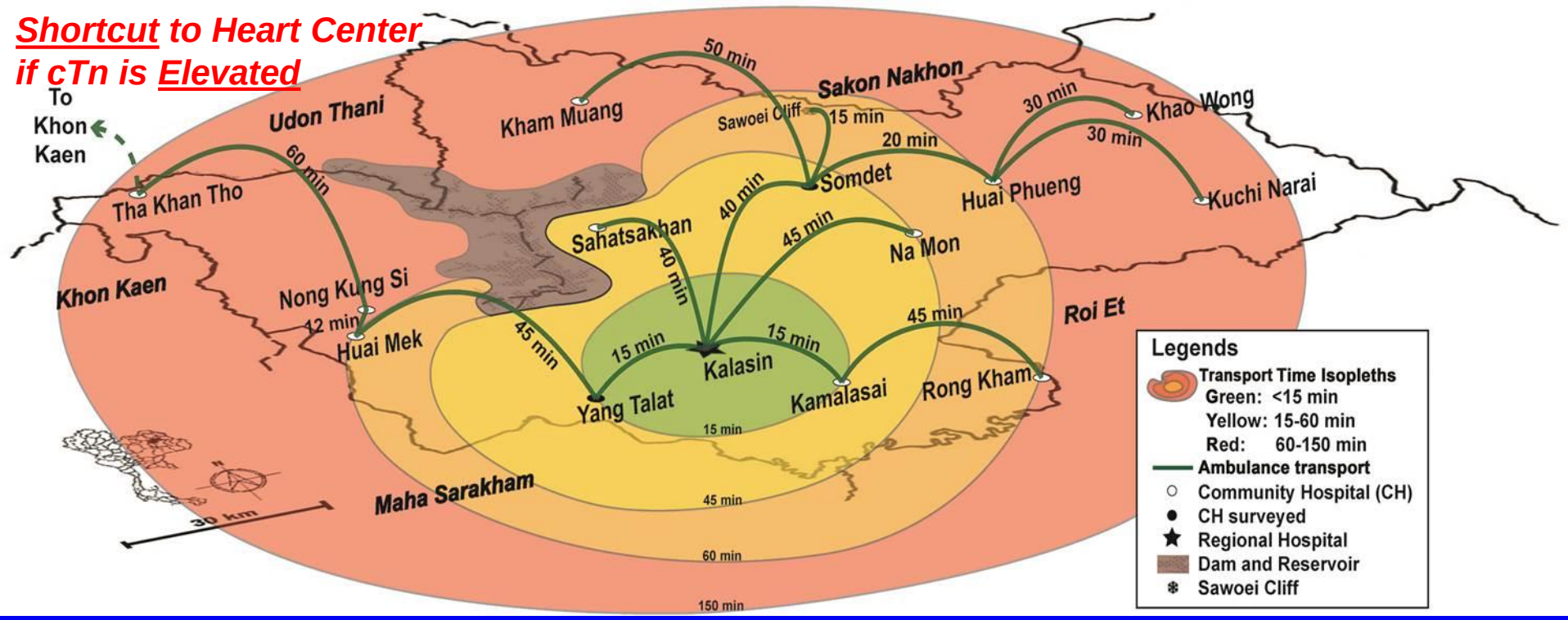
Step 3. The ECG and cTnT test results are transmitted wirelessly to the cardiologist on call.

Step 4. The ambulance is directed to the invasive center or nearest coronary care unit, depending on the diagnosis.

Conclusion: **"POCT performed by paramedics, nurses, or doctors can improve diagnostic accuracy where the ECG does not provide decisive information. This enables optimal triage and early aggressive treatment of patients who currently experience a very high mortality. Prehospital biomarkers provide strong prognostic information early on, allowing the ER to prepare optimally for patient arrival."**

From Sorensen JT and Stengaard C. Prehospital application of cardiac biomarkers for decision support in patients with suspected AMI. In: Kost GJ, Ed., *Global Point of Care*, 2015.

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



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

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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[b] *Knowledge Optimization®, Davis, CA*
[c] *Affiliate Faculty, College of Population Studies, Chulalongkorn University, Bangkok, Thailand*
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3455 Tupper Hall, Davis, CA 95616

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

THE SPATIAL CARE PATH™

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

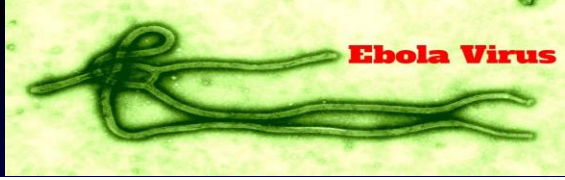
- ***Hypothesis:*** *Integrates prevention and intervention to shift the focus upstream to the patient site early on, in order to save resources, time, and lives, and to stop outbreaks.*

- ***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—Thailand, Brazil, & others.*

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.

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)

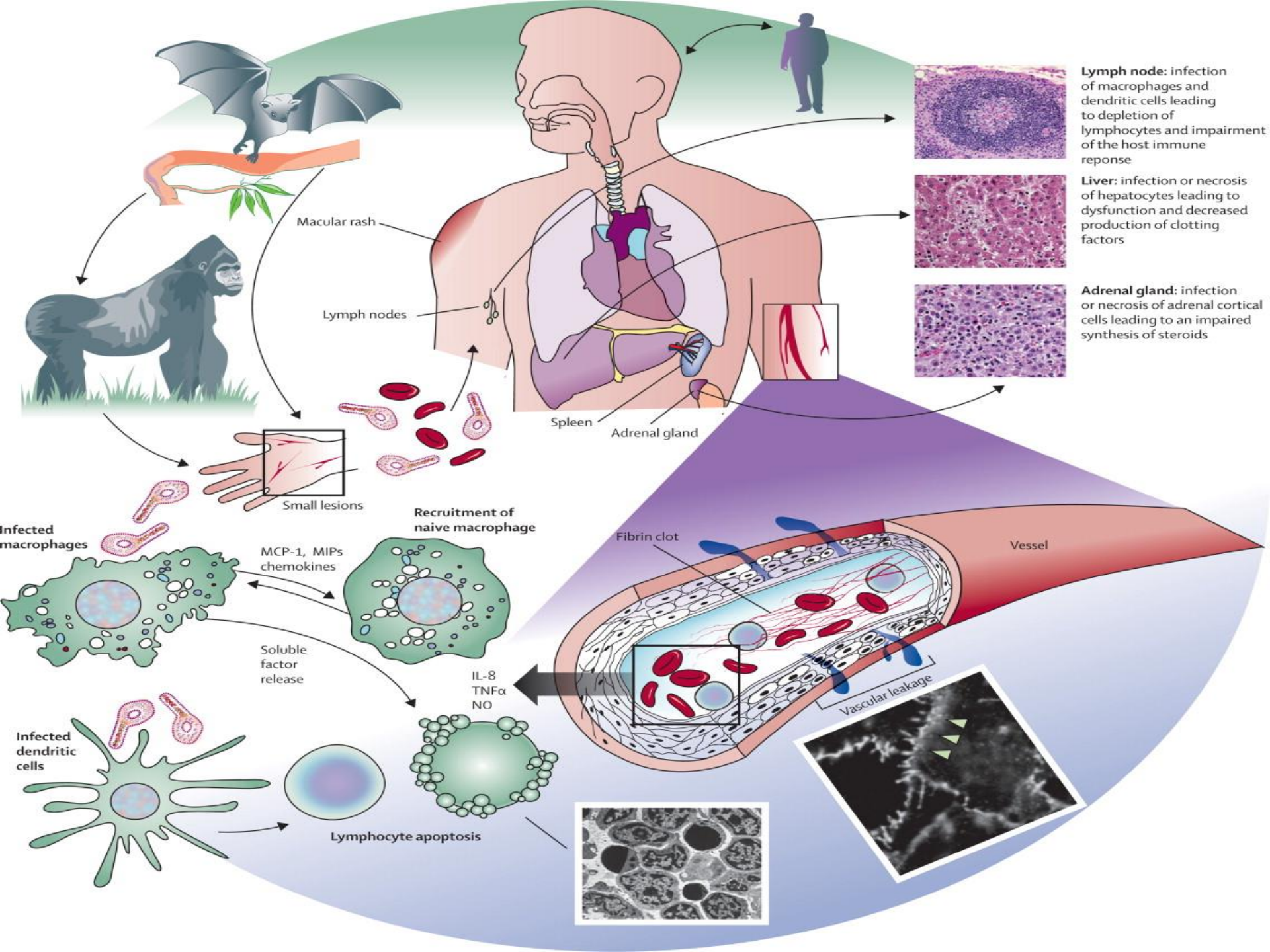
Epizootic Cycle

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.

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

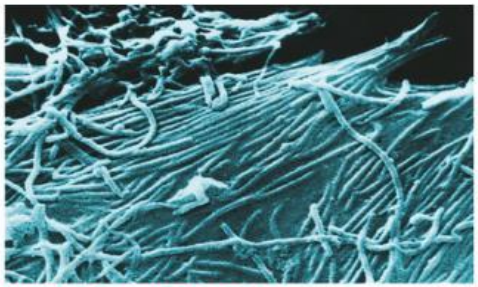
Human-to-human transmission is a predominant feature of epidemics.

CDC


Macular rash
Lymph nodes
Spleen
Adrenal gland
Small lesions
Infected macrophages
MCP-1, MIPs chemokines
Recruitment of naive macrophage
Soluble factor release
IL-8
TNFα
NO
Infected dendritic cells
Lymphocyte apoptosis
Fibrin clot
Vessel
Vascular leakage
Lymph node: infection of macrophages and dendritic cells leading to depletion of lymphocytes and impairment of the host immune reponse
Liver: infection or necrosis of hepatocytes leading to dysfunction and decreased production of clotting factors
Adrenal gland: infection or necrosis of adrenal cortical cells leading to an impaired synthesis of steroids

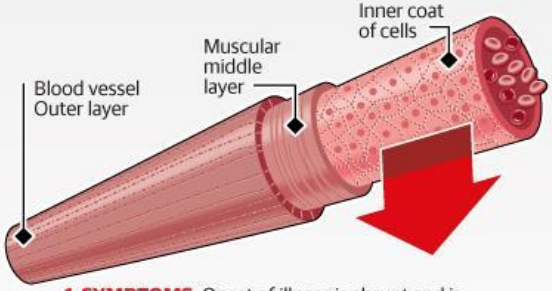
WHAT MAKES EBOLA SO DEADLY

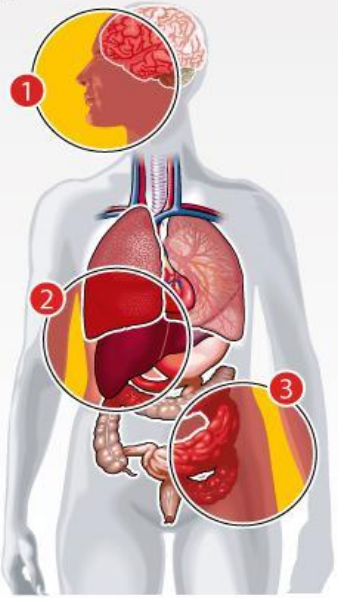
Ebola is a viral illness which infects through direct contact with blood or bodily fluids of a sick person or animal, or with contaminated objects. It leads to haemorrhage and organ failure and kills up to 90% of victims



INFECTION: Ebola genome contains four genes which together prevent dendritic cells – in skin, nose, lungs and digestive system – from sending messages to trigger immune system

UNCHECKED VIRAL GROWTH:
Virus spreads to cell types throughout body by binding glycoprotein to receptors on cell surfaces





1. SYMPTOMS: Onset of illness is abrupt and is characterized by fever, headache, joint and muscle aches, sore throat, red eyes, and weakness

2. CYTOKINE STORM:
Immune cells get caught in endless loop, releasing extreme levels of cytokines – proteins within cells which cause inflammation – and attracting yet more immune cells

3. SEPTIC SHOCK:
Infected cells detach from blood vessels, causing massive haemorrhage. Loss of blood leads to kidney and liver failure

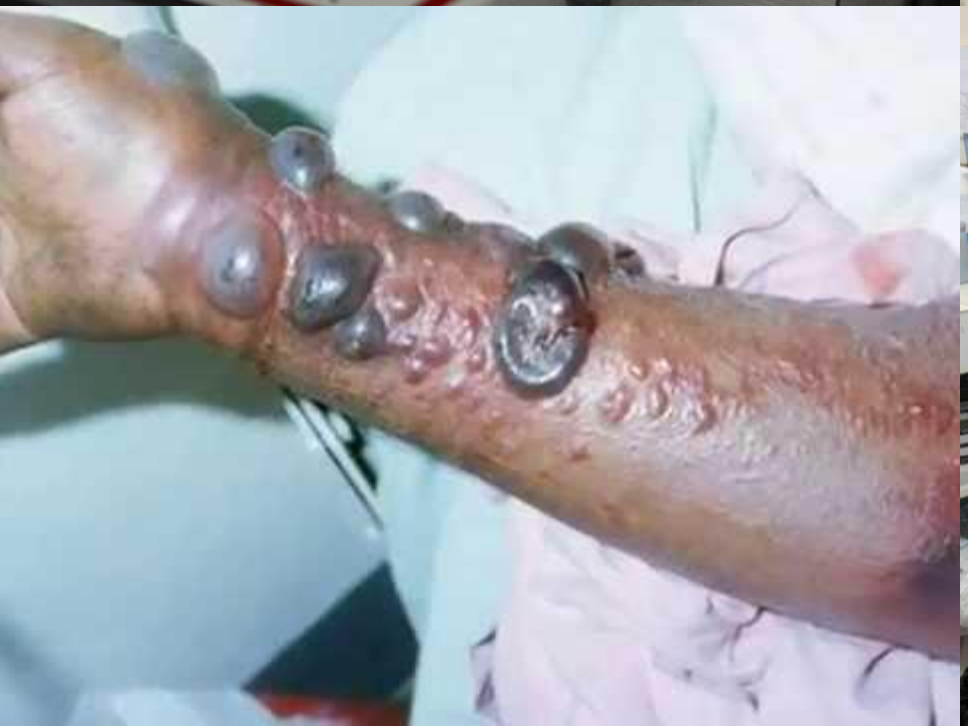
Source: University of Texas Medical Branch Picture: Public Library of Science GRAPHIC NEWS

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



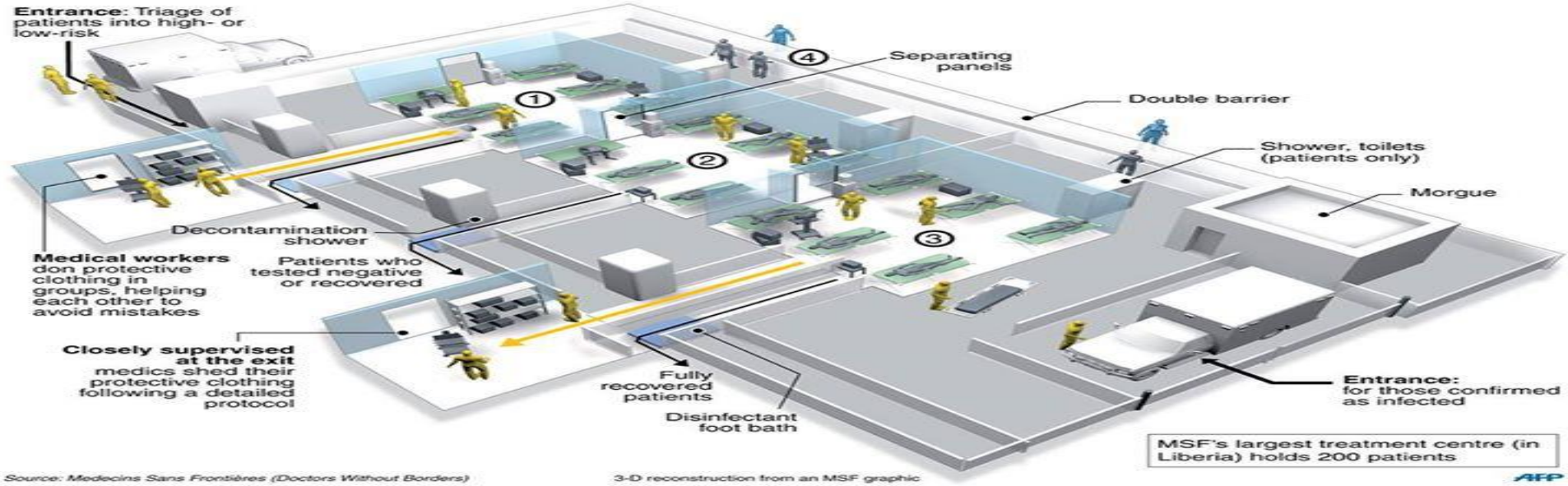
Inside an MSF Ebola treatment centre

① Low-risk infected
Patients are kept apart from the high-risk group while they wait for their blood test results.

② High-risk of infection
Those showing symptoms are kept apart from zone 1. Sent to zone 3 if they test positive.

③ Infected patients
There is no cure for Ebola, but good supportive care increases chances of survival.

④ Visiting area
No direct contact between patients and visitors to eliminate the risk of infection.



Source: Medecins Sans Frontières (Doctors Without Borders)

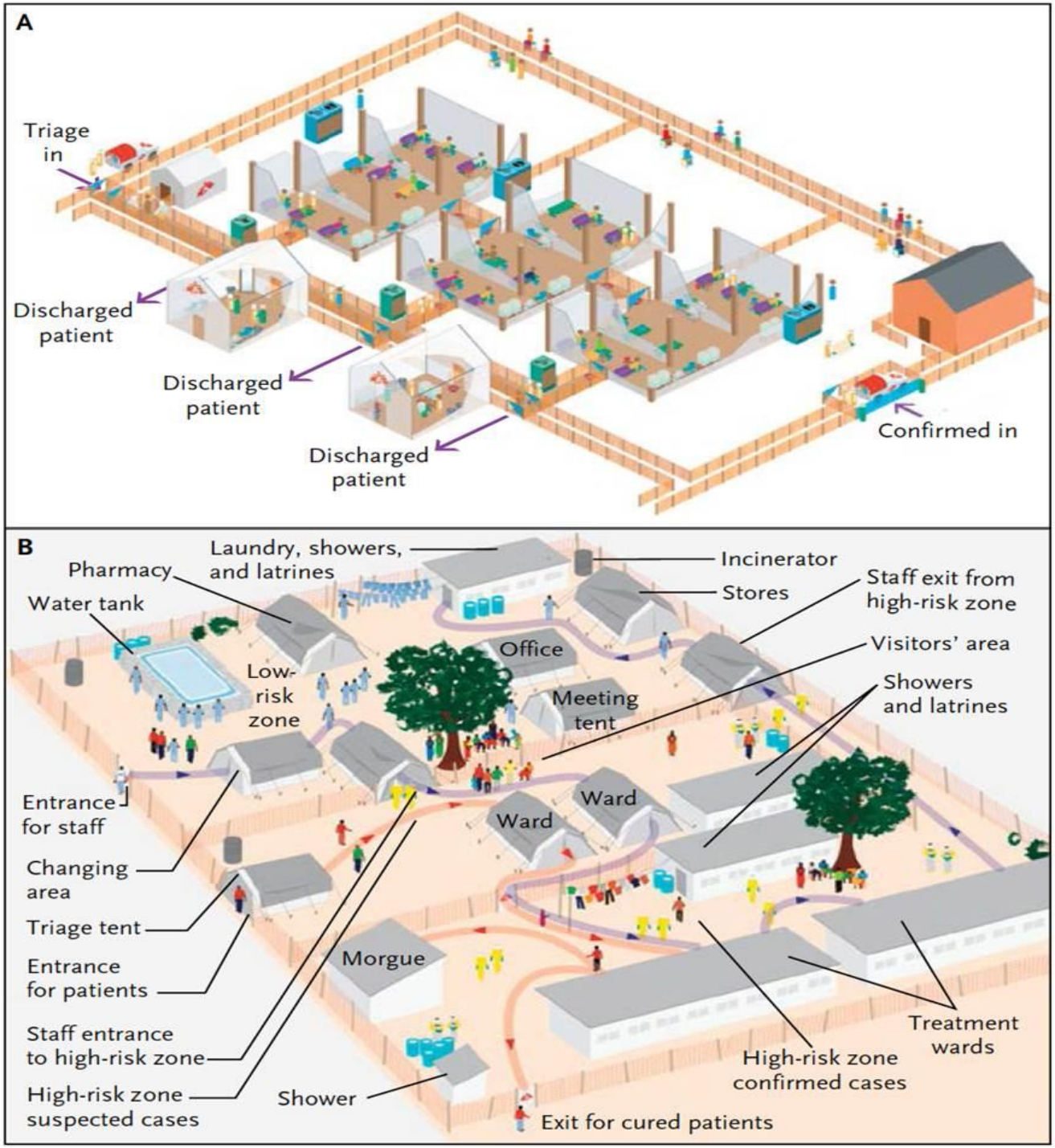
3-D reconstruction from an MSF graphic

AFP

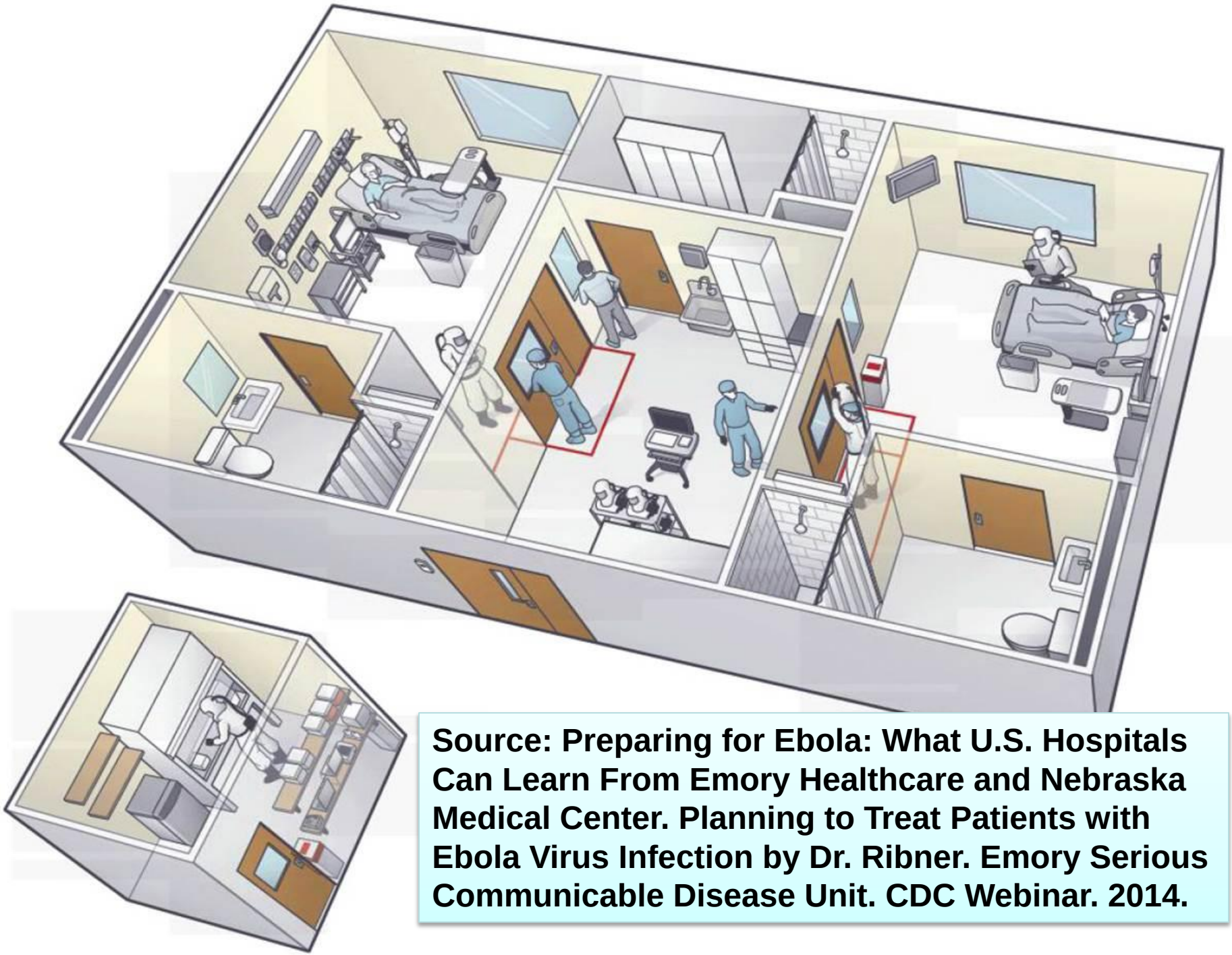
Ebola Containment

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.



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.

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

Warning!

KEY FEATURES	DESIRED	ACCEPTABLE
PRIORITY FEATURES		
Target population	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

"The Race to Diagnose"

Source: Baker A, Cape Town. *Time*. Vol. 184, No. 17, November 3, 2014, pages 28-29.

Spring 2014: Corgenix received a $2.9 million grant from the NIH. Disposable test administered at a clinic, in the home, or during airport arrival. Pinprick of blood from the finger of a patient. Positive result indicated by a dark red line on the test strip. Can only identify Ebola at symptom onset 8-10 days following exposure. Costs $2-8 per test, 100 of which fit in a portable cooler.

Spring 2015: Oraasure received a $10 million grant from HHS for POC Ebola test.

****

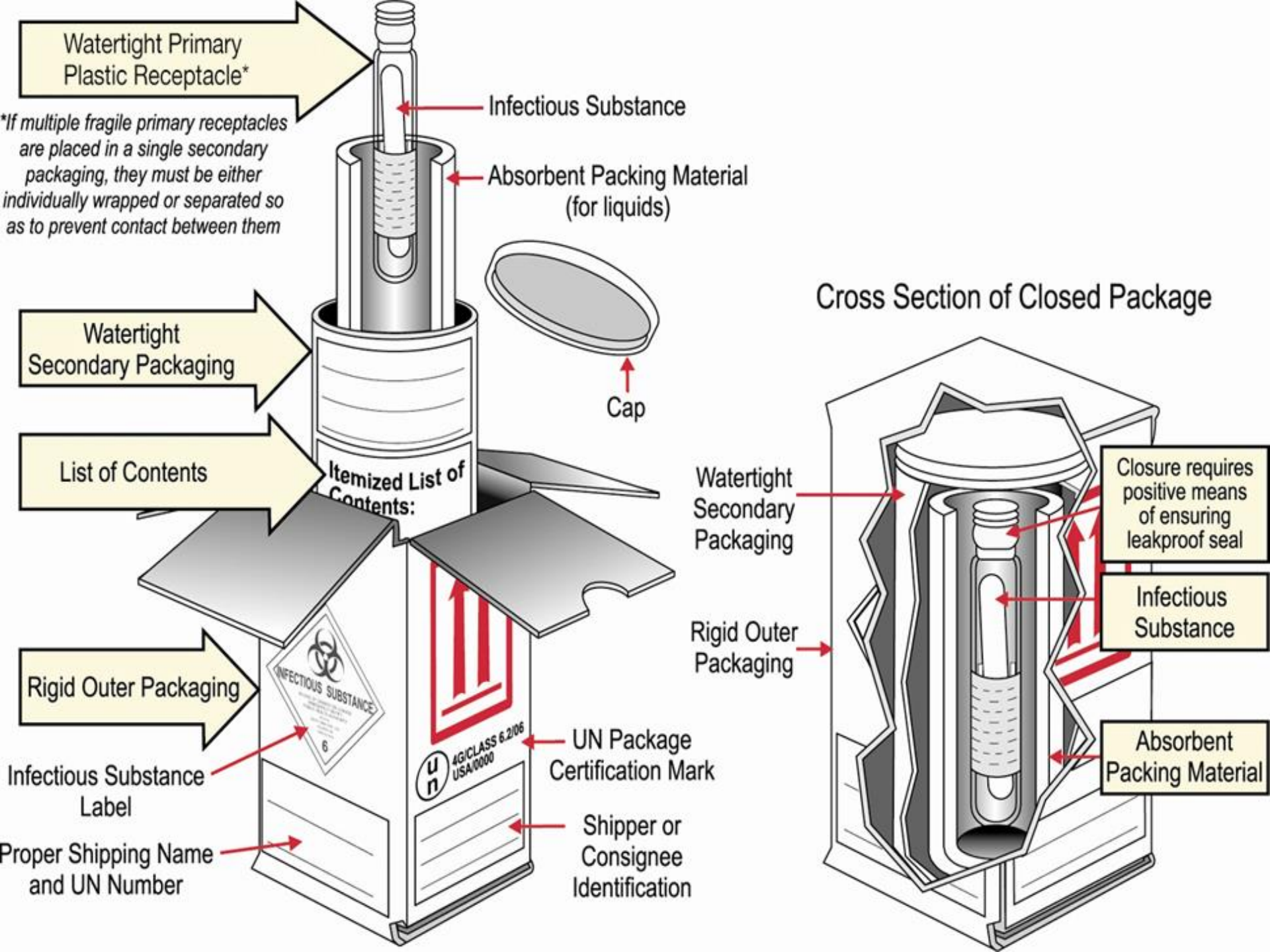
Before: US DOD considering Liberia request for 3 more diagnostic labs (total 8) in country. Sierra Leone has 4, and Guinea, 3. 100 tests per day now, but expect 10,000 new cases per week by December, according to the WHO. Need to get 70% of population with Ebola into isolation and care. **Now:** new outbreaks.

****

"With enough tests, we can shut it down. Without them, Ebola may be here to stay."

THE STATUS OF EMERGENCY USE AUTHORIZATIONS

Instrument(s) &/or Assay/Kit Manufacturer	Principle	Sample(s)	Time to Results	FDA Status
Xpert Ebola Assay Cepheid	rRT-PCR Cartridge-based	Blood	2 hrs	EUA 3/23/15
Corgenix ReEBOV & Fio Corporation[a]	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 hrs	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[b] procurement]
BioFire Defense Biothreat-E/NGDS bioMerieux[c] [in 300 hospitals]	Film Array EZV Auto'd. rRT-PCR	Blood, urine (if matched to blood)	1 hr	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[d] Handheld multiplex cartridge-based	Pinprick capillary blood	10 min	No EUA[e] (see above)
Lucigen AmpliFire [Douglas Sci., UTMB, CDC]	LAMP (isothermal) 1-step, battery-operated, portable[f]	RNA extract [plan 50 µL POC fingerstick capillary blood]	40 min	No EUA[e]
Biomarkers USAMRIID/ ECBC/TFS	Mass spectrometry	In development	NS	No EUA[e]


Watertight Primary Plastic Receptacle*
*If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated so as to prevent contact between them
Infectious Substance
Absorbent Packing Material (for liquids)
Watertight Secondary Packaging
Cap
List of Contents
Itemized List of Contents:
Rigid Outer Packaging
INFECTIOUS SUBSTANCE
6
4G/CLASS 6.2/06 USA/0000
UN Package Certification Mark
Infectious Substance Label
Shipper or Consignee Identification
Proper Shipping Name and UN Number
Cross Section of Closed Package
Watertight Secondary Packaging
Rigid Outer Packaging
Closure requires positive means of ensuring leakproof seal
Infectious Substance
Absorbent Packing Material

Oct. 31 not a holiday

Friday, Oct. 31 is a regular working day, Malacañang said yesterday.

Speaking over state-run dzRB radio, Presidential Communications Operations Office Secretary Herminio Coloma Jr. said the eve of All Saints' Day is not in the list of declared regular holidays and special non-working holidays.

Suspension of work would depend on the companies concerned, he added.

In Proclamation 655 in September 2013, President

Turn to Page 7

Poor health systems raise Ebola risk in Asia

SINGAPORE — The longer the Ebola outbreak rages in West Africa, the greater chance a traveler infected with the virus touches down in an Asian city.

How quickly any case is detected – and the measures taken once it is – will determine whether the virus takes hold in a region where billions live in poverty and public

Turn to Page 8

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VOL. XXIX NO. 92 • MONDAY, OCTOBER 17, 2014 • 11 SECTIONS, 74 PAGES ₱20 MM

LIVE IT!

A tourist offers a prayer as he lights a floating candle along the Mestizo River during the Raniag Twilight Festival in Vigan, Ilocos Sur Saturday night. ERNIE PEÑAREDONDO

Phl wants zero Ebola toll

Ebola precautions taken in Guangdong

by ZHENG CAIXIONG
in Guangzhou
zhengcaixiong@chinadaily.com.cn

Guangdong, a front-line region in preventing Ebola from spreading in the Chinese mainland, is going all out to stop an outbreak of the deadly virus in the southern province.

According to the Guangdong Provincial Center for Disease Control and Prevention, the province, which has a large

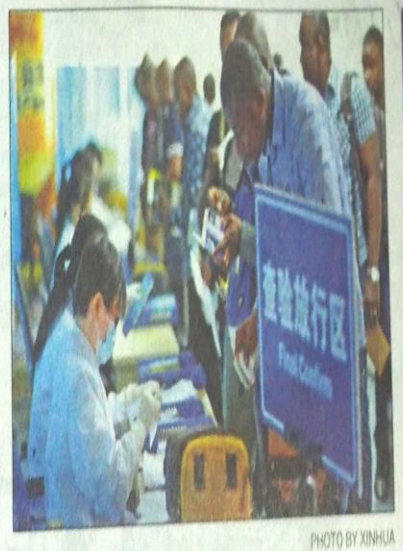


PHOTO BY XINHUA

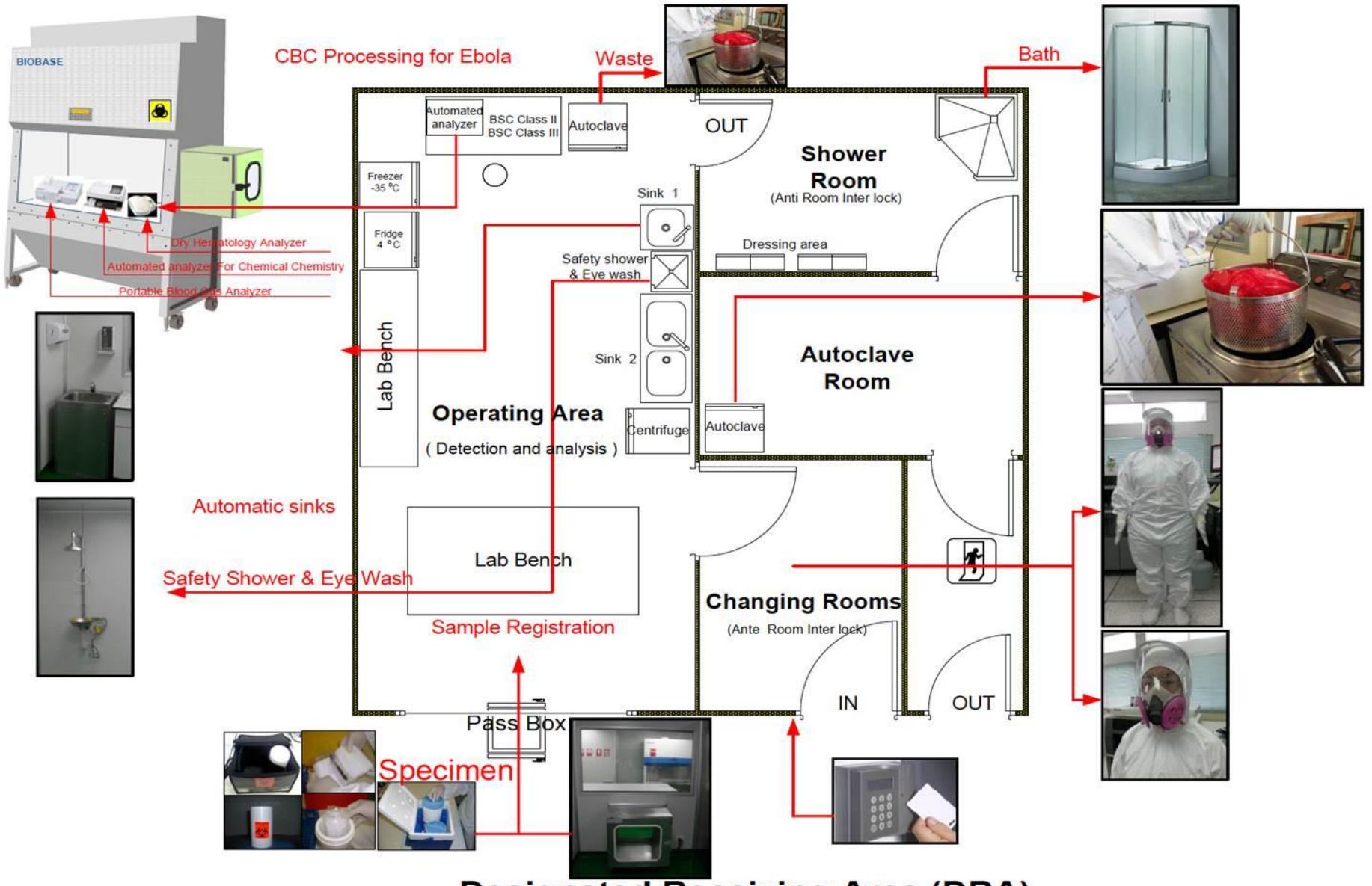
NO INFECTIONS FOUND

Inspection and quarantine authorities across China have recently intensified efforts to prevent the Ebola virus from entering China, and no confirmed infections have been found. China's top inspection and quarantine authority said on Wednesday.

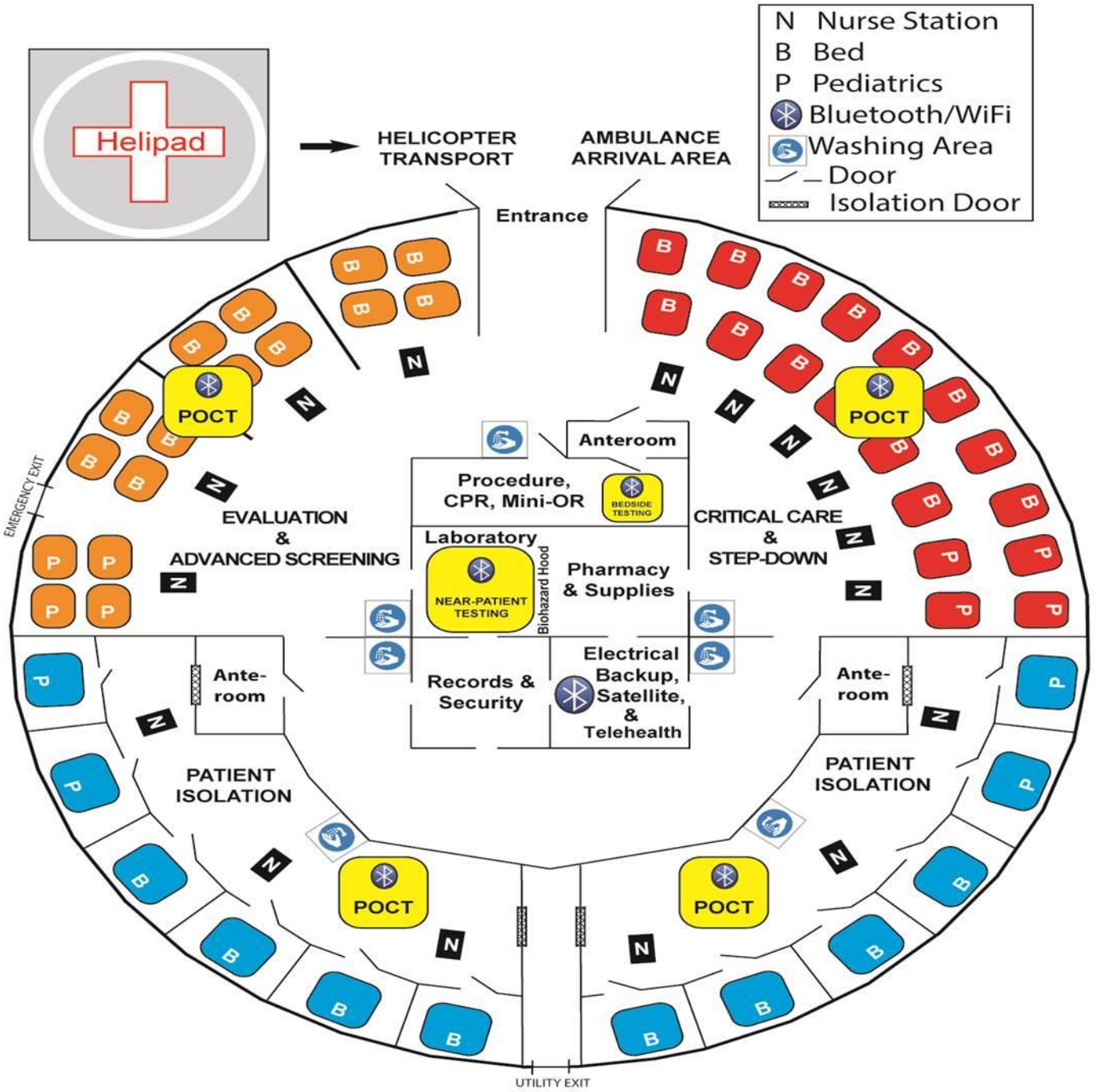
vent the deadly disease from spreading to China, as cases have spread to the United States and Europe.

Measures taken include requesting governments in affected West African countries to intensify inspections and quarantines of outbound travelers and requesting

Diagnostic Center



Alternate Care Facility for Ebola Triage and Care



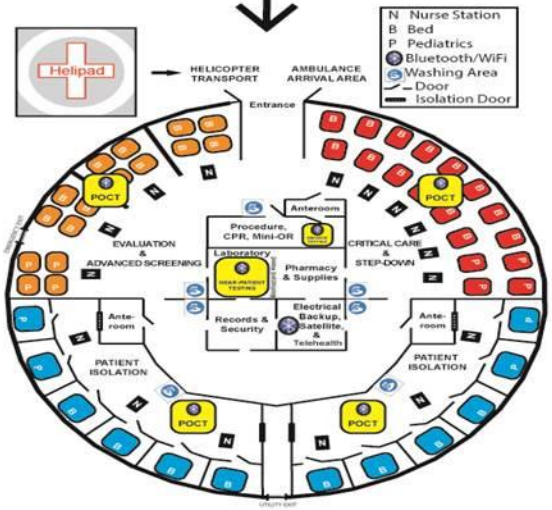
SPATIAL CARE PATH™

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

Point-of-Care Tests Established in Ebola Isolation Areas

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, $p0_2$, 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**)

Point-of-Care Tests Established in Ebola Isolation Areas

B. University of Nebraska Medical Center Biocontainment BSL-3 Laboratory[10]

Manufacturer Website	Instrument/ Method	Test(s)
Abbott www.Abbott.com	i-Stat	G3+ cartridge (pH, pCO_2, pO_2) & Chem8+ cartridge (Na^+, K^+, Cl^-, TCO_2, Ca^{++}, Glu, UN, Cr, Hct)
International Technidyne Corp. www.itcmed.com	Hemochron Signature Elite	Citrate prothrombin time (PT), citrate-activated partial thromboplastin time (aPTT)
Slide Agglutination	Manual	Blood & serum antibody typing (for transfusion)
Slide Preparation	Manual	Malaria—modified for the slide to be fixed in methanol 15 min before delivering to Core Lab for staining & interpretation
NS	Rapid manual assay	HIV Ab/Ag
Urine Dipstick	Manual dipstick	For tests not on strip, specimen transferred with precautions to Core Lab for non-decapped Dxl800 & DXC800i[f] analysis
NS	RPR	Syphilis (card assay)

Ebola Holding Units (4) in Sierra Leone, West Africa[f]

Developer Website	Method	Performance
United Kingdom's Defense Science & Technology Laboratory https://www.gov.uk/government/organisations/defence-science-and-technology-laboratory	Rapid diagnostic antigen test	Sensitivity 100%, 95% CI: 78.2–100. Specificity: 96.6%, 95% CI: 91.3–99.1. +/- predictive values: 79.0% (95% CI: 54.4–93.8)/100% (95% CI: 96.7–100).

Suite Environment, ARUP Institute for Clinical and Experimental Pathology

Manufacturer Website	Instrument/ Method	Tests, Evaluation Study Objectives
Abaxis www.abaxis.com	Piccolo Express	Liver Panel Plus[g] using disposable exact volume transfer pipettes and BSL-2 cabinet in BSL-3 suite environment for Ebola patient workup. Checked device air flow characteristics are suitable.

CDC REQUIREMENTS FOR EBOLA CENTERS

NEW 2015

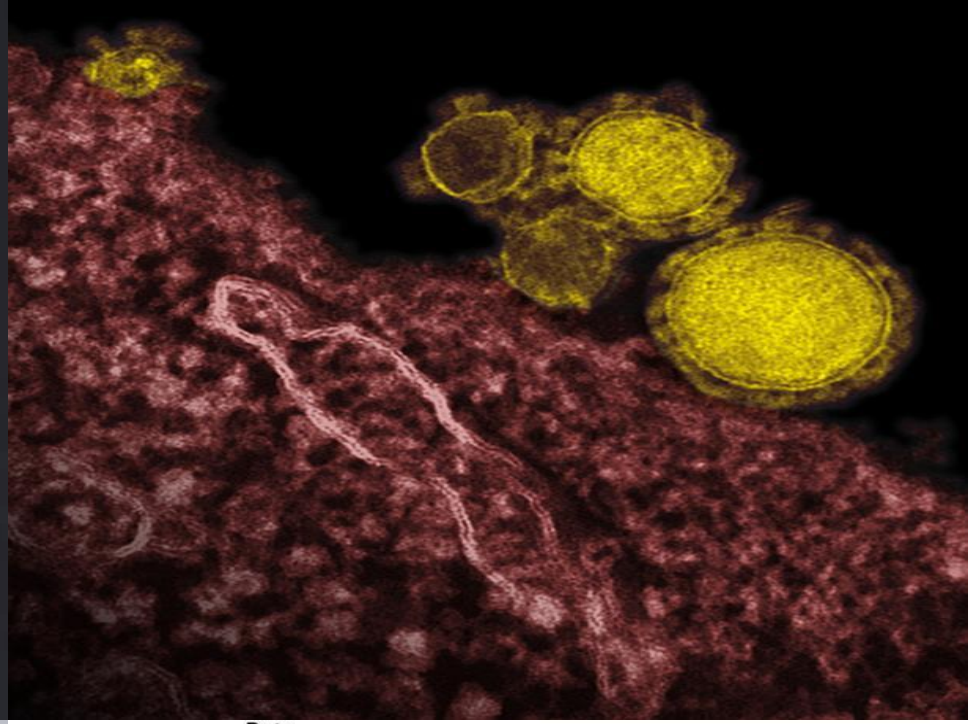
- Accept patients within eight hours of being notified,
- Have the capacity to treat at least two Ebola patients at the same time,
- Have respiratory infectious disease isolation capacity or negative pressure rooms for at least 10 patients,
- Conduct quarterly trainings and exercises,
- Receive an annual 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).

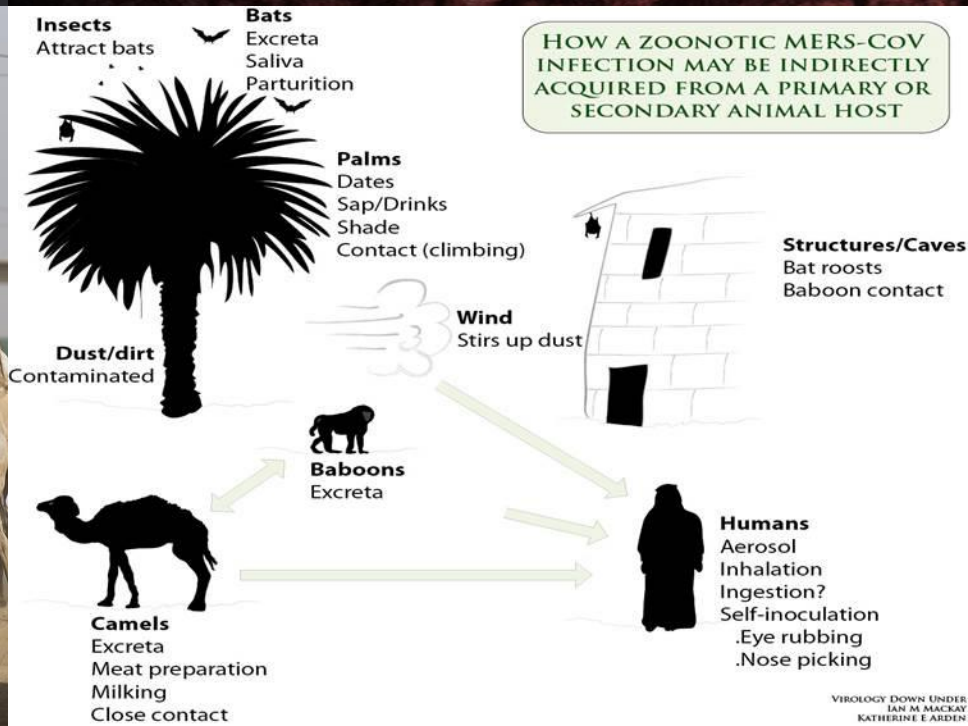
Source: ASPR Press Office. HHS selects nine regional Ebola and other special pathogen treatment centers. June 12, 2015. HSS.gov or http://www.hhs.gov/news

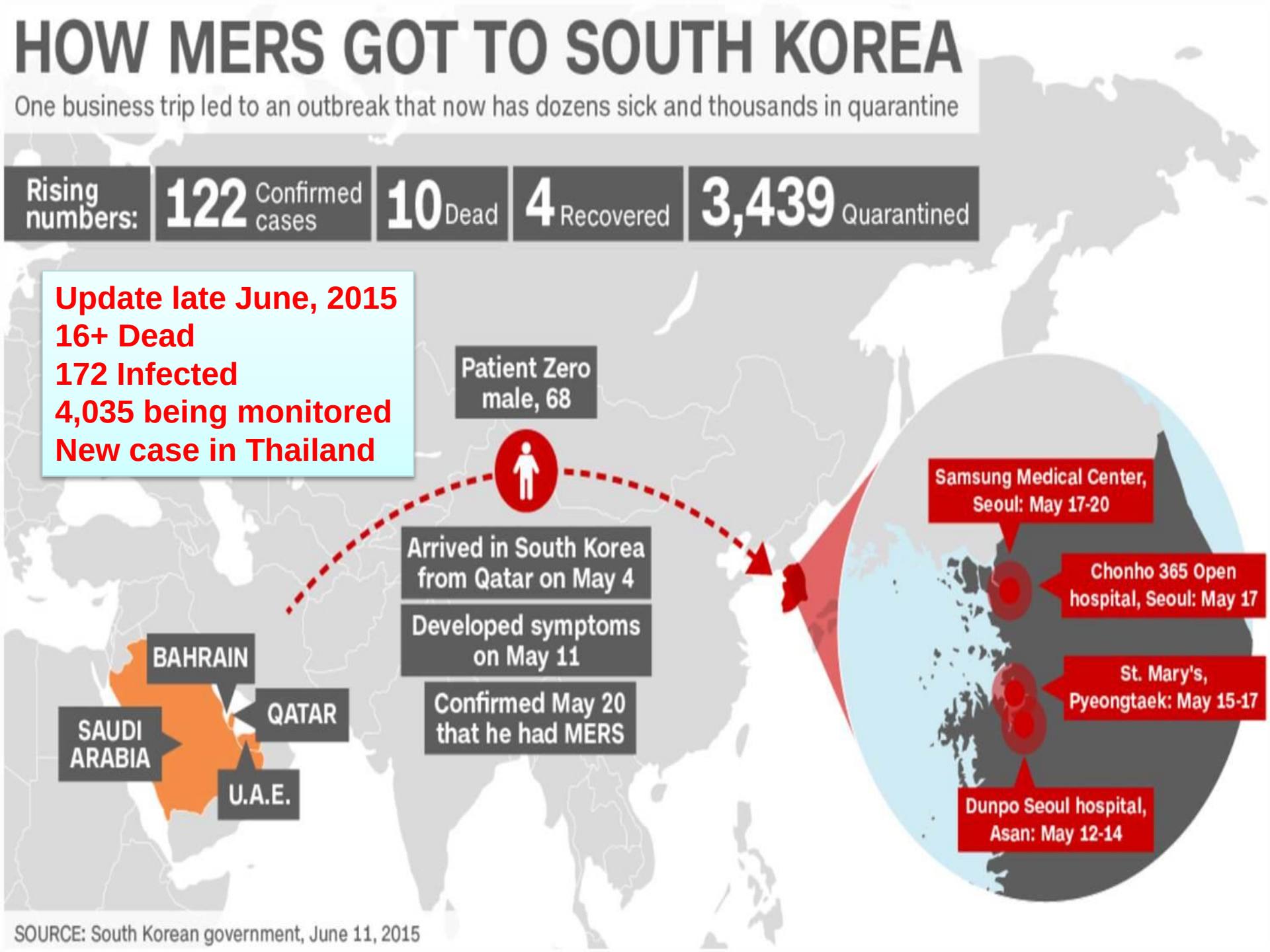
9 CENTERS, 5 YEARS—$29($10^6$), ~3.25 ea, $339.5 pkg

- New York City Department of Health and Mental Hygiene in partnership with New York City Health and Hospitals Corporation/HHC Bellevue Hospital Center in New York City
- Maryland Department of Health and Mental Hygiene in partnership with Johns Hopkins Hospital in Baltimore, Maryland
- Georgia Department of Public Health in partnership with Emory University Hospital and Children's Healthcare of Atlanta/Egleston Children's Hospital in Atlanta, Georgia
- Minnesota Department of Health in partnership with the University of Minnesota Medical Center in Minneapolis, Minnesota
- Texas Department of State Health Services in partnership with the University of Texas Medical Branch at Galveston in Galveston, Texas
- Nebraska Department of Health and Human Services in partnership with Nebraska Medicine - Nebraska Medical Center in Omaha, Nebraska
- Colorado Department of Public Health and Environment in partnership with Denver Health Medical Center in Denver, Colorado
- Washington State Department of Health in partnership with Providence Sacred Heart Medical Center and Children's Hospital in Spokane, Washington




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
Humans
Aerosol
Inhalation
Ingestion?
Self-inoculation
.Eye rubbing
.Nose picking
Camels
Excreta
Meat preparation
Milking
Close contact
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
Patient Zero male, 68
Arrived in South Korea from Qatar on May 4
Developed symptoms on May 11
Confirmed May 20 that he had MERS
BAHRAIN
QATAR
SAUDI ARABIA
U.A.E.
Samsung Medical Center, Seoul: May 17-20
Chonho 365 Open hospital, Seoul: May 17
St. Mary's, Pyeongtaek: May 15-17
Dunpo Seoul hospital, Asan: May 12-14
SOURCE: South Korean government, June 11, 2015


MADE IN
KOREA


설악건강원

Version 1. PLoS Curr. 2013 December 12; 5: ecurrents.outbreaks.62df1c7c75ffc96cd59034531e2e8364.
PMCID: PMC3871419
Published online 2013 December 12. doi: 10.1371/currents.outbreaks.62df1c7c75ffc96cd59034531e2e8364
Research

Reverse Transcription Recombinase Polymerase Amplification Assay for the Detection of Middle East Respiratory Syndrome Coronavirus

Ahmed Abd El Wahed,* Pranav Patel, Doris Heidenreich, Frank T. Hufert, and Manfred Weidmann

Ahmed Abd El Wahed, Department of Virology, University Medical Centre, Goettingen, Germany; Department of Virology, Faculty of Veterinary Medicine, Mansoura University, Mansoura, Egypt;
Contributor Information.

Abstract

The emergence of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in the eastern Mediterranean and imported cases to Europe has alerted public health authorities. Currently, detection of MERS-CoV in patient samples is done by real-time RT-PCR. Samples collected from suspected cases are sent to highly-equipped centralized laboratories for screening. A rapid point-of-care test is needed to allow more widespread mobile detection of the virus directly from patient material. In this study, we describe the development of a reverse transcription isothermal Recombinase Polymerase Amplification (RT-RPA) assay for the identification of MERS-CoV. A partial nucleocapsid gene RNA molecular standard of MERS-coronavirus was used to determine the assay sensitivity. The isothermal (42°C) MERS-CoV RT-RPA was as sensitive as real-time RT-PCR (10 RNA molecules), rapid (3-7 minutes) and mobile (using tubescanner weighing 1kg). The MERS-CoV RT-RPA showed cross-detection neither of any of the RNAs of several coronaviruses and respiratory viruses affecting humans nor of the human genome. The developed isothermal real-time RT-RPA is ideal for rapid mobile molecular MERS-CoV monitoring in acute patients and may also facilitate the search for the animal reservoir of MERS-CoV.

Middle East Respiratory Syndrome Coronavirus (MERS-CoV) EUA Information

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheets and Labeling	EUA Determination and Declaration	PREP Act Declaration (if applicable)
CDC Novel Coronavirus 2012 Real-time RT-PCR Assay	June 10, 2014	Authorization (PDF, 2.2 MB)	FR notice	• Health-care • Patients • Contacts (PDF, 1.2 MB)	Determination and Declaration - HHS	*(see Determination)*

In response to CDC's request to amend this EUA, on June 10, 2014 FDA reissued the June 5, 2013 EUA in its entirety with the CDC-requested amendments incorporated. The amendments authorize the expanded use of the CDC assay to include testing persons who may not be exhibiting signs and symptoms associated with MERS-CoV infection, but who meet certain epidemiological risk factors. The EUA amendments also include a new fact sheet for contacts of MERS cases and revisions/updates to the instructions for use and fact sheets for patients and health care professionals. This device will be distributed by CDC to qualified laboratories.


건양대학교병원
KONYANG UNIV. HOSPITAL

POLICY & GUIDELINES

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

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

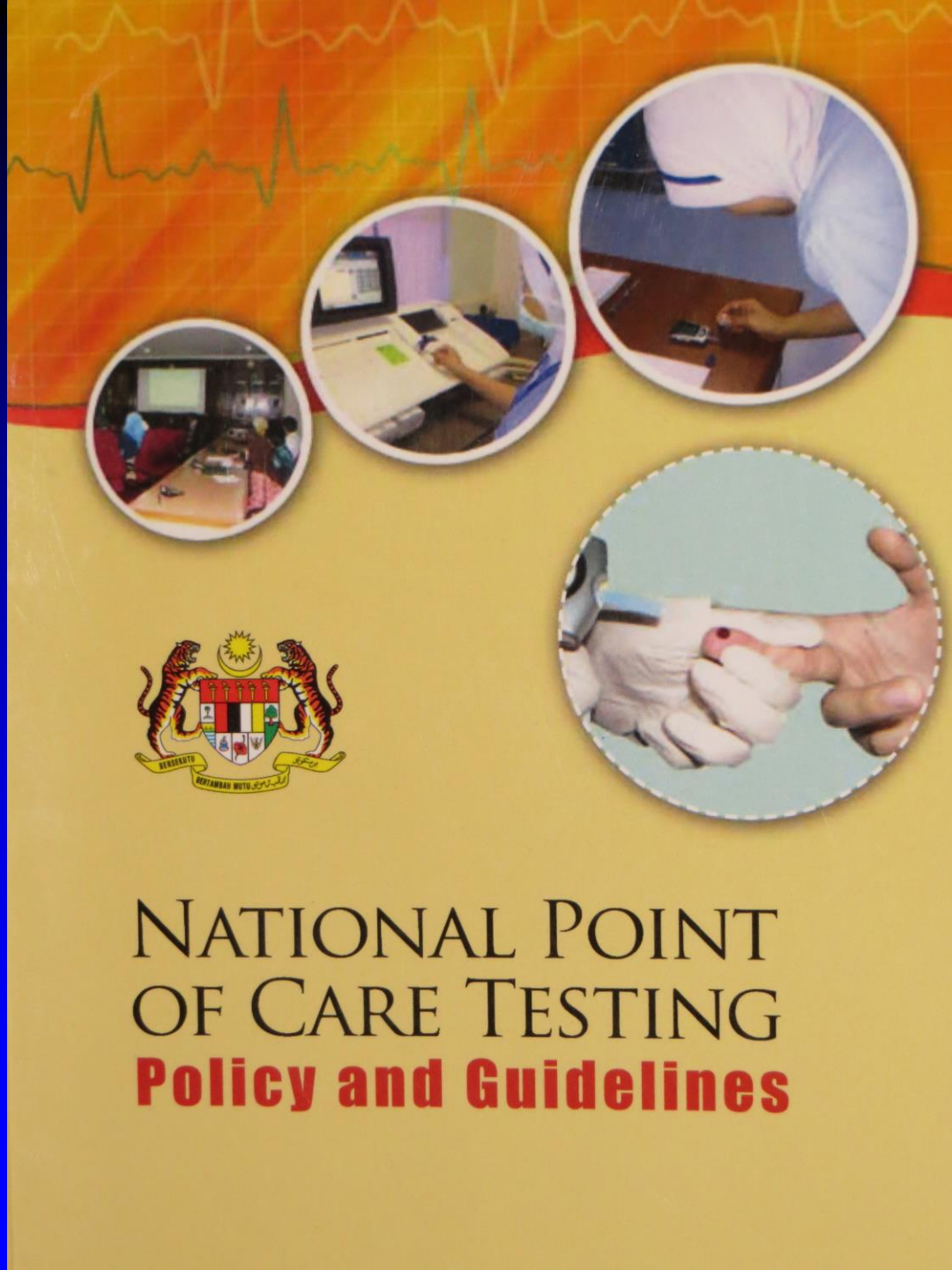
- **Endorsed by the Malaysia Ministry of Health—entire country**

- **One of the world's first nationally harmonized approaches to point-of-care testing, the new culture**

- **Needs extension based on "*Emergency and Disaster POC Testing*" (CLSI POCT16-coming!)**

- **Thailand MOPH national guidelines coming this year!**

- ***Philippines in planning stage.***

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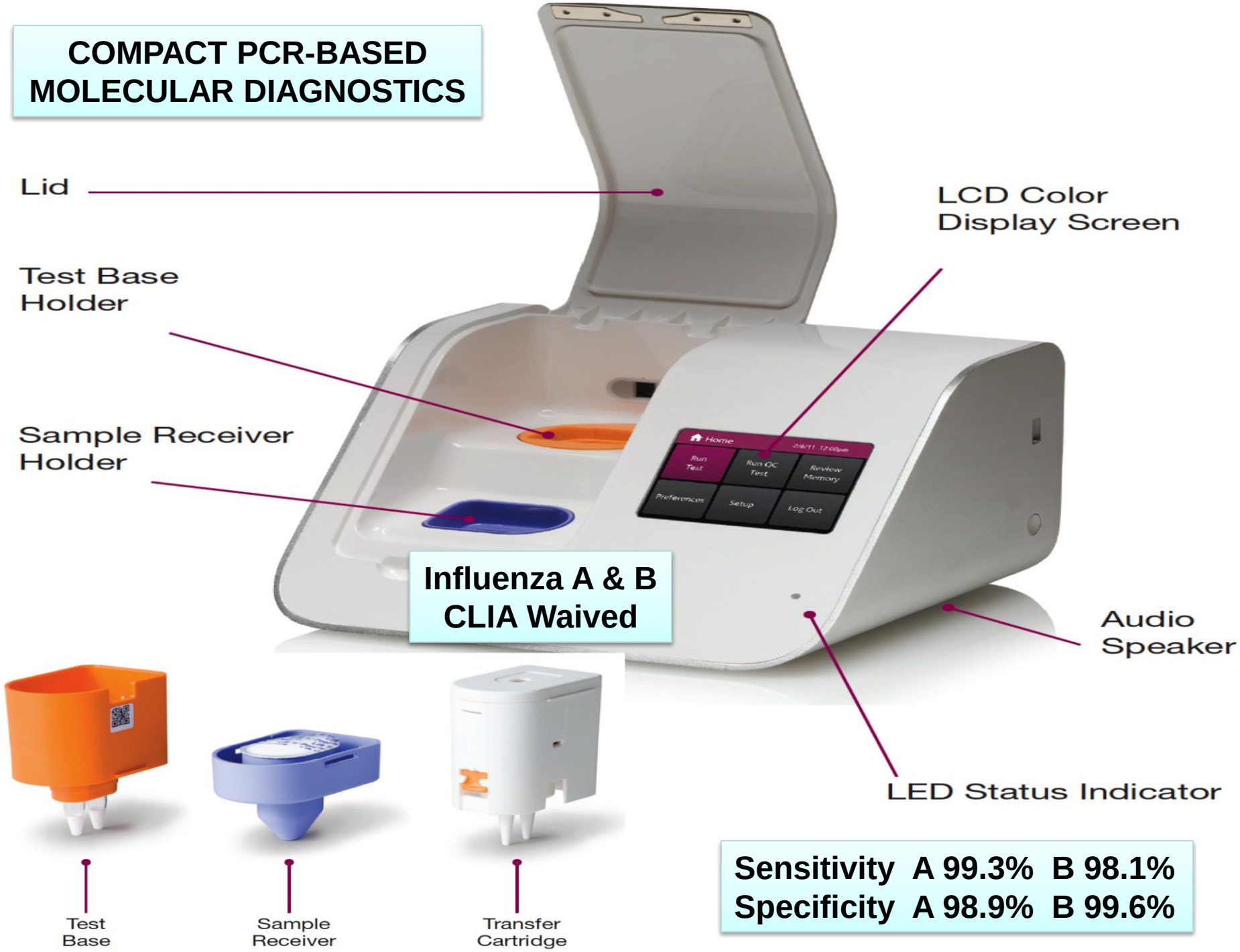
SNUH 서울대학교병원
DANGER

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.

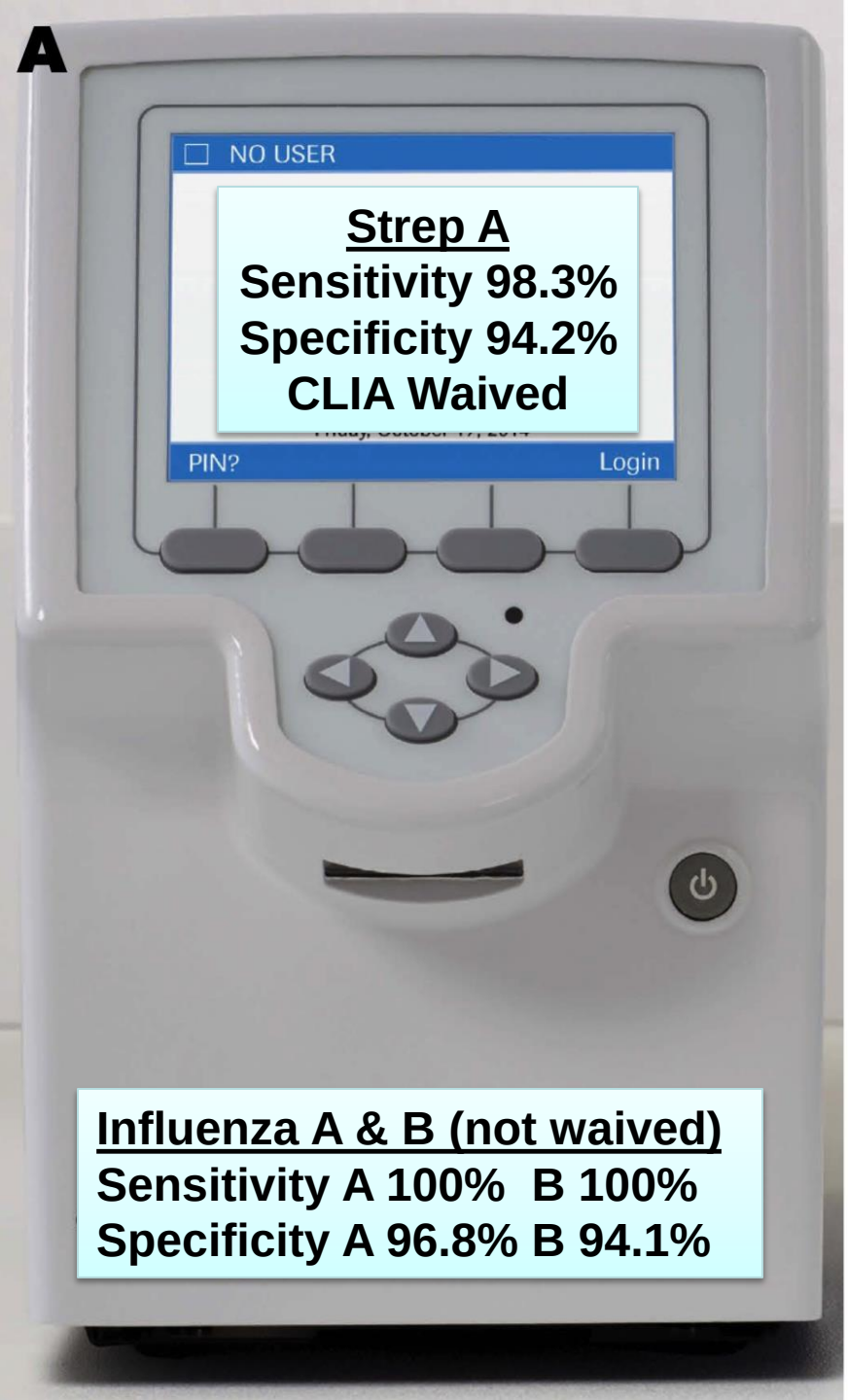
COMPACT PCR-BASED MOLECULAR DIAGNOSTICS



Influenza A & B
CLIA Waived

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

A



Influenza A & B (not waived)
Sensitivity A 100% B 100%
Specificity A 96.8% B 94.1%

B

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

43

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

471

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 frontier!***

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.***

DISCLOSURES (…*WITH APPRECIATION!*)

- **Major long-term funding**—National Institute of Biomedical Imaging and Bioengineering (NIBIB), National Institutes of Health, U54 Point-of-Care Technologies Center and ARRA/PPP funds (substantial portions of the results in this presentation, completed)

- **Industry contributions of counsel, equipment, reagents, and in some cases travel support**—Abbott, Alere, HemoCue, Nova Biomedical, Roche Diagnostics (Malaysia, Switzerland, Thailand, & USA), Connect Diagnostics (Thailand), et al. (including in China)

- **The University of California**—UC Davis Outreach and International Programs and UC Systemwide grants and travel awards; Faculty research awards

- **Various Donors**—matching funds for global development, education, and research

- **Fulbright Scholar Award**—Point-of-Care Testing, Demography, and Economics research; teaching, mentoring, and lecturing in SE Asia (10 countries)

- **Ministries of Public Health**—currently sponsoring the development of national guidelines in Thailand, previously in Malaysia, and soon in development in the Philippines

- **Collegial and Professional**—Chulalongkorn and Srinakharinwirot (SWU) Univs., Bangkok, Thailand, and others; POCT Task Force, IFCC (travel funds); & CPOCT Division, AACC

ACKNOWLEDGEMENTS

Point-of-Care Testing Center for Teaching and Research (POCT•CTR), founded 1995 and continuing 20 years, and the UC Davis POC Technologies Center [U54, NIBIB, NIH], 2007-2014

FOUNDERS

Gerald J. Kost, MD, PhD, MS, FACB; Richard F. Louie, PhD, FACB; and Nam K. Tran, PhD, MS, FACB

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