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# Public health education should include point-of-care testing: lessons learned from the covid-19 pandemic

Gerald J. Kost

Fulbright Scholar 2020-2022, ASEAN Program

Director, Point-of-care Testing Center for Teaching and Research [POCT•CTR]

Emeritus Professor, Pathology and Laboratory Medicine, School of Medicine, UC Davis, United States

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#### **Corresponding author:**

Gerald J. Kost, MD, PhD, MS, FAACC 506 Citadel Drive, Davis CA 95616 Unites States

Phone: 1-530-574-3945 E-mail: <u>GeraldKost@gmail.com</u>

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# ABSTRACT

#### Goal

The goal is to present key principles of point-of-care testing (POCT) in educational curricula that meet critical needs for rapid decision-making in disasters, outbreaks of highly infectious diseases, emergency management, and complex crises.

#### **Observations**

The coronavirus disease 19 (COVID-19) pandemic unequivocally proved the value of POC strategies. Striking needs identified by COVID-19 challenges have yet to be entirely fulfilled. A comprehensive national survey showed absence of POCT training in public health colleges, schools, and programs. Fundamental improvements in national structuring of POC knowledge, skills, experience, training, dissemination, accreditation, and licensing are necessary, so that multidisciplinary public health teams can respond effectively and efficiently by geospatially optimizing the control and mitigation of highly infectious diseases and other critical challenges.

#### **Conclusions**

Four sets of POCT learning objectives were developed for public health and other educational institutions. Global implementation of POC diagnostics in the hands of trained personnel will help avoid untimely worldwide crises, huge economic losses, uncounted excess mortality, and sudden disruptive surges of dangerous infectious threats to personal security and cultural stability.



# **GOAL, BACKGROUND AND METHODS**

#### Goal

To create a long-term public health paradigm of rapid response diagnosis at points of need, this article identifies necessary skills in point-of-care testing (POCT) for new teaching curricula in colleges, schools, and programs of public health (1,2), in order that faculty can educate public health students and practitioners in POC strategies for highly infectious diseases, emergency management, and crisis preparedness.

#### Public health disconnect

The disconnect between current public health practice with testing performed in distant slow reference laboratories versus the demonstrated value of rapid COVID-19 testing in communities directly at points of need may continue to threaten family lives and societal values, strong motivators for change in preparation for future outbreaks and epidemics virtually certain to occur. The world goal is to prevent geospatially limited episodes from developing into the next global pandemic.

# Mobile testing

Enhancing fundamental knowledge and practical expertise of those working in mobile testing modes, such as vans equipped with portable instruments, will help meet urgent demands for geospatially optimizing containment of COVID-19 and other highly infectious diseases.

#### **Methods**

Principles and strategies for pandemic response were derived from lessons learned following the COVID-19 outbreak in Wuhan, China in 2019 and its early spread to America and Southeast Asia (3-5), and before that, from the Ebola epidemic that devastated Western Africa in 2014 and still alarms the continent with recurrences in the Democratic Republic of the Congo and elsewhere (6-10).

# **Learning objectives**

Essential learning objectives were extracted from an original lecture (~500 slides) and workshop course for POC operators and coordinators created for limited-resource settings by Kost et al. (11) This practicum has been taught worldwide for several years, typically in the format of two morning lectures followed by an afternoon hands-on workshop (wet lab) where students using POC devices generate real-time results.

# Mathematical and geospatial optimization

Designs for public health POCT curricula were aided by quantitative mathematical and pattern recognition analyses of COVID-19 diagnostics and POC geospatial approaches applied to the current pandemic, which were published open access in the Archives of Pathology and Laboratory Medicine (12-14) and Frontiers of Public Health (15), respectively.

#### **POCT IN PUBLIC HEALTH EDUCATION**

A national survey of public health institutions by Kost et al. (1) identified future directions for POCT curricula in public health. The survey showed absence of instruction, hands-on training, and accredited courses in POCT in American colleges, schools, and programs of public health education. Public health certification requirements and textbooks generally do not include POCT instruction.

In the national survey (1), the topic, "POC HIV/ HCV ED" testing, appeared in only one course, and "POC diagnostics in local clinics," in one other. Only one book, Global Point of Care: Strategies for Disasters, Emergencies, and Public Health Resilience (16), and one online course on public health preparedness (17) address POCT for disaster and public health crisis intervention.

A 2021 review of PubMed searches and worldwide web searches revealed public health educational institutions have not yet incorporated POCT in curricula. Public health curricula do not address POCT in isolation units during quarantine or societal implementation of POCT broadly in communities, despite unequivocally proven need for POC strategies that enhance standards of care during the current COVID-19 pandemic (3).

#### **PUBLIC HEALTH CURRICULA**

Tables 1 through 4 present integrated modular sets of POCT learning objectives customized for public health students. Table 1 learning objectives focus on the mission and the basic principles of POCT (1). Sections II. A. and B. build technical skills. Collaboration with clinical chemists, laboratory scientists, clinical pathologists, inventors, and entrepreneurs will ensure high quality instruction in POC technologies and their design. A recent paper in this journal provided collaborative guidance for training and competency in POCT (18).

Sections II and III in Table 2 cover the general use of POCT in health maintenance, noncommunicable disease, and communicable threats (1). Section IV emphasizes how to position POCT in small-world networks (19) and the use of

geographic information systems (20). The reader can refer to the papers and chapters cited for details that will aid instruction.

Table 3, titled Public Health Preparedness and Emergency Management, includes a special Section I.B. of learning objectives addressing POC strategies for COVID-19. It also references the Clinical and Laboratory Standards Institute guidance for Emergency Use Authorization (EUA) tests (21), because the FDA EUA process has been used extensively for COVID-19 diagnostics implemented in the United States. The learning objectives include hands-on workshops in Section I.C. Several of the entries could be assigned as timely Master of Public Health theses.

Table 4 enhances opportunities to embed POC principles and practice in standards, policy, guidelines, project management, and value propositions, so as to form infrastructure for sustainable funding and perpetual improvement in rapid response (1). Please also see Kost (14) for a summary of standards of care guidelines specifically for the use of COVID-19 rapid antigen tests, which have become available worldwide in the fight against COVID-19.

# **DISCUSSION AND CONCLUSIONS**

Point-of-care testing is inherently fast, intrinsically spatial, and immediately actionable. It adds value by decreasing therapeutic turnaround time, speeding decision-making, and quickly enabling correct treatment. The mobility of POCT reduces risk by gatewaying testing before air travel, for facilitated immigration, at drive-ins/ups/-throughs, in walk-bys and pharmacies, and for other optimal spatially isolated testing sites crucial to economic opening, safe spacing (social distancing), and successful tackling of risky COVID-19 exposure.

Public health policies and guidelines should sustain POC rapid response, as recommended

by the logic map of Figure 1. Support can come from the Centers for Disease Prevention and Control, Food and Drug Administration, General Accountability Office, National Institutes of Health, the United Nations, United States Agency for International Development, World Health Organization, and non-government organizations (NGOs). Public health graduates populate these entities, so their awareness of POC strategies is vital to assimilation of POC strategies and their future planning.

The long-term challenge is to train adequate numbers of public health officials who can deliver diagnostic testing in communities worldwide. It makes sense to "train the trainers," that is, develop new cadres of public health graduates who will enthusiastically reach out to the community and train those at the bedside or onsite in the field in the principles and practice of POCT. Tables 1-4 provide the educational tools to do that.

Educators should modify accreditation standards, so that POCT knowledge will be validated in public health certification exams and sustained long-term to recraft the profession for this type of point-of-need response. Experts from several disciplines can participate productively extending their didactic efforts, methods, and inventions (22-27) in support of public health educators and their curricula.

The COVID-19 pandemic showed us that community contagion inevitably leads to outbreaks in convalescent care homes and deaths among the elderly and highly vulnerable. Therefore, high performance POCT (12-14) must be deployed for screening, triage, and contact tracing of both patients and staff with results immediately available on a daily basis. This represents just one example. Public health leadership can customize course content to meet local community needs for diagnostics by selecting topics from Tables 1-4.

Multiple crises tend to occur simultaneously, and when they do, fixed resources become disabled by electrical shutdowns, physical isolation, and supply failures (16). Communities designate or construct alternate care facilities and plan near-patient critical care testing in support of critically ill and quarantined patients. They implement action plans for patient isolation units close to or just outside emergency rooms to avoid contagion inside and install adjacent isolators and isolation laboratories with POC instrumentation.

Training of community health providers must include the use of PPE and, importantly, practice in operating POC devices while wearing PPE. Mobile vans can be equipped with molecular diagnostics that detect highly infectious threats with high sensitivity and specificity, as well as rapid antigen, antibody, and multiplex SARS-CoV-2 + Influenza A/B tests for COVID-19 (5). This will help avoid crowding emergency rooms with potentially contagious patients, because testing will minimize both false negatives (high sensitivity) who spread disease, and false positives (high specificity) who may be committed to units housing infected patients and become infected themselves (12-14).

Government agencies should provide adequate resources and funding (see Figure 1) to sustain community resilience and improve medical and economic outcomes. Grass roots knowledge and skills in POCT, such as awareness of how to improve emergency diagnostics on ambulances (28,29), will help public health leadership create regional safety, while coordinating point-of-impact testing and important countermeasures, such as vaccination and drive-through testing sites (30-33). In fact, POC coordinators, a new and emerging subspeciality professional group in the POC field, can share responsibility for problem-solving strategies at points of need in America and abroad (34).

Table 1 Curriculum		n and learning objectives—mission, principles, and practice
Section & topics		Learning objectives
Part I.		Getting started—the mission
Goals, objectives, and overview of uses in public health		<ul> <li>Define POCT as testing at or near the site of care and appreciate that the definition does not depend on the instrument format or size</li> <li>Understand the fundamental goals and objectives of POCT for rapid and effective evidence-based decision making at points of need</li> </ul>
Needs		<ul> <li>Introduce situations where POCT has proven benefits for public health</li> <li>Describe the need for POCT in outbreaks, epidemics, and the current pandemic, as well as in disasters and complex public health crises</li> <li>Understand the importance of generating fast results, so that triage can be performed efficiently and immediately</li> </ul>
Companion Tests		<ul> <li>Why do POC monitoring of temperature, oxygen saturation, respiratory rate, and other key primary variables (e.g., d-Dimer) provide layers of protection, defense, and assessment along spatial care paths</li> </ul>
Part	II.	Fundamental principles and practice of POC testing
A. Tech	nical	
Needs asse	essment	<ul> <li>Develop competency in needs assessment for POC diagnostics in public health</li> <li>Apply to healthcare settings limited-resource countries</li> </ul>
Instrument formats, selection, and validation		<ul> <li>Recognize basic formats for disposable, handheld, portable, and transportable POC technologies that perform in vitro testing</li> <li>Describe disposable POC tests, including smartphone modules, and their advantages, disadvantages, and marginal cost-effectiveness</li> <li>Have the ability to select and validate the correct instruments</li> </ul>
Non-invasive monitoring versus <i>in vitro</i> diagnostic testing		<ul> <li>Consider the operating principles of non-invasive devices, namely pulse oximetry for monitoring of oxygen saturation, and continuous hemoglobin monitoring</li> <li>Compare in vivo, ex vivo, and in vitro approaches and advantages</li> </ul>

Specimen processing	<ul> <li>Contrast whole-blood versus plasma analysis, also dry blots</li> <li>Outline specimen processing and suitable sample types for testing in the field, primary care, and emergency room</li> <li>Review special requirements associated with isolation laboratories</li> </ul>
Quality assurance (QA), quality control (QC), and proficiency testing (PT)	<ul> <li>Identify "waived tests" under CLIA '88 and compare other POC tests</li> <li>Know the definition and importance of quality assurance, including internal quality control and external quality assessment</li> <li>Learn the five basic elements of the individualized quality control plan (IQCP), including environmental stress; how to customize QA, QC, and PT; and the importance of continuous quality improvement</li> <li>Recognize confounding factors in diagnostic testing</li> </ul>
Environmental stresses	<ul> <li>Overview the effects of environmental stresses on POC instruments and reagents, and how to avoid adverse consequences</li> <li>Study methods for modulating environmental conditions for POC reagent storage and transportation</li> </ul>
Multiplex molecular diagnostics	<ul> <li>Gain a basic appreciation of multiplex assays used for the detection of viruses, bacteria, and fungi, that is, pathogen detection</li> <li>List advantages, disadvantages, costs, and limitations</li> <li>Show examples of current POC disposable tests and instruments commercially available</li> </ul>
B. Design & build	
Design criteria	Read WHO and other POC device performance specifications
Commercialization	Understand custom POC test clusters, basic manufacturing requirements, commercialization processes, and timelines
Regulatory oversight	<ul> <li>Review routine FDA 510(K) clearance and pre-market approval (PMA)</li> <li>Outline the FDA system of classification of diagnostic tests (i.e., CLIA-waived, moderately complex, and complex) and the criteria for home testing.</li> <li>Assess the ramifications for implementation, personnel, and use</li> </ul>
FDA and WHO emergency use declarations	<ul> <li>Study the process, legal requirements, and terms of FDA emergency use authorizations (EUAs) and WHO emergency use assessment and listings (EUALs)</li> <li>Locate EUA and EUAL listings and documentation of tests on the web</li> </ul>

Accreditation options	<ul> <li>Understand the definition of accreditation and why an organization would engage in it</li> <li>Discuss the main considerations and steps leading to accreditation</li> <li>Consider inspections options for POCT [e.g., College of American Pathologists, Joint Commission, and CMS (for waived testing)]</li> </ul>
Part III.	Practicum
Device hands-on experience	<ul> <li>Demonstrate CLIA '88 waived and moderately complex POC tests</li> <li>Learn how to perform common POC tests, how to operate mobile POC instruments, and security features (e.g., UN &amp; PW)</li> <li>Watch demonstration videos of transportable whole-blood analyzers and test clusters for critical care and support of patients in isolation</li> </ul>
Results interpretation	Use case studies to demonstrate how to interpret basic test results
Performance evaluation	<ul> <li>Attend a workshop illustrating POC performance evaluation, such as regression analysis, Bland-Altman plots, and locally-smoothed (LS) median absolute difference ("LS-MAD") curves and maximum absolute difference ("LS-MaxAD") curves</li> </ul>
Trouble shooting	<ul> <li>Gain experience at trouble shooting POC tests and devices</li> <li>See examples of error codes and how to respond to them</li> </ul>
Establishing a POC program	<ul> <li>Understand the steps necessary to establish a successful POC testing program</li> </ul>

# Table 2 Curriculum and learning objectives—public health sciences

Section & topics	Learning objectives
Part I.	Integration of POC and public health expertise
Roles of public health	<ul> <li>Recognize the benefits of teamwork among public health practitioners, POC Coordinators, reference laboratories, and clinical laboratories</li> </ul>
personnel and POC Coordinators	Develop personnel resources and a database of skill sets in advance of disasters, emergencies, complex crises, and epidemics
	<ul> <li>Understand that public health students and professionals could become POC Coordinators</li> </ul>

Training, credentialing, and assuring competency  Part II.  Pert II.  Pregnancy  Explore sensitivity, timing, and interferences, and the technical differences in disposable urine tests versus plasma assays  Appreciate why plasma glucose standardization is necessary for consistent performance of blood glucose meters  Develop patient plans for self-testing of capillary whole-blood glucose  Correlate prevalence, demographics, and public health implications of evidence-based POC diagnosis using POC cTn on ambulances  Acute coronary syndromes and acute myocardial infarction  Acute myocardial infarction  Acute coronary syndromes and acute myocardial infarction  Part III.  Communicable diseases (examples)  • List and analyze approaches to multidisciplinary credentialing  • Specify requirements for maintaining competency and annual reviews  Explore sensitivity, timing, and interferences, and the technical differences in disposable urine tests versus plasma assays  • Explore sensitivity, timing, and interferences, and the technical differences in disposable urine tests versus plasma assays  • Explore sensitivity, timing, and interferences, and the technical differences in disposable urine tests versus plasma assays  • Appreciate the POC thbA1c testing in the diagnosis and monitoring of prediabetes versus diabetes  • Develop patient plans for self-testing of capillary whole-blood glucose  • Correlate prevalence, demographics, and public health implications of evidence-based POC diagnosis in poor and rich nations  • Study Spatial Care PathsTM (SCPs) for rapid home rescue of patients with acute chest pain  • Apply evidence-based medicine (EBM) and learn why current POC cardiac troponin (cTn) tests are limited to ruling in (not ruling out) acute myocardial infarction  • Strive to use POC cTn in rural areas to eliminate social inequity by rapidly diagnosing acute myocardial infarction and starting intervention  • Apply diagnosing acute myocardial infarction and starting intervention  • Appreciate the POC methods of screening		
Pregnancy  • Explore sensitivity, timing, and interferences, and the technical differences in disposable urine tests versus plasma assays  • Appreciate why plasma glucose standardization is necessary for consistent performance of blood glucose meters  • Understand the role of POC HbALc testing in the diagnosis and monitoring of prediabetes versus diabetes  • Develop patient plans for self-testing of capillary whole-blood glucose  • Correlate prevalence, demographics, and public health implications of evidence-based POC diagnosis in poor and rich nations  • Study Spatial Care PathsTM (SCPs) for rapid home rescue of patients with acute chest pain  • Apply evidence-based medicine (EBM) and learn why current POC cardiac troponin (cTn) tests are limited to ruling in (not ruling out) acute myocardial infarction  • Read about prehospital diagnosis using POC cTn on ambulances  • Strive to use POC cTn in rural areas to eliminate social inequity by rapidly diagnosing acute myocardial infarction and starting intervention  • Appreciate the POC methods of screening for HIV, including pregnant women for prevention of transmission and algorithms for newborns  • Study the advantages of simultaneous multiplex testing for concurrent diseases, such as TB  • Apply EBM principles to influenza testing and understand predictive values and their use from the viewpoint of the primary care	credentialing, and	<ul> <li>Specify requirements for maintaining competency and annual reviews</li> <li>Learn how to document competency of Disaster Medical Assistance</li> </ul>
differences in disposable urine tests versus plasma assays  Appreciate why plasma glucose standardization is necessary for consistent performance of blood glucose meters  Understand the role of POC HbA1c testing in the diagnosis and monitoring of prediabetes versus diabetes  Develop patient plans for self-testing of capillary whole-blood glucose  Correlate prevalence, demographics, and public health implications of evidence-based POC diagnosis in poor and rich nations  Study Spatial Care PathsTM (SCPs) for rapid home rescue of patients with acute chest pain  Apply evidence-based medicine (EBM) and learn why current POC cardiac troponin (cTn) tests are limited to ruling in (not ruling out) acute myocardial infarction  Read about prehospital diagnosis using POC cTn on ambulances  Strive to use POC cTn in rural areas to eliminate social inequity by rapidly diagnosing acute myocardial infarction and starting intervention  Part III.  Communicable diseases (examples)  Appreciate the POC methods of screening for HIV, including pregnant women for prevention of transmission and algorithms for newborns  Study the advantages of simultaneous multiplex testing for concurrent diseases, such as TB  Apply EBM principles to influenza testing and understand predictive values and their use from the viewpoint of the primary care	Part II.	Health maintenance and noncommunicable diseases (examples)
Prediabetes and diabetes  Develop patient plans for self-testing of capillary whole-blood glucose  Develop patient plans for self-testing of capillary whole-blood glucose  Correlate prevalence, demographics, and public health implications of evidence-based POC diagnosis in poor and rich nations  Study Spatial Care PathsTM (SCPs) for rapid home rescue of patients with acute chest pain  Acute coronary syndromes and acute myocardial infarction  Part III.  Communicable diseases (examples)  Appreciate the POC methods of screening for HIV, including pregnant women for prevention of transmission and algorithms for newborns  Study the advantages of simultaneous multiplex testing for concurrent diseases, such as TB  Apply EBM principles to influenza testing and understand predictive values and their use from the viewpoint of the primary care	Pregnancy	
Acute coronary syndromes and acute myocardial infarction  • Apply evidence-based medicine (EBM) and learn why current POC cardiac troponin (cTn) tests are limited to ruling in (not ruling out) acute myocardial infarction  • Read about prehospital diagnosis using POC cTn on ambulances  • Strive to use POC cTn in rural areas to eliminate social inequity by rapidly diagnosing acute myocardial infarction and starting intervention  Part III.  Communicable diseases (examples)  • Appreciate the POC methods of screening for HIV, including pregnant women for prevention of transmission and algorithms for newborns  • Study the advantages of simultaneous multiplex testing for concurrent diseases, such as TB  • Apply EBM principles to influenza testing and understand predictive values and their use from the viewpoint of the primary care		<ul> <li>consistent performance of blood glucose meters</li> <li>Understand the role of POC HbA1c testing in the diagnosis and monitoring of prediabetes versus diabetes</li> <li>Develop patient plans for self-testing of capillary whole-blood glucose</li> <li>Correlate prevalence, demographics, and public health implications</li> </ul>
<ul> <li>Appreciate the POC methods of screening for HIV, including pregnant women for prevention of transmission and algorithms for newborns</li> <li>Study the advantages of simultaneous multiplex testing for concurrent diseases, such as TB</li> <li>Apply EBM principles to influenza testing and understand predictive values and their use from the viewpoint of the primary care</li> </ul>	syndromes and acute	<ul> <li>with acute chest pain</li> <li>Apply evidence-based medicine (EBM) and learn why current POC cardiac troponin (cTn) tests are limited to ruling in (not ruling out) acute myocardial infarction</li> <li>Read about prehospital diagnosis using POC cTn on ambulances</li> <li>Strive to use POC cTn in rural areas to eliminate social inequity by rapidly diagnosing acute myocardial infarction and starting</li> </ul>
HIV  Pregnant women for prevention of transmission and algorithms for newborns  Study the advantages of simultaneous multiplex testing for concurrent diseases, such as TB  Apply EBM principles to influenza testing and understand predictive values and their use from the viewpoint of the primary care	Part III.	Communicable diseases (examples)
Influenza A and B values and their use from the viewpoint of the primary care	HIV	<ul> <li>pregnant women for prevention of transmission and algorithms for newborns</li> <li>Study the advantages of simultaneous multiplex testing for</li> </ul>
	Influenza A and B	values and their use from the viewpoint of the primary care

	<ul> <li>See examples of portable CLIA-waived instruments (Liat, Roche Diagnostics; Alere-i, Abbott) useful during flu season</li> </ul>
Malaria	<ul> <li>Review new POC tests (e.g., fingerprick Ag Plasmodium falciparum) and uses in Africa and other endemic areas</li> </ul>
Strep throat screening	<ul> <li>Review primary care practices related to screening</li> <li>Understand necessary follow-up testing</li> </ul>
Tuberculosis and resistance testing	<ul> <li>Cover instrumentation for TB diagnosis and resistance testing [e.g., the GeneXpert MTB/RIF test as a marker for multidrug resistant TB (MDR TB)], by drawing on the foregoing instruction in molecular diagnostics</li> </ul>
ŭ	Establish appropriate settings and conditions for testing
	<ul> <li>List and abate environmental stresses (e.g., temperature and dust)</li> </ul>
Part IV.	Geospatial science & geographic information systems (GISs)
Small-world networks	Define, illustrate, and analyze healthcare SWNs
(SWNs)	<ul> <li>Set the stage for community public health practice using POCT in optimized SWN healthcare delivery systems</li> </ul>
	Explain how to set up and analyze a GIS
GIS applications to	Establish SCPs within SWNs for rapid diagnosis and treatment
health systems	<ul> <li>Assess the impact of GIS analysis of SWNs and SCPs</li> </ul>
	Integrate smartphone POCT-GIS for sentinel case tracking

# Table 3

Curriculum and learning objectives—public health preparedness, emergency management, and the COVID-19 crisis

Section & topics	Learning objectives
Part I.	Preparedness for outbreaks, epidemics, and isolation
A. Test metrics	
Dynamic evidence-based medicine	<ul> <li>Compare sensitivity, specificity, and predictive values of POC tests</li> <li>Point out that false negatives, FN(t), are a function of time, and therefore, sensitivity and the ability to rule out disease are dynamic characteristics when testing patients with evolving infections</li> <li>Explain why 95% confidence intervals for diagnostics introduce peaks and valleys of uncertainty that vary with prevalence for infectious targets</li> </ul>

B. Past perspective	
Ebola virus and other highly infectious diseases	<ul> <li>Document how the 2014-16 Ebola virus disease epidemic and cases entering the U.S. proved unequivocally the need for POCT</li> <li>Overview how POCT could have curtailed the 2014-16 epidemic</li> <li>Compare how rapid response limited the recent 2017+ outbreaks</li> <li>Survey POC technologies available for Ebola virus disease and other high-risk pathogens</li> </ul>
B. COVID-19 pandemic	Special section
Metrics of testing	<ul> <li>Compare and contrast molecular diagnostics, antigen assays, and antibody tests used to diagnose COVID-19, plot temporal trends, detect stealth infections, and judge immunity, including detection of variants (e.g., Delta)</li> <li>Identify how sensitivity and specificity impact PPV, NPV, PV GM2, FP/TP, FN/TN, false omission rates, and other test metrics in settings of low, moderate, and high prevalence</li> <li>Observe that patients with false negative results can spread SARS-CoV-2 unknowingly, and false positives can place people at danger when quarantined with who have COVID-19</li> <li>Show how uncertainty, in terms of 95% confidence intervals, impact test results</li> </ul>
FDA Emergency Use Authorizations (EUAs)	Outline FDA procedures and criteria for obtaining EUAs for COVID-19 tests, visit the FDA EUA website (https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas), and inspect authorization documents
Management of EUA tests	<ul> <li>Consult Clinical and Laboratory Standards Institute white paper EP43-Ed1, "Implementing a Laboratory Test Under Emergency Conditions," for method establishment, guidance on method implementation, and general management of EUA tests, including their potential retirement</li> </ul>
Safe spacing & contagion	<ul> <li>Learn mobile POC strategies, such as drive-up/drive-through testing, kiosks at points of need, elderly access, home self-testing, and other safe approaches</li> <li>Describe the role of POCT in contact tracing, its effectiveness or lack thereof, and the economics of pursuing superspreaders, reinfections, and herd immunity</li> </ul>

- Predictive value performance patterns suggest Tier 2 positive percent agreement (sensitivity) of 95% and negative percent agreement specificity) of 97.5% — should become the minimum performance threshold for RAgTs. See reference 14 for details of tiers, performance patterns, and other details of RAgT clinical use.
- Consider the current community prevalence and its impact on test results, especially in the high range of prevalence.
- Self- and home test using a RAgT kit as soon as signs or symptoms arise and within the first 3 to 5 days for optimal detection of SARS-CoV-2.
- When self- and home testing, repeat the test at 36 hours and follow the protocol specified by the manufacturer. Repeat testing will improve the performance of low and sub-tier tests.
- Establish performance metrics (e.g., PPA, NPA, CI, and LOD) in diverse large multicenter populations with a full range of SARS-CoV-2 viral loads. Explicitly characterize the reference method (e.g., Ct brackets).
- Harmonize preanalytical and assay methods. Do not compare to an inferior test.
- Test free of charge everywhere, anytime. Test at home, when traveling, or any place in the world, and use the results to avoid and manage risk, not to punish.
- When a person is not vaccinated, test weekly with a PCR assay or twice per week using a dual test RAgT kit if in the workplace, university, or similar environments.
- Avoid stigmatizing positive test results by requiring unnecessary prolonged quarantine or shameful detention. Do not use test results to intimidate. Instead, optimize human resources.
- End quarantine when test results turn negative. Allow work and other activities to resume with minimal personal and economic loss.
- Create a positive and reassuring social milieu, a point of care culture of self-motivated frequent testing, so that empowered individuals can stop variant outbreaks and avoid spread to highly vulnerable people.
- Expect COVID-19 to become endemic worldwide. Adapt by vaccinating, testing, and empowering. Diagnostic testing allows us to calibrate and manage our own personal risk.

Maximize the
effectiveness of rapid
antigen tests (RAgTs)
and empower without
intimidating

C. Workshops	Highly infectious diseases
Personal protective equipment (PPE)	<ul> <li>Don PPE and practice performing POC tests, then doff the PPE and show that work was performed without personal exposure</li> </ul>
Isolation laboratory and quarantine	<ul> <li>Be able to read floor plans, design an isolation laboratory, equip it with POCT, and route specimen workflow</li> <li>Understand specifications for biosafety cabinets and limits to performing molecular diagnostics and POC tests within them</li> <li>Identify special aspects of personnel training and protection</li> </ul>
Spatial care pathsTM	<ul> <li>Demonstrate sentinel case discovery, 911 intent, and fastest rescue routes in healthcare SWNs</li> <li>Place POCT to optimize efficiency and effectiveness</li> </ul>
IQCP, its five key components, and plan design	<ul> <li>Practice designing individualized quality control plans (IQCP)</li> <li>Remember the five components of the testing process: specimen, test system, reagent, environment, and testing personnel</li> <li>Sketch out an IQCP for POCT in an isolation laboratory associated with a hospital and in an alternate care facility</li> </ul>
Global pandemic preparedness	<ul> <li>Write a summary of POC strategies used in different countries to mitigate the COVID-19 pandemic and avoid saturation of hospital resources, such as ICU beds</li> <li>Describe how POCT pivots community resources to optimize public health planning in the Unites States, then compare limited-resource settings</li> <li>Define the specific roles of molecular diagnostics, antigen assays, and antibody tests, and which are available in portable or hand-held formats for testing onsite</li> <li>Consider the economic tradeoffs of lockdowns, testing, and vaccination</li> </ul>
Part II.	Disasters, emergencies, complex crises, and rapid response
Disaster caches and complex crises	<ul> <li>List the test clusters in DMAT POCT caches, the three US sites of storage, personnel training, and regional deployment, including Alaska and Hawaii</li> <li>Recognize necessary steps in opening and using the compact and larger laboratory caches, test clusters, and their different purposes</li> <li>Review the basics of specimen collection and sample preparation, including for infectious diseases, under challenging field conditions</li> </ul>

	•	Recognize the analytical limitations of POCT under disaster and complex crisis conditions
Performance standards	•	Establish QC criteria necessary to complete before using POC devices from caches in the field during emergencies and disasters  Develop backup procedures in case of QA failures  Know National Disaster Medical System routines for maintaining high levels of performance when using POCT from caches in the field
Telehealth	•	Gain familiarity with field connectivity and telecommunications
Alternate care facilities	•	Integrate DMAT resources with community alternate care facilities
Bioterrorism	•	Be aware of major threats, methods of detection, containment

# Table 4

Curriculum and learning objectives—public health preparedness, emergency management, and the COVID-19 crisis

Section & topics	Learning objectives
Part I.	Standards, policy, and guidelines
A. Lectures	
International Organization for Standardization (ISO)	<ul> <li>Outline the purpose and contents of ISO 22870:2016, "Point-of-care testing: Requirements for quality and competence," and associated standards (e.g., ISO 15189:2012, Medical laboratories)</li> </ul>
CDC, FDA, and WHO	<ul> <li>Review the guidelines and documents published by the CDC, FDA, and WHO for POC needs, technologies, and public health response</li> </ul>
General Accountability Office (GAO)	<ul> <li>Analyze recent General GAO reports, webcasts, and documents regarding POC technologies for epidemics, molecular diagnostics, and cost-effective healthcare systems in the U.S. and abroad</li> </ul>
Global status	<ul> <li>Compare and contrast national POCT policy and guidelines that have been established in Malaysia and Thailand, and their advantages and shortcomings (e.g., lack of disaster POC)</li> </ul>
B. Workshops	
Procedures	<ul> <li>Understand the necessity for a set of written policies and procedures for POC testing</li> </ul>
	Be able to identify the core content of a policy or procedure

Policy and guidelines workshop	Give learners the opportunity to draft an outline of the contents of national POCT policy and guidelines for a limited-resource country
Part II.	Project management and POC value propositions
Project management and the POC committee	<ul> <li>Understand the basic principles of project management</li> <li>Consider how to analyze and effectively manage stakeholders</li> <li>Understand the importance of the POC committee, anticipatory planning, and preparation for community projects</li> </ul>
How to write a business case and develop value propositions	<ul> <li>Understand what information should be included in a business case</li> <li>Be able to analyze the cost-effectiveness and value of POC testing</li> <li>Identify key issues to address when implementing a new POC service</li> </ul>
Part III.	Global and future vision
Course summary	<ul> <li>Recap what we have learned and what we can do with our knowledge to improve public preparedness, response, and health outcomes</li> </ul>
Learner presentations	Have teams of learners share studies of POC applications with which they have personal experience or have gleaned from literature
Future vision	<ul> <li>Understand the role of POC technologies in future public health initiatives, disaster preparedness, and stopping spread of outbreaks of highly infectious diseases in America and other countries</li> <li>Place POCT on vans, ambulances, ships, aircraft, space flights, space stations, and planetary colonies</li> <li>Realize that the principles and practice of POCT will evolve to maintain high standards of care adapted for mobile and remote settings as well as potential extraterrestrial life and encounters</li> </ul>

The COVID-19 pandemic called us all to action, action that can be sustained through creative public health education in POCT. Knowledge learned, taught, and shared worldwide will help fill resilience gaps as the Delta variant becomes a global endemic disease and ubiquitous POCT to deal with it, the new normal.



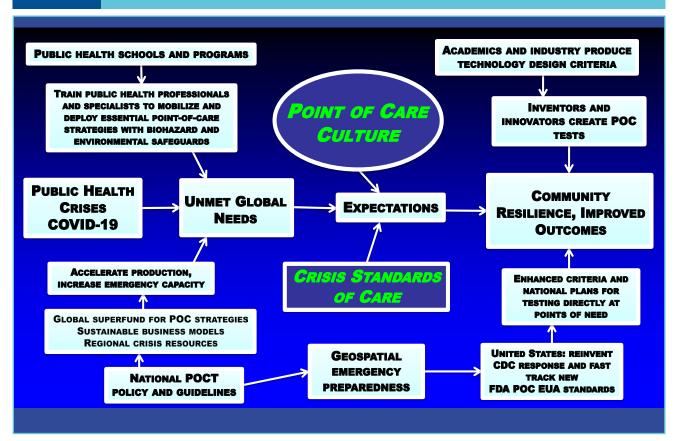
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Figure 1

The incorporation of POC knowledge, skills, and culture in public health will lead to community resilience and improved outcomes
— an integrative roadmap



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