

## A POINT-OF-CARE TEST FOR H1N1 INFLUENZA

### To the Editor:

I read the recent article by Louie et al<sup>1</sup> with a great interest. Louie et al<sup>1</sup> 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.<sup>2</sup> 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.

Viroj Wiwanitkit, MD

**Author Affiliation:** Visiting Professor, Hainan Medical College, Haikou, China.

**Correspondence:** Viroj Wiwanitkit, Wiwanitkit House, Bangkhuae, Bangkok, Thailand 10160 (vviroj@yahoo.com).

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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.<sup>1</sup> 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.<sup>2</sup>

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).<sup>3</sup>

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<sup>4</sup> 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.<sup>5</sup> Our vision for future technologies includes rapid discovery, POC tests, and vaccine production within the same time frame.

Richard F. Louie, PhD  
Gerald J. Kost, MD, PhD  
University of California, Davis-Lawrence  
Livermore National Laboratory  
Point-of-Care Technologies Center

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## VOLUNTEER ADVOCACY: THE NEED FOR NATIONAL WORKERS' COMPENSATION

### To the Editor:

Early in 2009, Congress introduced HR 635, the National Commission on State Workers' Compensation Laws Act. The first examination of workers' compensation since 1972, this act has significance not only for Americans injured while on the job but also for emergency workers and volunteers who put themselves at risk when responding to the call of duty.

Tens of thousands of volunteers from nearly every state in the country answered that call in New York City after September 11, 2001. Most had no better or worse insurance coverage than any other American: unemployed volunteers and lower-skilled workers had little or no coverage, whereas unionized workers had insurance from federal and state jurisdictions or private plans. Those with any insurance were subject to the same constraints—high deductibles, copays, and lifetime caps. Neither public nor private health insurance plans cover work or volunteer-related injuries or illnesses. Responders apply for workers' compensation simply hoping that their medical costs and lost wages will be covered. Reimbursement has been especially difficult for World Trade Center responders because evidence that illness or injury is a direct result of working at the emergency site is still evolving, and this has been known to contribute to both private and public employers' denial of claims. Of particular significance are application deadlines: Workers must apply within specified time periods that were established in the past for typical, long-term injury claims. Only recently have some states added provisions for chronic illnesses such as bronchial disease or cancers that emerge over time. HR 847, the 9/11 Health and Compensation Act, was reintroduced to Congress in February 2009. Even if enacted, it does no more than move along the same continuum of fragmented, inequitable, and inconsistent health care (both short- and long-term) for volunteer rescuers involved in large- and small-scale incidents.

The system of state control over workers' compensation established in the progressive era has not been significantly altered. The most serious threat to state domination occurred when the National Commission on State Workmen's Compensation Laws submitted its report to the President and Congress in 1972.<sup>1</sup> The report contained 84 recommendations to improve the programs and it recommended that Congress enact 19 mandatory standards for state programs. Although full compliance with the standards was never achieved, no federal mandates have ever been enacted by Congress.<sup>2</sup> HR 635, introduced to evaluate the effectiveness of state workers' compensation laws, is the first examination since the 1972 commission report.

Widespread attention to universal health insurance in the United States brings the possibility that concerns of emergency workers and volunteer responders will be addressed. For some, there is an argument that fundamental reform of the health care system will "absorb the health care component of workers' compensation."<sup>2</sup> However, even in a country like Canada, which provides universal health insurance via a single-payer model, a separate federal workers' compensation program exists.

In the present age of instant communications and global technology, volunteers come from a wide geographic area. Additionally, the major initiatives since September 11, 2001 aimed at recruiting, training, and maintaining a disaster volunteer workforce necessitate a consistently equitable national workers' compensation program. Since the terrorist attacks, insurers have been taking a closer look at their exposure to disasters, both natural and manmade. Some forecasts indicate that workers' compensation claims for terrorism could cost an insurer anywhere from \$300,000 to \$1 million per employee, depending on the state.<sup>3</sup> This has caused many areas to be classified as high risk which, in turn, has led to steep increases in the cost of insurance and added to more inconsistency in coverage across states.

HR 635 is only a first step. An additional but significant policy consideration is how workers' compensation in the United States should be structured to support universality of access and high-quality care for both workers and volunteers. As the country moves toward a national system of universal health care, the needs of emergency workers and volunteers must not be forgotten.

Deborah Viola, PhD  
Peter S. Arno, PhD  
Catherine Tegtmeier, RN, CFRN, CMTE  
New York Medical College

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