



eLITERATURE REVIEW

eInfluenza Review

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Current Perspectives on the Clinical Diagnosis of Influenza

In this issue...

The combination of influenza vaccine shortages in past years along with the emergence of limited but lethal human infection with avian influenza H5N1 strains have brought considerable medical and media attention to the influenza virus. Somewhat lost among these important problems are new reports documenting the difficulties healthcare providers have in regularly diagnosing influenza in both the office and the hospital.

In this issue, we review the growing body of data detailing differential diagnostic predictors of influenza in a season of wintertime fevers and respiratory tract infections, the limitations of both clinical diagnosis and laboratory testing, the current state of rapid influenza diagnostics, and recently published recommendations from professional associations regarding prevention to avoid complications such as cardiopulmonary disease and stroke.

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Length of Activity

1.0 hours Physicians
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November 30, 2008

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Guest Faculty Disclosure

Paul G. Auwaerter, MD, has disclosed that he has served on the Speaker Bureau for Sanofi Aventis and Schering-Plough and as a consultant for Pfizer, Ortho-McNeil and Schering-Plough. He also disclosed that he is a Stock Shareholder for Johnson and Johnson.

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At the conclusion of this activity, participants should be able to:

- Describe the most accurate clinical predictors of influenza;
- Discuss the issues surrounding the under-diagnosis of influenza and the current emphasis on preventative measures;
- Identify the limitations of current influenza diagnostics and the technological improvements currently under development.

COMMENTARY

With more than 200,000 cases annually in the United States, and upwards of an all-cause influenza-related mortality of more than 50,000 deaths in some years^[1], there is ample opportunity for all clinicians to encounter influenza in medical offices, emergency departments, and hospitals. These numbers raise the question: how well are healthcare providers diagnosing influenza infection?

The answer appears to be: not as well as we should. Poehling and colleagues recently reported on a four-year prospective study of fevers and respiratory tract infections in children under five who underwent diagnostic viral culture and influenza polymerase chain reaction testing of respiratory specimens^[2]. They found that, compared to study-confirmed influenza cases, only 28% of hospitalizations and 17% of ambulatory visits were properly diagnosed by clinicians. Others have also reported substantial under-reporting of influenza when physician-ordered tests are solely used for generating surveillance information^[3,4]. These tests were least effective in the very young, as well as in the elderly, with this latter group often presenting with non-traditional symptoms of influenza such as acute exacerbations of chronic obstructive lung disease, cardiovascular events, stroke, or diabetic decompensations.

Part of the problem may lie in our current conceptions of influenza infection. The common symptoms of influenza are typically believed to be abrupt onset of fever, cough, headache, myalgia, and malaise. Call et al reviewed the world literature on the subject of syndromic diagnosis of influenza and found that no sign or symptom alone could strongly lead to a diagnosis of influenza^[5]. The best available information suggests that during influenza season, the abrupt onset of fever and cough in individuals 60 years of age or older did increase the likelihood ratio to 5.4 (95% CI 2.8-7.7), but this finding did not hold for younger age groups. By contrast, the absence of fever or cough made influenza diagnosis less likely. Perhaps the best single study on this subject was performed by Monto et al, finding that the clinical determination of epidemic influenza, fever and cough yielded a sensitivity of 79%^[6].

Will rapid viral diagnostics be of help to the clinician in securing an influenza diagnosis? In hospitals, direct fluorescent-antibody (DFA) staining of respiratory specimens may offer a result within hours, but these tests are not practical in office settings. Rapid diagnostic tests are available (such as the Directigen Flu

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A+B, ZstatFlu, XPECT Flu A/B) that have been compared to viral culture and DFA, yielding a sensitivity of 72-95% with a specificity of 76-84% [7]. The Quick Vue A + B test was studied recently and found to have a sensitivity of 82% compared to culture [8]. Although these tests may help secure an influenza diagnosis or rule it out if pretest probability of infection is low, they have not been especially popular with physicians since the accuracy of their own clinical influenza diagnosis appears to be approximately equivalent to the performance of these rapid tests.

New methodologies may offer improved diagnosis, including surveillance for emerging strains of influenza that may pose a threat for pandemics such as H5N1. As discussed by Townsend et al, a FluChip based upon microarray technology may offer promise of improved diagnosis of type and subtype along with more rapid turn-around [9]. Commercial availability may come about within a year, and the FluChip could offer both clinicians and public health officials more up-to-date information on specific strains of influenza circulating in their communities.

Since clinical diagnosis of influenza remains less than ideal, efforts at optimizing prevention continue to yield a more substantial likelihood of impact. Unlike children and younger adults, older individuals may present with non-respiratory illnesses such as acute coronary syndrome, cerebrovascular disease or diabetic decompensations as manifestations of influenza infection. One large study examining >39,000 people in a United Kingdom general practice found that respiratory tract infection appeared to predispose individuals to myocardial infarction and stroke (incidence ratio 4.95, 95% CI 4.43-5.53 and 3.19, 95% CI 2.81-3.62 respectively) during the first three days of diagnosis, falling thereafter in the ensuing weeks [10]. Another study concluded that influenza immunization protected at-risk patients from acute coronary syndrome compared to placebo [11].

Since a majority of patients at risk for cardiovascular disease remain unimmunized, new guidelines have been published attempting to enlist the support of subspecialists such as cardiologists and endocrinologists to administer influenza vaccination to their patients [12,13]. Together with improved immunization in children, this may well decrease the overall burden of influenza infection in the United States in future years.

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INFLUENZA IN CHILDREN: AN UNDIAGNOSED BUT COMMON CAUSE OF OUTPATIENT VISITS

Poehling KA, Edwards KM, Weinberg GA, Szilagyi P, Staat MA, Iwane MK, Bridges CB, Grijalva CG, Zhu Y, Bernstein DI, Herrera G, Erdman D, Hall CB, Seither R, Griffin MR; New Vaccine Surveillance Network. **The underrecognized burden of influenza in young children**. N Engl J Med. 2006 Jul 6;355(1):31-40.

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Poehling et al report on a multi-site study that prospectively evaluated children less than 5 years of age presenting with an acute respiratory tract infection or fever in both ambulatory and inpatient settings. Over a four year period (2000-2004) 3359 children were enrolled, with about 50% under six months of age, and 80% less than two years of age. Most common presenting symptoms included fever (93%), cough (87%), and rhinorrhea (83%), although infants under 6 months of age had fever and cough less commonly. All children were evaluated for influenza by nasal/throat swab for viral culture and PCR.

Significantly, of the influenza confirmed cases found in the study, only 28% of hospitalized children and 17% of ambulatory visits had a correct diagnostic impression of influenza by their providers. Commonly reported diagnoses instead of influenza included bronchiolitis, pneumonia, asthma flare, seizure, fever/sepsis, and viral illness. About 35% of children presented within 48 hours of symptom onset, making them potentially eligible for antiviral administration if influenza were considered at the time. Between 11%-26% of children had received influenza immunization, with the higher percentages in those children with recommendations specifically for receiving vaccine.

As the above data show, a substantial majority of outpatient visits for febrile or respiratory illness in children were due to influenza without apparent clinical recognition by their providers. The authors estimate that influenza-related outpatient visits are 10 times (for ages 0-5 months) to 250 times (for ages 24-59 months) as common as hospitalizations. Since high hospitalization rates led to the CDC recommendations to universally immunize children 6-23 months of age^[1], this new information would further support recommendations for wider and improved influenza immunization in children. Such broad immunization would likely translate into substantial prevention and potentially significant economic benefits with reduced illness, office visits, and hospitalizations. Findings of this nature have supported efforts to more highly target childhood influenza immunization (in addition to the usual high risk groups), and have added to the growing sense that childhood influenza may very well be the most important driver of influenza in any given season.

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HOW CAN CLINICIANS BEST IDENTIFY PATIENTS WITH INFLUENZA?

Call SA, Vollenweider MA, Hornung CA, Simel DL, McKinney WP. **Does this patient have influenza?** JAMA. 2005 Feb 23;293(8):987-97. Review. PMID: 15728170.

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Call et al provide a case-based scenario, including a review of 915 articles published since 1966 pertaining to the clinical assessment of influenza. The authors' main objective was to gauge the precision of influenza diagnosis based upon presenting signs and symptoms, with a secondary objective to assess the performance of rapid diagnostic tests for influenza. This study used a typical MEDLINE structured search strategy, with subsequent data extraction and analysis by two independent reviewers.

The reviewers' inclusion criteria required study designs that were prospective (cohort or randomized control trials), that included primary clinical signs for assessment of diagnosis, that had primary data available for independent analysis, and that provided laboratory evidence of influenza infection. They identified only ten studies that met these standards, and, after additional review, were able to base their final data on only six studies that included a total of 7105 patients.

Studies looking at patients regardless of age found that the likelihood of influenza was less (defined as a likelihood ratio <0.5) if there was an absence of a) fever, b) cough, or c) nasal congestion. Subjective symptoms often associated with influenza – such as complaints of feverishness, myalgia, malaise, sneezing or sore throat – provided no discrete diagnostic value.

For patients aged 60 or older, the combination of both fever and cough with an acute onset appeared to be diagnostically useful, with likelihood ratios of 1.9 and 5.0 in two of the studies meeting inclusion criteria.

The authors further report that for diagnostic testing, direct fluorescent-antibody testing of respiratory samples is the method many hospitals use to render a diagnosis within hours. Polymerase chain reaction (PCR) tests may offer better sensitivity and specificity, but are not widely available. Point-of-care rapid testing (tests such as the QuickVue A+B Test, Directigen Flu A+B, and others) are available, but given reduced sensitivity and specificity (ranges 59%-81% and 70%-99% respectively) they offer little additional information if there is a substantial probability of influenza diagnosis based upon acknowledged presence of epidemic influenza in the local community.

Not unexpectedly, no individual clinical finding was strong enough to either rule-in or rule-out a diagnosis of influenza. Subjective symptoms such as feverishness, headache, and myalgia are notoriously difficult to base precise diagnoses upon, and it appears influenza is no different in this regard. While healthcare providers have been taught that fever, headache, myalgia and cough are the classic components of an influenza infection, these same symptoms can be seen with a myriad of other infections during the respiratory season, especially in children and younger adults.

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While the authors provide a careful analysis of the data, their findings were limited in that diagnostic confirmation for influenza was required as a gold standard against which to compare syndromic presentations; however, the studies that met this inclusion criterion used different testing methods. One included study used only viral culture data, which may be less sensitive in the detection of influenza virus than polymerase chain reaction methods or careful serological studies using acute and convalescent samples. Other potentially confounding considerations include that many patients in these studies came from vaccine studies which may not be representative of patients in primary care practices, and that these multinational data may be less cohesive due to the introduction of language and cultural differences.

While the best clinical predictors remain the acute onset of fever and cough during the influenza season, the data supported this finding only in populations aged 60 or older. Diagnostic rapid point of care testing may be helpful if positive (increasing likelihood five-fold) or negative (virtually ruling out influenza as a diagnosis if prior clinical probability is low), but generally does not offer substantial benefit to healthcare providers evaluating patients in ambulatory settings. The authors recommend, therefore, that practitioners are best served using their own clinical assessment for diagnosing influenza in the general population, especially since therapeutic intervention is most efficacious if started within 48 hours of symptom onset. If influenza is known to be circulating in the community, then abrupt onset of fever and cough may be an imperfect but best available measure.

NEW TECHNOLOGIES TO AID IN THE RAPID DIAGNOSIS OF INFLUENZA

Townsend MB, Dawson ED, Mehlmann M, Smagala JA, Dankbar DM, Moore CL, Smith CB, Cox NJ, Kuchta RD, Rowlen KL. **Experimental evaluation of the FluChip diagnostic microarray for influenza virus surveillance.** J Clin Microbiol. 2006 Aug;44(8):2863-71.

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Townsend et al report on the use of a microarray (FluChip-55) following viral RNA extraction and amplification to rapidly identify the H1N1, H3N2, and H5N1 strains of influenza types A and B. In this study, a total of 72 influenza virus isolates were analyzed, with the FluChip correctly identifying 95% of isolates with 72% accuracy for subtyping. The investigators examined viral RNA which bypassed the traditional generation of complementary DNA for reverse-transcriptase PCR, thereby greatly abbreviating the time required for testing. The lower subtyping accuracy was attributed to problems with traditional nucleic acid amplification rather than difficulty with the microarray. False positive rates were judged as 1% and false negative rates as 4% of isolates.

Robotic laboratory machines using microarray chip technology hold great promise for the rapid diagnosis of infectious diseases: this study was able to evaluate influenza samples within 11 hours as opposed to 4 or more days by traditional methods. The FluChip could help evaluate respiratory samples for the presence of seasonal influenza as well as emerging strains of potentially pandemic influenza such as avian influenza H5N1.

The investigators have stated that they hope to have a commercially available product within one year with an eventual target of less than 2-7 hours turnaround time. Although they note that the amount of RNA present in a patient sample is inadequate to achieve this goal by the present methodology, they expect novel detection techniques currently in development to overcome this existing limitation.



They anticipate the more immediate use of this technology will likely be for public health laboratories to track influenza strains rapidly, so clinicians can be informed more quickly about what pathogens are circulating in their communities.

INFLUENZA IMMUNIZATION AND CARDIOVASCULAR DISEASE

Davis MM, Taubert K, Benin AL, Brown DW, Mensah GA, Baddour LM, Dunbar S, Krumholz HM; American Heart Association; American College of Cardiology; American Association of Cardiovascular and Pulmonary Rehabilitation; American Association of Critical Care Nurses; American Association of Heart Failure Nurses; American Diabetes Association; Association of Black Cardiologists, Inc; Heart Failure Society of America; Preventive Cardiovascular Nurses Association; American Academy of Nurse Practitioners; Centers for Disease Control and Prevention and the Advisory Committee on Immunization. **Influenza vaccination as secondary prevention for cardiovascular disease: a science advisory from the American Heart Association/American College of Cardiology.** J Am Coll Cardiol. 2006 Oct 3;48(7):1498-502.

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American Diabetes Association. **Standards of medical care in diabetes – 2006.** Diabetes Care 2006;29(Suppl. 1):S4-S42.

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Both the AHA/ACC and the ADA have recently issued guideline statements reviewing the rationale behind supporting annual influenza immunization with inactivated vaccine in those with coronary and other atherosclerotic diseases.

With influenza-related death more common in people with cardiovascular disease (CVD), the Journal of the American College of Cardiologists report presented the best evidence for supporting immunization as protective. Of key interest is the FLUVACS (FLU Vaccination in Acute Coronary Syndromes) study, the only randomized clinical trial available that addresses this question prospectively. Here 301 patients were randomized after myocardial infarction or angioplasty to receive immunization or placebo. At one year, cardiovascular mortality in the vaccinated group was 2% compared to 8% in the unvaccinated group (relative risk 0.25 compared to the unvaccinated, 95% CI 0.30-0.86)^[1]. In addition, other literature cited, based on cohort or case-control studies, supports vaccine-associated reductions in stroke, heart failure, and cardiovascular hospitalizations^[2-5].

Importantly, no higher rate of cardiovascular complications appeared to occur as a consequence of influenza immunization, including a >39,000 CVD patient cohort in the United Kingdom examined for 90 days after vaccination^[6].

This advisory statement, endorsed by multiple disciplines, has been directed toward cardiologists, neurologists, and endocrinologists, specialists who do not typically view themselves as important in the decision to recommend or to give influenza immunization (a province usually of primary care providers). Since only 1 of every 3 adults with heart disease received influenza immunization in 2005 (CDC, unpublished data cited in the article), outpatient visits to cardiology practices may be a prime opportunity to vaccinate. Only 50% of cardiology practices are thought to stock influenza vaccine.

Synopsizing the recommendations:

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1. The AHA and ACC advise that inactivated influenza vaccine be given to all individuals with CVD as a component of secondary prevention of coronary and atherosclerotic diseases unless contraindications exist.
2. Influenza immunization remains below-target in CVD groups and preventative benefits are not what they could be.
3. Providers who care for CVD patients should stock vaccine and promote immunizations with strong recommendations and/or standing orders.

The American Diabetes Association has likewise added an influenza immunization statement to their newly published practice guidelines. They recommend annual vaccination for all diabetics over the age of 6 months, based in part on case-control information suggesting a 79% decrease in hospitalization rates among diabetics during an influenza epidemic^[7].

Together, these guideline statements urge specialists to strongly advise and/or administer annual influenza vaccine, with the objective of increasing immunization coverage beyond what is currently accomplished through primary care directives.

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