Letters to the EDITOR

A POINT-OF-CARE TEST FOR H1N1 INFLUENZA

To the Editor:

I read the recent article by Louie et al[1] with a great interest. Louie et al[1] mentioned point-of-care test (POCT) deficiencies and also raised policy recommendations that will enhance preparedness. Indeed, the POCT is confirmed for its usefulness in the management of emerging infection, including H1N1 influenza.[2] However, the preparedness for emerging infectious diseases such as H1N1 influenza can still be questionable. It is no doubt that we can prepare for the reemergence of known diseases, but newly emerging diseases are usually unpredictable. The role of the POCT in diagnosis must be based on the data for already-existing emerging infectious diseases. The actual role of the POCT might be in molecular epidemiology as a tool for surveillance of old diseases and for monitoring of a new mutation that can lead to a newly emerging infection.

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1. 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 2):S193-S202.
2. Kost GJ, Hale KN, Brock TK, et al. Point-of-care testing for disasters: needs assessment, strategic planning, and future design. *Clin Lab Med*. 2009;29 (3):583-605.

Louie et al reply:

On April 17, 2009, the Centers for Disease Control and Prevention (CDC) determined that 2 cases of febrile respiratory illness occurring in children residing in southern California were caused by the swine influenza A (H1N1) strain.[1] On April 27, 2009, the CDC submitted the first complete coding sequence to GenBank for the H1N1 virus, A/California/04/2009 (H1N1), which had been isolated from a patient in California on April 1, 2009.[2]

The Food and Drug Administration (FDA) issued an Emergency Use Authorization for the H1N1 virus real-time reverse transcriptase-polymerase chain reaction Detection Panel developed by the CDC on April 27, 2009. The assay was made available to public health and reference laboratories, but technical complexity required licensed clinical laboratory technologists to perform the test. To increase accessibility for use in emergency, disaster, or rural settings, this process could be modified to produce simple but highly accurate and precise methods designed for the point of care (POC).[3]

POC tests for seasonal influenza were available at the time of the 2009 H1N1 outbreak; however, the subsequent pandemic highlighted the need for subtyping and antimicrobial resistance data to enhance patient triaging, treatment decisions, and proper resource allocation (eg, medications, isolation, ventilators), especially for critically ill patients. The influenza virus continuously evolves to generate not only significant health risks for the global community but also challenges for the practical production of POC tests.

Wiwanitkit[4] notes correctly that existing POC immunoassays for seasonal influenza A and B did not detect the 2009 H1N1 strain reliably. His observation highlights the need for rapid discovery of novel pathogens and the equally fast innovation of FDA-approved POC tests for pandemic strains. POC and near-patient pathogen detection typically use immunologic- or nucleic acid–based methods. The quality of assays depends in part on the primer designs, which are derived from available knowledge of the genomic sequences for the target pathogens. Simply put, knowledge takes time, and delays increase risk.

Strategic development of new POC technologies should minimize discovery to detection time (DDT). Even with delays in virus genomic identification, implementation of the final product as a licensed POC detection test will help ensure no further delays at the bedside. Hence, minimizing DDT has the potential to enhance impact on patient care. The National Institute of Biomedical Imaging Bioengineering POC Technologies Centers, working jointly with industry, can play an important role in reducing DDT and quickly putting new tests into clinical use.

Any properly developed, licensed, and quality-assured test, POC or not, must be evaluated for sensitivity, specificity, and predictive values. This evaluation phase takes time as well. In the case of the H1N1 assay, the urgent need for a confirmatory test for the new strain motivated the FDA to invoke Emergency Use Authorization status for the laboratory-based nucleic acid test that was developed by the CDC.

In addition to POC assays for pathogen detection, acceleration of parallel development of vaccines will help prevent the spread and escalation of pandemics. The 2009 H1N1 led to the development and FDA approval of 4 vaccines on September 15, 2009.[5] Our vision for future technologies includes rapid discovery, POC tests, and vaccine production within the same time frame.

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