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Evidence-Based Point-of-Care Device Design for Emergency and Disaster Care

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Keywords

Diagnostics; Pathogen Detection; Survey; Trade-off Questions; Visual Logistics

Introduction

The 2004 tsunami in Southeast Asia and Hurricane Katrina in 2006 illustrated the need for POCT in disaster settings and the vulnerability of point-of-care (POC) devices to harsh disaster environments.¹⁻⁵ Therefore, device developers must identify POC prerequisites for emergencies and disasters. The goal of this research was to better define diagnostic device design criteria in order to resolve technological gaps for POC emergency and disaster testing. To achieve this goal the POC Technologies Center developed and administered an emergency and disaster care needs assessment survey.

Methods

We targeted the readership of *Point of Care*. Two-hundred (200) journal readers were invited to participate. Contact information and permission were provided by the publisher, Lippincott Williams and Wilkins (Philadelphia, PA). We deleted journal subscribers without e-mail addresses or inadequate contact information. This research was approved by the UC Davis Institutional Review Board.

The survey is based on extensive literature review with the assistance of the Warfare Analysis Laboratory Exercise (WALEX)⁶, disaster medicine experts, and other expert input. It has four sections: 1) demographics, 2) device design questions, 3) trade-off questions, and 4) pathogen test cluster questions. Survey questions utilize “visual logistics,” graphics for portraying questions and concepts without lengthy or laborious text.

We created an online survey tool using SurveyMonkey (Portland, OR) to simplify distribution, increase response rate, and ease the burden on the respondent. We sent a personalized invitation letter by email and U.S. Postal Service. For geographic regions of low response, we followed up by phone and sent a hard copy of the survey via Federal Express with a self-addressed stamped return envelope.

The survey displayed three question formats: a) multiple choice questions to determine device design, b) questions that ranked target pathogens and functions for a test cluster (1 to n, 1 best, n worst), and c) trade-off questions in which two hypothetical devices with different design

specifications were compared (e.g., a device with high sensitivity that is not portable and a device that is highly portable but has low sensitivity). Respondents then selected which of the two devices they preferred.

We used SPSS 15 (SPSS, Chicago, IL) statistical software and analyzed multiple choice questions using the non-parametric Chi-Square for Goodness-of-Fit test and the Binomial Distribution Test. Mean weighted scores were analyzed using Analysis of Variance (ANOVA) and Tukey's Multiple Comparison test. To verify the significance of the ANOVA, we used a non-parametric Mann-Whitney U test. We analyzed trade-off questions using multivariate logistic regression. Statistical significance is defined as: * $p < 0.05$; ** $p < 0.01$; and *** $p < 0.001$.

Survey respondents assigned ranks, R_j , with $j = [1, n_r]$, where n_r is the number of possible ranks for each factor, F_i , with $i = [1, n_f]$, and n_f is the number of factors given for selection. Scores were calculated using the following equation: $S_j = (n_r + 1) - R_j$. We determined the weighted score (WS) by summing the product of each score and corresponding frequency as follows:

$$WS_i = \sum_{j=1}^{n_r} S_j \times F_{ij}$$

The frequency, F_{ij} , is the number of times survey respondents assigned an individual factor a specific rank. When respondent designated the same rank for two or more factors, an average rank was assigned to each factor and positions of factors with lower ranks were adjusted accordingly.

Of two hundred journal readers contacted, 100 responded for a response rate of 100/200 (50%). Of the 100 respondents, 76 were geographically distributed across the U.S. The remaining 24 were outside of the U.S. with 10 from Europe, 5 from Australia, 4 from Asia, 3 from Canada, 1 from South America, and 1 from Africa. Survey participant specialties were: laboratorians (55), medical doctors (13), point-of-care coordinators (12), industry (10), research scientists (7) and nurses (3).

Results

Survey respondents selected handheld devices more frequently than portable or transportable devices in three settings (disaster, 90/94; urgent care, 51/93; and emergency room, 57/93). Clinical sensitivity, time to result, clinical specificity, and battery capability were independent predictors of device selection for trade-off responses (Table). The table presents adjusted odds ratios.

For sample collection method, respondents preferred test cassette collection to Vacutainer collection in disaster settings ($p < 0.001$, $N_{\text{disaster}}=88$). However, respondents preferred Vacutainer collection in the urgent care setting ($p < 0.05$, $N_{\text{urgent care}}=87$), and there was no statistically significant preference in emergency room settings (Figure 1). Survey respondents preferred direct sample collection to coupled-direct sample collection in disaster settings ($p < 0.01$, $N_{\text{disaster}}=84$), but preferred coupled-direct sample collection to direct sample collection in urgent care and emergency room settings ($p < 0.05$, $N_{\text{urgent care}}=84$; $P < 0.05$, $N_{\text{emergency room}}=83$) (Figure 2).

In the three settings surveyed, respondents selected a device that stores all biohazard waste in a test cassette more frequently than a device that stores waste in a reservoir that is periodically emptied ($p < 0.001$, $N_{\text{disaster}}=84$, $N_{\text{emergency room}}=83$, $N_{\text{urgent care}}=83$) (Figure 3). For result

processing, survey respondents preferred a device that processes a single patient sample for multiple pathogens over a device that processes multiple patient samples for a single pathogen in both urgent care and emergency room settings ($p<0.001$ $N_{\text{emergency room}}=78$, $N_{\text{urgent care}}=79$). There was no statistically significant preference for either results processing approach in disaster settings.

Survey respondents selected first responders most frequently (78.2%) as the POCT operator of diagnostic devices in disaster settings. Respondents selected nurses (14.1%), medical technologists (5.1%), and patients/victims (2.6%) less frequently. Respondents ranked patient-side testing (WS 203) the highest for field POCT locations compared to vehicle testing locations (WS 137) and tent testing locations (WS 122) ($p<0.001$ $N=80$).

For POCT locations in a hospital following a disaster, testing at the bedside (WS 242.5) was ranked the highest compared with testing inside the hospital unit (WS 227.5), satellite laboratory testing (WS 164.5), or central laboratory testing (WS 164.5). Survey respondents ranked patient-side testing higher in pair-wise comparison with central or satellite laboratory testing ($p<0.001$, $N=80$). Testing inside the hospital unit also was ranked higher in pair-wise comparison with central or satellite laboratory testing ($p<0.001$, $N=80$). However, there was no significant difference in rank between testing at the patient-side and inside the hospital unit.

Survey respondents ranked ABO typing (WS 265.5), HIV 1/2 (WS 256.5), and hepatitis B virus (WS 209.5) the highest for a point-of-care emergency blood donor screening test. ABO typing was ranked higher in pair-wise comparison with the other targets except HIV 1/2 ($p<0.05$, $N=60$) (Figure 4). MRSA was ranked higher in pair-wise comparison with the other pathogens for a bloodstream infection test cluster (WS 389, $p<0.01$, $N=47$) (Figure 5).

Pandemic (H1N1) 2009 ("swine" flu) influenza (WS 350), avian influenza (H5N1) (WS 337.5), and severe acute respiratory syndrome (WS 327) viruses were ranked the highest for a respiratory pandemic infectious disease test cluster at the point of care. Pandemic H1N1 was ranked higher in pair-wise comparison with the other pathogens except avian influenza, SARS, and influenza A/B ($P<0.001$, $N=64$) (Figure 6).

Survey respondents ranked methicillin resistant *Staphylococcus aureus* (MRSA) (WS 298), *Vibrio cholera* (WS 274), and *Salmonella typhi* (WS 257) as the three most important pathogens to test for at the point of care in a general disaster setting. MRSA was ranked higher in pair-wise comparison with other pathogens, except *Vibrio cholera* and *Salmonella typhi*, for a general disaster setting test cluster ($p<0.01$, $N=46$).

Discussion

The results from POC readers defined critical device design criteria. The World Health Organization (WHO) recommends rapid diagnosis of Influenza strains.⁷ Pandemic (H1N1) 2009 ("swine" flu), H5N1 (avian influenza), and influenza A/B were in the top four pathogens ranked by survey respondents for a respiratory pandemic infectious disease test cluster. For POC emergency blood donor screening, survey respondents felt it was important to type blood as well as test for infectious pathogens such as HIV 1/2 and hepatitis virus. In a disaster setting survey respondents selected MRSA, *Vibrio cholera*, and *Salmonella typhi* as the top three pathogens to test for at the point of care. These results match pathogens commonly found after disasters.⁸⁻¹⁷ MRSA also was selected most frequently to test for in bloodstream infections followed by *Streptococcus pneumoniae*, *Staphylococcus aureus*, and *Escherichia coli*.

In emergency room, disaster, and urgent care settings, survey respondents selected devices that were highly portable, possibly because high portability allows for more rapid diagnosis and ease of operation. In disaster settings, respondents selected test cassette-based direct-sample

collection possibly because of a reduction in potential contamination. In urgent care settings, respondents selected coupled-direct Vacutainer-based collection.

Vacutainers commonly are used for blood collection. Septifast (Roche Diagnostics, Pleasanton CA) requires Vacutainers be de-capped in a biosafety level 2 cabinet, thereby removing the test from the point of care.¹⁸ Furthermore, re-puncturing a Vacutainer to collect the contents presents a significant contamination risk.¹⁹ To function safely at the point of care the sample should be processed to exclude pathogen entry and biohazard exit. Generally, this would translate to a cassette design, such as respondents favored (refer to Figures 1 and 2).

Respondents preferred a single patient multiple pathogen test in both emergency room and urgent care unit settings. There was no significant preference for either result processing method in disaster settings. Visual logistics identified preference for highly portable devices. However, odds ratios showed high clinical sensitivity, rapid processing time, high clinical specificity, and battery power topped the list (see Table).

Survey respondents preferred patient-side testing in both field and hospital settings during disasters. However, for hospital settings the preference for patient-side testing was not significantly different from testing inside the hospital unit. Survey respondents believe that first responders should operate POC devices in disaster settings. First responders would be the initial medical professionals to arrive at a disaster scene, and thus should be equipped with POC devices to help triage any potential disaster victims.

This survey sampled the readership of *Point of Care*. Geographic and profession distribution reflect that of the journal. There were more respondents from the North Eastern U.S. and many respondents classified themselves as laboratorians.

Conclusions

Results from this survey highlight gaps in point-of-care diagnostic device design. Survey respondents indicated by preference that designs must match clinical settings. Survey respondents identified top pathogens for POCT (e.g., MRSA and Pandemic 2009 H1N1). This survey defined current problems (e.g., sample collection method, biohazard disposal, and device format) that need to be overcome in POC diagnostics. The next step is to address these gaps with new and improved point-of-care technologies, for emergency and disaster care.

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References

1. Kost GJ, Tran NK, Tuntideelert M, Kulrattanamaneepon S, Peungposop N. Katrina, the tsunami and point-of-care testing: optimizing rapid response diagnosis in disasters. *Am J Clin Pathol* 2006;126:513–520. [PubMed: 16938656]
2. Kost GJ. Newdemics, public health, small-world networks, and point-of-care testing. *Point of Care* 2006;5:138–144.

3. Louie RF, Sumner SL, Belcher S, et al. Thermal stress and point-of-care testing performance: suitability of glucose test strips and blood gas cartridges for disaster response. *Disaster Med public Health Prep* 2009;3:13–17. [PubMed: 19293739]
4. Hale KH, Brock TK, Kost GJ. Disasters require POC technology. *Medical Laboratory Observer* 2009;4142(4):44–45.
5. Kost, GJ.; Hale, KN.; Brock, TK., et al. Point-of-care testing for disasters: needs assessment, strategic planning, and future design. In: Lewandrowski, K.; Wells, A., editors. *Clinics in Laboratory Medicine*. Pennsylvania: Saunders; 2009. p. 583-605.
6. Nolen, JM. Johns Hopkins APL Tech Dig. Vol. 21. 2000. The WALEX Process; p. 225-230.
7. Louie RF, Kitano T, Brock TK, Derlet R, Kost GJ. Point-of-care testing for pandemic influenza and biothreats. *Disaster Med Public Health Prep* 2009;3(suppl 3):S193–S202. [PubMed: 19797963]
8. Hiransuthikul N, Tantisiriwat W, Lertutsahakul K, et al. Skin and soft tissue infections among tsunami survivors in Southern Thailand. *Clin Infect Dis* 2005;41:e93–e96. [PubMed: 16231248]
9. Uckay I, Sax H, Harbarth S, et al. Multi-resistant infections in repatriated patients after natural disasters: lessons learned from the 2004 tsunami for hospital infection control. *J Hosp Infect* 2008;68:1–8. [PubMed: 18079019]
10. Rajendran P, Murugan S, Raju S, et al. Bacteriological analysis of water samples from tsunami hit coastal areas of Kanyakumari District, Tamil Nadu. *Indian J Med Microbiol* 2006;24:114–116. [PubMed: 16687861]
11. Ivers LC, Ryan ET. Infectious diseases of severe weather-related and flood-related natural disasters. *Curr Opin Infect Dis* 2006;19:408–414. [PubMed: 16940862]
12. Center for Disease Control and Prevention. Update on CDC's response to Hurricane Katrina – September 19th, 2005. [January 2010]. <http://www.cdc.gov/od/Katrina/09-19-05.htm>
13. MMWR. *Vibrio* illnesses after Hurricane Katrina – multiple states, August – September 2005. *Morb Mortal Wkly Rep* 2005;54:928–931.
14. MMWR. Infectious disease and dermatologic conditions in evacuees and rescue workers after Hurricane Katrina—multiple states, August-September, 2005. *Morb Mortal Wkly Rep* 2005;54:961–964.
15. MMWR. Norovirus out-break among evacuees from Hurricane Katrina – Houston, TX, September 2005. *Morb Mortal Wkly Rep* 2005;54:1016–1018.
16. Sinigalliano C, Gidley M, Shibata T, et al. Impacts of Hurricanes Katrina and Rita on the microbial landscape of the New Orleans area. *Proc Natl Acad Sci U S A* 2007;104:9029–9034. [PubMed: 17488814]
17. Louie RF, Tang Z, Albertson TE, et al. Multiplex PCR detection enhancement of bacteremia and fungemia. *Crit Care Med* 2008;36:1487–1492. [PubMed: 18434904]
18. Louie RF, Lau MJ, Lee JH, et al. Multicenter Study of the Prevalence of Blood Contamination on Point-of-Care Glucose Meters and Recommendations for Controlling Contamination. *Point of Care* 2005;4:158–163.

Figure 1. Sample Collection Method Comparison

Visual logistics for two sample collection methods: Vacutainer with a hub versus test cassette with a hub. Survey respondents preferred a test cassette (right) in disaster settings (N=88). However, survey respondents preferred Vacutainer collection (left) in urgent care settings (N=87). [* $p < 0.05$; *** $p < 0.001$]

Figure 2. Sample Collection: Direct versus Indirect

Visual logistics for two sample collection methods: direct sample collection versus coupled-direct sample collection using a hub. Survey respondents preferred direct sampling in disaster settings ($N_{\text{disaster}} = 84$) and coupled-direct in urgent care and emergency room settings ($N_{\text{urgent care}} = 84$ and $N_{\text{emergency room}} = 83$). [$** P < 0.01$, $* P < 0.05$]

Figure 3. Biohazard Waste Disposal

Visual logistics for two biohazard waste disposal methods: a device that stores biohazard waste in a storage reservoir versus a device that stores all biohazard waste in the disposable test cassette. Survey respondents preferred a disposable test cassette in the three settings ($N_{\text{disaster}} = 84$, $N_{\text{urgent care}} = 83$, and $N_{\text{emergency room}} = 83$). [*** $P < 0.001$]

Figure 4. Emergency Blood Donor Screening

Respondents ranked six target functions from 1 to 6, with 1 being the most important for an emergency blood donor screening test cluster. Respondents ranked ABO typing higher in pair-wise comparison with other functions with the exception of HIV 1/2 testing (N=60). [* , p<0.05]

Figure 5. Bloodstream Infection Pathogen Test Cluster

Respondents ranked nineteen pathogens from 1 to 19, with 1 being the most important for a blood stream infection test cluster. Respondents ranked methicillin resistant *Staphylococcus aureus* (MRSA) higher in pair-wise comparison with other pathogens (N= 47). [**, p<0.01]

Figure 6. Respiratory Pandemic Pathogen Test Cluster

Respondents ranked sixteen pathogens from 1 to 16, with 1 being the most important for a respiratory pandemic pathogen test cluster. Respondents ranked Pandemic 2009 H1N1 (“swine” flu) higher in pair-wise comparison with other pathogens. However, H1N1 was not statistically different than Avian Influenza, Severe Acute Respiratory Syndrome, or Influenza A/B (N=64). [***, $p < 0.001$]

Table
Trade-off Design Criteria: Survey Responses

Design Attribute	Adjusted Odds Ratio	95% CI	p Value
Clinical Sensitivity	3.513	3.033-4.069	<0.001
Time to Result	2.931	2.504-3.430	<0.001
Clinical Specificity	1.734	1.504-1.999	<0.001
Battery Capability	1.509	1.300-1.753	<0.001
Portability	- -	--	NS

N=89 U.S. and Foreign Respondents

Abbreviations: CI, Confidence Interval; NS, not statistically significant