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Assessing Point-of-Care Device Specifications and Needs for Pathogen Detection in Emergencies and Disasters

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Abstract

Background—We assessed point-of-care device specifications and needs for pathogen detection in urgent care, emergencies, and disasters.

Methods—We surveyed American Association for Clinical Chemistry members and compared responses to those of disaster experts. Online SurveyMonkey questions covered performance characteristics, device design, pathogen targets, and other specifications.

Results—For disasters, respondents preferred direct sample collection with a disposable test cassette that stores biohazardous material ($P<0.001$). They identified methicillin-resistant *Staphylococcus aureus*, *Salmonella typhi*, *Vibrio cholerae*, *Escherichia coli*, *Staphylococcus aureus*, and *Streptococcus pneumoniae* as high priority pathogens. First responders were deemed the professional group who should perform POC testing in disasters ($P<0.001$).

Conclusions—Needs assessment now is requisite for competitive funding, so the results in this report will be useful to investigators preparing grant applications. Point-of-care devices used in disasters should address the needs of first responders, who give high priority to contamination-free whole-blood sampling, superior performance pathogen detection, and HIV-1/2 blood donor screening. There was surprising concordance of preferences among different professional groups, which presages formulation of global consensus guidelines to assist high impact preparedness.

Keywords

Device design; direct sample collection; first responders; pathogen detection; and test cluster

INTRODUCTION

Disasters disrupt or destroy infrastructure, including hospital laboratory services and microbiology testing.^{1–3} The earthquakes in Japan and Haiti and other recent devastating events revealed the need for rapid diagnostic testing and alternate care facilities that provide triage areas for victims, sites for near-patient testing, and controlled environments for instruments.^{2,4,5}

Additionally, rapid infectious disease testing is lacking in emergency response despite the increasing worldwide prevalence of high-risk pathogens and morbidity and mortality associated with open wounds, traumatic crush, and sudden sepsis.^{2,6–15} Modern nucleic acid

detection approaches offer an opportunity for point-of-care (POC) testing to supply valuable diagnostic information rapidly when traditional microbiology laboratories and blood culture are not accessible, either acutely or long term.

Therefore, the goals of this research were to assess critical needs for POC testing and to inform inventors, innovators, investigators, manufacturers, and users of priorities for pathogen tests and operating specifications for POC devices.

METHODS

Online e-Survey

We developed an online survey (www.surveymonkey.com-SurveyMonkey, Portland, OR) through literature review, as well as multidisciplinary consultations with experienced professionals, such as bioengineers, infectious disease experts, and emergency medicine physicians, and intensivists.^{16–18} The survey minimized time needed to read text and instead oriented respondents to engineering design concepts through visual logistics;^{16–18} it can be viewed by using a web browser and the following link: <https://www.surveymonkey.com/s/ClinicalChemistry>. The Institutional Review Board of the University of California Davis approved this research.

Demographics

We divided the United States into eight regions based on climate, geography, population density, and state lines, including the District of Columbia, as follows: 1) Northwest—OR, ID, WY, WA, and MT; 2) Northern mid-United States—ND, SD, NE, MN, IA, WI, and IL; 3) Northeast—MI, IN, OH, PA, DC, MD, DE, NJ, NY, CT, RI, MA, VT, NH, and ME; 4) Southwest—CA, NV, UT, and AZ; 5) Southern mid-United States—CO, NM, KS, OK, TX, LA, AR, and MO; 6) Southeast—MS, TN, KY, WV, VA, NC, SC, AL, FL, and GA; 7) Alaska; and 8) Hawaii. An additional group was comprised of foreign respondents.

Participants

Members of the American Association for Clinical Chemistry (AACC) accessible by list serve (N = 6,518) were invited to participate by an email broadcast containing the survey description and hyperlink. The survey opened May 5, 2010 and closed June 2, 2010. A reminder was sent two weeks after the survey opened. Complex survey data were collated and analyzed through 2010 and 2011. We also stratified results by profession groups (i.e., laboratorian, POC coordinator, medical doctor, researcher, industry, and disaster responder).

Terminology

The survey used the following definitions: a) test cassette—a device that contains and analyzes a biological sample; b) direct sampling—sample collection that does not require transfer of the biological sample for analysis; c) coupled sampling—sample collection that uses a hub to couple a needle to the device; and d) alternative care facility (ACF)—locations, preexisting or created, that serve to expand the capacity of a hospital or community to accommodate or care for patients during disasters, or to protect the general population from infected individuals during mass casualty incidents.^{5,19}

Ranking-scoring and trade-off question

For ranking questions, respondents gave preferences from 1 to 10 with 1 being the best or highest possible. Ranks were changed to scores such that a ranking of 1 yielded a score of 10, and a ranking of 10, a score of 1. Trade-off questions compared two devices with different attributes. These five attributes included: high (> 90%) or low (< 80%) clinical

sensitivity, high (90%) or low (< 80%) clinical specificity, high or low portability, fast (1 hr) or slow (> 1 hr) time to results, and high or low importance of battery operation. Each respondent selected the preferred device, given a mix of attributes arbitrated and established from experience with two prior surveys,^{16–18} in twenty-seven trade-off questions distributed throughout the body of the survey to avoid attention fatigue. These questions were analyzed as a group.

Statistical analyses

Questions focusing on device design and critical pathogen targets were formatted and analyzed as follows: a) multiple choice questions were analyzed using the Chi Square for Goodness of Fit test, b) ranking questions were analyzed using Analysis of Variance (ANOVA) and Tukey's Multiple Comparison Test, and c) trade-off questions were analyzed using multivariate logistic regression to generate adjusted odds ratios (OR) and confidence intervals (CI) (SPSS 19, Chicago, IL; www.spss.com). When relevant, the actual number of respondents who completed a specific question is reported below. P levels are indicated by asterisks: * P<0.05, ** P<0.01, *** P<0.001.

RESULTS

Respondents

Two hundred and fourteen geographically diverse responses were received for a 3.28% (214/6,518) response rate. The respondents were located across the world with 177 from the United States in reasonable distribution (except Hawaii) as follows: Region 1, 12 (6.8%); Region 2, 25 (14.1%); Region 3, 53 (29.9%); Region 4, 36 (20.5%); Region 5, 20 (11.3%); Region 6, 29 (16.4%); Region 7, 2 (1.1%); and Region 8, 0 (0%). The remaining 37 respondents were distributed across 24 countries including Argentina, Australia, Brazil, Canada, China, Croatia, Finland, Greece, Haiti, India, Japan, Libya, Mauritius, Nepal, Nigeria, Portugal, Russia, Singapore, Spain, Sweden, Turkey, United Arab Emirates, United Kingdom, and the Virgin Islands.

Device Design

Figure 1 shows respondents preferred a test cassette sample over a vacuum blood collection tube (Vacutainer) sample in disasters, and conversely, a Vacutainer sample to a test cassette sample in urgent care and emergency department settings. In these latter two settings, respondents selected coupled sampling over direct (Figure 2); however, they selected direct sampling over coupled in disasters. In emergency department and urgent care settings, respondents preferred testing a single patient for multiple pathogens (Figure 3), while in the disaster setting, there was no statistically significant preference.

In emergency department, urgent care, and disaster settings when choosing either a reservoir that stores waste or a disposable test cassette that contains all waste, respondents wanted biohazard waste to remain within the disposable test cassette in all settings (P<0.05), with strong preference (P<0.001) for disposable cassette storage of waste specifically in the disaster setting by laboratorians, POC coordinators, medical doctors, and industry (not illustrated).

Infectious disease testing

For disasters, respondents ranked MRSA higher (n= 100, P<0.05) in pair-wise comparison with other pathogens (Figure 4.A), except *Salmonella typhi*, *Vibrio cholerae*, *Escherichia coli*, *Staphylococcus aureus*, and *Streptococcus pneumoniae*, which ranked second through sixth, respectively, and for which group rankings were not significantly different. Respondents ranked (Figure 4.B) methicillin resistant *Staphylococcus aureus* (MRSA)

higher in pair-wise comparison with other pathogens for infectious disease testing in the bloodstream ($n=83$, $P<0.001$). *Escherichia coli*, *Staphylococcus aureus*, *Streptococcus pneumoniae*, and *Pseudomonas aeruginosa* were ranked second, third, fourth, and fifth, respectively.

Pandemics and blood donor screening

Respondents ranked Influenza A/B, Severe Acute Respiratory Distress Syndrome virus, and the Pandemic (H1N1) 2009 Influenza higher in pair-wise comparison with other pathogens except Avian Influenza for pandemic testing ($n=93$, $P<0.05$). Respondents ranked HIV 1/2, Hepatitis B Virus, and Hepatitis C Virus higher in pair-wise comparison with other pathogens for an emergency blood donor screening test ($n=92$, $P<0.001$). Respondents ranked ABO typing and HIV 1/2 significantly higher than Hepatitis B and C virus, a complete blood count, and a blood smear ($n=99$, $P<0.01$).

Performance characteristics, instrument operator, and location

High clinical sensitivity (OR 3.449, 95% CI 3.007–3.956), time to result (OR 2.474, 95% CI 2.133–2.870), high clinical specificity (OR 1.932, 95% CI 1.689–2.210), and battery operation (OR 1.263, 95% CI 1.098–1.452) were predictors of respondent device selection. Portability was not a significant predictor.

Figure 5 displays respondent preferences for which profession should operate POC testing during disaster response. Respondents ranked testing at the victim's side higher in pair-wise comparison with testing at a centralized tent or a vehicle ($P<0.001$, $n=131$). More than one half (53%) of respondents selected that their disaster response network has an alternate care facility.

DISCUSSION

Device specifications

Survey respondents preferred disaster-ready POC devices that directly sample into a test cassette, which stores all biohazard material for easy disposal. When asked to explain the reasoning behind their choices in free response queries, respondents cited minimizing contamination when performing infectious disease testing outside of the laboratory. They also indicated that a direct sampling test cassette is more practical for use in the field or in an alternate care facility compared to sampling indirectly using a Vacutainer and then transferring the sample for analysis, which risks contamination.

In urgent care and emergency department settings, respondents preferred coupled sample collection using a Vacutainer and analyzing a single sample for multiple pathogens. Respondents cited the desirability of drawing a single sample and having multiple testing options to fully evaluate each patient.

Pathogen test clusters

Infectious diseases can cause significant morbidity and mortality during disaster response.^{2,6–15} Respondents identified high priority pathogens, such as methicillin resistant *Staphylococcus aureus*, *Salmonella typhi*, *Vibrio cholerae*, *Escherichia coli*, *Staphylococcus aureus*, and *Streptococcus pneumoniae*, which commonly are encountered during disaster response.^{6–15} Developing rapid near patient infectious disease testing for priority pathogens could improve sepsis management, a problem identified by Farfel et al. in Haiti.²

During mass casualty events blood donation supplies will likely not meet the increased patient demand.²⁰ Respondents identified HIV 1/2 virus, ABO typing, and Hepatitis B and C

viruses as priority targets for a rapid POC device that can address the need for emergent blood donation screening during mass casualty events when traditional transfusion services infrastructure is destroyed.

Performance characteristics

Point-of-care testing has the unique ability to provide critical diagnostics during the shortages in resources and healthcare availability experienced during disasters, such as Hurricane Katrina.¹ When developing new POC devices for disasters high clinical sensitivity (>90%), high clinical specificity (>90%), rapid processing speed, and the ability to operate on battery power were all predictive of device selection by survey respondents. A high value attribute of POC testing is the ability for flexibility and adaptability; therefore, POC tests should be easy to use and function in austere low resource environments. First line medical and disaster responders should be equipped with devices to perform critical tests at the point of need.⁴

Alternative care facilities

Farfel et al.² showed the feasibility and benefit of running an alternate care facility in Haiti following the earthquake. Local disaster response networks should create plans for rapid deployment when hospitals are destroyed or inundated, including working with accreditation agencies regarding tests that are not CLIA-waived. Some respondent disaster networks did not have an alternate care facility. In these cases, local emergency rooms could become saturated with patients quickly.

Disaster response networks should educate the public and healthcare providers about disaster planning, ensuring efficient deployment, and response strategies. Disaster response sites could be set up as small-world networks²¹ with each node containing time critical POC testing and connecting to an alternate care facility or community hospital with the ability to perform tests that require limited resources.

Impact

Despite a small response rate of 3.28%, this survey reflects diverse geographic input from twenty-five countries by six professional groups who responded. Surprisingly, several results matched those from prior surveys (Table 1), which reflected input from an even broader international group. Differences among professional specialties were minor, but important for preparedness planning.

For example, respondents generally favored the same approaches to multiplexing for emergency and urgent care (Table 1C), and the top ranked organisms agreed for bloodstream infections and blood donor screening (Table 1E & 1F). The survey focused on whole blood, but processing other sample types (e.g., wound, sputum, and urine) would broaden disease recognition and impact, since organisms, such as MRSA, can enter the body and bloodstream through open wounds.

Limitations

We cannot rule out that some individuals participated in more than one of the surveys (conducted anonymously), thereby biasing the results, although duplications would be unlikely as a result of the first survey, which assessed needs of disaster care experts on the editorial boards of *Disaster Medicine and Public Health Preparedness* and the *American Journal of Disaster Medicine*.¹⁸ Additionally, our response rate and distribution is similar to that seen in a 2008 survey of critical values reporting by Dighe et al. that surveyed *Clinical Laboratory News* subscribers associated with AACC.²² Although important, bioterrorism agents were beyond the scope of the present survey, but should not be ignored by

policymakers. Future surveys should assess the needs of infectious disease, microbiology, and transfusion/blood bank experts, who may or may not have been represented among the respondents here, since the AACC now includes a molecular diagnostics division and specialists who bridge these areas.

CONCLUSIONS

- This survey provides guidance for further development of POC technologies. Now, needs assessment is deemed requisite for competitive funding, as illustrated by the requirement for formal needs assessment and impact analysis in a request for applications for POC Technologies Centers by the National Institute of Biomedical Imaging and Bioengineering at the NIH.²³
- Survey participants believe that first line responders should operate rapid, highly sensitive, and simultaneously highly specific POC devices for use during disaster triage, transportation, and patient care.
- Near-patient testing for high priority pathogens, including methicillin resistant *Staphylococcus aureus*, will help fill the need for infectious disease testing, which, in view of the embryonic state of mobile molecular detection technologies, we recommend be placed in alternate care facilities,^{5,19,24,25} where well-defined layouts provide opportunities to control environmental conditions and to properly triage victims without overloading local emergency rooms.
- The surprising outcome of the comparison of related surveys in this report (see the Table) is the extent of agreement among different professional disciplines, which logically presages the formulation of future global consensus guidelines to assure effective disaster preparedness. A guideline project ("Emergency and Disaster Point-of-Care Testing, POCT-15," Drs. Kost and Nichols, Co-Chairs) is underway at the Clinical Laboratory Standards Institute.
- Emergency and disaster response networks, modeled on naturally occurring small-world networks,²¹ can be used to help create plans to carefully educate POC operators, such as ambulance emergency personnel.
- Future research can fine-tune pathogen test clusters for different sample types and diseases, address training requirements and accreditation issues, and help assess how to improve crisis standards of care for pathogen detection and for other kinds of diagnostic testing at the point of need.²⁶

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Figure 1. Test Cassette versus Vacutainer Sample Collection

Respondents preferred test cassette sampling in disasters and vacuum blood collection tube (Vacutainer) sampling in urgent care and emergency department settings. Bracketed asterisks correspond to the p-values for the entire population while asterisks within each stacked column represent the p-values for specific professional groups. [*** $P < 0.001$, ** $p < 0.01$, and * $p < 0.05$.]

Figure 2. Coupled versus Direct Sample Collection

In disasters, respondents preferred direct sampling, but in urgent care and emergency department settings, coupled sampling. [*** $P < 0.001$, ** $p < 0.01$, and * $p < 0.05$.]

Figure 3. Pathogen Sample Processing Strategy

Respondents could select either testing multiple different patients for a single pathogen or testing a single victim or patient for multiple different pathogens. Respondents preferred single patient multiple pathogen testing in urgent care and emergency department settings. [*** P<0.001, ** p<0.01, * p<0.05.]

Figure 4. Priorities for Pathogen Detection

Frame A. For disaster settings, respondents ranked MRSA higher ($n=100$, $*P<0.05$, $***P<0.001$) in priority in pair-wise comparison with other pathogens except *Salmonella typhi*, *Vibrio cholerae*, *Escherichia coli*, *Staphylococcus aureus*, and *Streptococcus pneumoniae*. **Frame B.** Respondents ranked MRSA higher in pair-wise comparison with other pathogens for infectious disease testing in the bloodstream ($n=83$, $P<0.001$).

Figure 5. Point-of-care Testing Operator

Respondents selected medical technologists, nurses, first responders, or victims as the group preferred to perform point-of-care testing during disasters. Respondents selected first responders most frequently (***) $P < 0.001$.

Table 1

Ranking of Needs Assessment Survey Results

Question Focus: Sample Collection/Processing Method with Settings and Pathogen Types in Specific Settings with Priority	Survey of the AJDM ^c and DMPHP ^c Editorial Boards	Point of Care Journal Readership Survey	American Association for Clinical Chemistry—the present report
A. Test Cassette vs. Vacutainer with Hub for Sample Collection (25, 87, 172) ^b			
Disaster	Cassette	Cassette	Cassette
Urgent Care	NS ^a	Vacutainer	Vacutainer
Emergency	NS ^a	NS ^a	Vacutainer
B. Direct vs. Coupled Direct Sample Collection (23, 83, 168) ^b			
Disaster	NS ^a	Direct	Direct
Urgent Care	NS ^a	Coupled	Coupled
Emergency	NS ^a	Coupled	Coupled
C. Sample Processing: Multiple pathogens/single patient vs. Single pathogen/multiple patients (26, 78, 143) ^b			
Disaster	NS ^a	NS ^a	NS ^a
Urgent Care	Multiple Pathogen Single Patient	Multiple Pathogen Single Patient	Multiple Pathogen Single Patient
Emergency	Multiple Pathogen Single Patient	Multiple Pathogen Single Patient	Multiple Pathogen Single Patient
D. Disaster Pathogens (19, 47, 100) ^b			
1 (Priority)	<i>Vibrio cholerae</i>	MRSA	MRSA
2	<i>Staphylococcus aureus</i>	<i>Vibrio cholerae</i>	<i>Salmonella typhi</i>
3	<i>Escherichia coli</i>	<i>Salmonella typhi</i>	<i>Vibrio cholerae</i>
E. Bloodstream Infection Pathogens (21, 49, 83) ^b			
1	MRSA	MRSA	MRSA
2	<i>Escherichia coli</i>	<i>Staphylococcus aureus</i>	<i>Escherichia coli</i>
3	<i>Pseudomonas aeruginosa</i>	<i>Streptococcus pneumoniae</i>	<i>Staphylococcus aureus</i>
F. Blood Donor Screening Pathogens (24, 62, 92) ^b			
1	HIV 1/2	HIV 1/2	HIV 1/2
2	Hepatitis B Virus	Hepatitis C Virus	Hepatitis B Virus

Question Focus: Sample Collection/Processing Method with Settings and Pathogen Types in Specific Settings with Priority	Survey of the AJDM ^c and DMPHP ^c Editorial Boards	Point of Care Journal Readership Survey	American Association for Clinical Chemistry—the present report
3	Hepatitis C Virus	Hepatitis B Virus	Hepatitis C Virus

^aNS is not statistically significant, and applies in 1A–1C for the binary comparisons listed in the left column.

^bNumbers in parentheses represent total subjects who responded to the editorial board, POC, and AACC surveys, respectively.

^cAJDM is the *American Journal of Disaster Medicine*, and DPHPH, *Disaster Medicine and Public Health Preparedness*.