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Challenges With New Rapid Influenza Diagnostic Tests

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To the Editors

Rapid influenza diagnostic tests (RIDTs) are often used at point-of-care due to their ease of use and rapidly available results. Most tests are lateral flow immunoassays that detect chromatographic changes if an influenza antigen is present in the respiratory specimen. These tests have high specificity (therefore, a positive is almost certainly a true positive) but low sensitivity (therefore, will often miss true cases).[1,2] A newer immunofluorescence assay, Sofia A+B FIA (Quidel, San Diego, CA), demonstrated increased sensitivity but maintained high specificity.[3] However, on December 3, 2012, Quidel issued a voluntary recall of certain lots of Sofia A+B because of false positive results.[4]

In August 2011, we began a prospective cohort study of children aged ≤36 months at Queen Sirikit National Institute of Child Health, the largest pediatric referral hospital in Thailand. Children (equal numbers of high risk and healthy) are followed for 2 years and parents contacted weekly to inquire about whether their child had acute respiratory illness. Ill children came to the hospital and had a combined nasal and throat swab collected and tested for influenza viruses by realtime reverse transcription polymerase chain reaction (rRT-PCR).[5] In addition, a separate nasal swab was taken and tested using 1 of 2 RIDTs made by Quidel (QuickVue A+B during August 2011 to January 20, 2013; Sofia A+B during January 21, 2013 to May 2013).

Of the 1152 specimens tested with QuickVue A+B, 59 (5.1%) were positive by rRT-PCR. Compared with rRT-PCR, Quick-Vue A+B had a sensitivity of 55.9% (33/59; 95%

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confidence interval (CI): 42.4–68.8%) and a specificity of 99.4% (1086/1093; 95% CI: 98.7–99.7%). Seven (0.6%) were false positive on QuickVue A+B. Of the 370 specimens tested with Sofia A+B, 12 (3.2%) were positive by rRT-PCR. Compared with rRT-PCR, Sofia had a sensitivity of 100% (12/12; 95% CI: 73.5–100.0%) and a specificity of 61.2% (219/358; 95% CI: 55.9–66.3%). One-hundred thirty nine (38.8%) were false positive on Sofia. Of the 139 false positives, 123 (88.5%) were influenza B and 16 were influenza A. There was no difference in the time between illness onset and specimen collection date between true and false positives (median days = 2; $P = 0.96$), nor was there a difference between the prevalence of influenza during the 2 periods (5.1% vs. 3.2%, $P = 0.1$). Two lots of the Sofia assay were used and both had poor specificity (data not shown).

We learned that the assay lots we purchased were made after the recognized problem that led to the recall was corrected. Nevertheless, our data suggest that continuing problems exist. We share these data to alert others using this assay to the risk of false positives.

Our findings further support the limitations in using RIDTs for clinical decision making.[6] In Thailand, the Clinical Practice Guidelines recommend oseltamivir treatment for 2 groups of patients: (1) patients with complicated or severe influenza (ie, pneumonia, alteration of conscious, loss of appetite or dehydration and symptoms worsening after 48 hours of illness) and (2) patients with a high risk of having severe influenza (ie, pregnancy, obesity or chronic medical conditions). They also state that oseltamivir should also be considered in children <2 years of age or persons >65 years of age. In Thailand, the use of RIDTs is not recommended for deciding on a course of treatment. Further, we caution that newer RIDTs using immunofluorescence may need additional field evaluations.

References

1. Chartrand C, Leeflang MM, Minion J, et al. Accuracy of rapid influenza diagnostic tests: a meta-analysis. Ann Intern Med. 2012; 156:500–511. [PubMed: 22371850]
2. Centers for Disease Control and Prevention. Evaluation of 11 commercially available rapid influenza diagnostic tests–United States, 2011–2012. MMWR Morb Mortal Wkly Rep. 2012; 61(43):873–876. [PubMed: 23114254]
3. Lewandrowski K, Tamerius J, Menegus M, et al. Detection of influenza A and B viruses with the Sofia analyzer: a novel, rapid immunofluorescence-based *in vitro* diagnostic device. Am J Clin Pathol. 2013; 139:684–689. [PubMed: 23596120]
4. US Federal Drug Administration. Class 2 recall Sofia influenza A + B FIA, Kit #20218. 2013. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=115438. Accessed July 15, 2013
5. Centers for Disease Control and Prevention. CDC protocol of realtime RTPCR for influenza A (H1N1). 2009. Available at: http://www.who.int/csr/resources/publications/swineflu/realtimept-pcr/en/index.html. Accessed March 3, 2010
6. Centers for Disease Control and Prevention. Guidance for clinicians on the use of rapid influenza diagnostic tests. 2013. Available at: http://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm. Accessed July 15, 2013