# Accuracy and Impact of a Point-of-Care Rapid Influenza Test in Young Children With Respiratory Illnesses

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**Objective:** To determine whether a point-of-care rapid influenza test impacts the diagnostic evaluation and treatment of children with acute respiratory illnesses.

Design: Randomized controlled trial.

**Setting:** Pediatric emergency department and acute care clinic of a children's hospital.

**Participants:** Children aged younger than 5 years with fever or acute respiratory symptoms during 2 influenza seasons (2002 through 2004).

**Interventions:** Surveillance days were randomized to performance or no performance of a point-of-care rapid influenza test. All children had a nasal and throat swab obtained for laboratory tests. The rapid test group had another nasal swab obtained for the QuickVue Influenza Test (Quidel Corp, San Diego, Calif), which was performed by nurses; results were shared immediately with treating physicians.

pared with results of the viral culture or 2 polymerase chain reaction assays for influenza. Diagnostic test ordering and antibiotic prescribing were compared for the groups.

**Results:** Of 468 enrolled children, 306 were from the emergency department and 162 from the clinic. Overall, 88 children (19%) had influenza infection. Of 205 children in the rapid test group, 51 (25%) had influenza infection. The rapid influenza test was 82% sensitive and 99% specific. In the emergency department, fewer children in the rapid test group had diagnostic tests ordered than in the no rapid test group (39% vs 51%, P=.03). There was no difference in test ordering in the clinic or in antibiotic prescribing in either setting. The use of antivirals was low.

**Conclusions:** Point-of-care rapid influenza tests were sensitive and specific and were associated with less diagnostic testing in the emergency department.

Main Outcome Measures: Rapid test results were com-

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NFLUENZA VIRUS CAUSES FEBRILE and respiratory illnesses in 10% to 30% of children each winter. Children aged younger than 2 years are hospitalized with influenza-related illnesses at rates that are comparable with rates for persons aged 65 years or older,<sup>1,2</sup> a group widely appreciated to have high morbidity from influenza. Although influenza infections are common among children, many remain undiagnosed because clinical manifestations of influenza disease can overlap significantly with those of other viral or bacterial infections. In addition, viral culture confirmation of influenza disease takes days to weeks and does not effectively support clinical decision making.

With the development and use of point-of-care rapid influenza tests, we

hypothesized that such tests would impact patient care by reducing unnecessary diagnostic testing, decreasing antibiotic use, and increasing antiviral use. In this study, we evaluated the impact of using a rapid test for influenza among outpatient children with fever or acute respiratory symptoms and used viral culture and polymerase chain reactions assays to independently define influenza positive and negative. Because rapid tests for influenza have reported sensitivities of approximately 75%,<sup>3</sup> we evaluated the accuracy of the point-of-care rapid influenza test and accounted for the fact that a rapid influenza test will miss some children who have influenza infection. We also performed a randomized controlled trial of a point-of-care rapid influenza test to measure its impact on clinical care of young children who presented to the

(REPRINTED) ARCH PEDIATR ADOLESC MED/VOL 160, JULY 2006 713 pediatric emergency department or an acute care clinic with fever or acute respiratory symptoms during 2 consecutive influenza seasons.

#### **METHODS**

## STUDY POPULATION

Eligible children were younger than 5 years of age; resided in Davidson County, the county encompassing Nashville, Tenn; and presented to the university-based pediatric emergency department or acute care clinic with fever or acute respiratory symptoms during the 2002-2003 or 2003-2004 influenza season. The reason for the county restriction was that this study was part of a large surveillance effort of the New Vaccine Surveillance Network.4 Eligible children presented with any of the following symptoms: cough, rhinorrhea, wheezing, difficulty breathing, fever, sore throat, apnea, or ear pain. Children were excluded if they were enrolled within the prior 4 days or had fever and neutropenia from chemotherapy. Enrollment times and days reflected the operational hours of each clinic setting. Children were enrolled 3 days per week in the pediatric emergency department and 1 day per week in the acute care clinic. During enrollment days, parents of consecutive eligible children were approached. Study days were prospectively randomized to the performance or no performance of a point-of-care rapid influenza test with equal numbers of study days for each group.

#### STUDY DESIGN

Informed written consent was obtained from the parent/ guardian of each enrolled child. A research nurse administered a standardized questionnaire containing demographic information, history of presenting illness, and medical history. Nasal and throat swabs were obtained from all enrolled children for viral culture and polymerase chain reactions (PCRs) for influenza virus and were performed by research laboratory personnel blinded to the results of the rapid influenza tests. An additional nasal swab, a recommended specimen according to the instructions for the QuickVue Influenza Test (Quidel Corp, San Diego, Calif), was obtained in those randomized to the performance of the point-of-care rapid test. After the patient visit, the medical record was reviewed to determine the diagnostic tests ordered and treatments prescribed.

The Vanderbilt Pediatric Emergency Department is the only pediatric emergency department in middle Tennessee and provides care for approximately 30 000 children per year. The majority of children reside in Davidson County and have Medicaid insurance. The university-based acute care clinic serves approximately 11 000 children, of which nearly 80% reside within Davidson County and have Medicaid insurance.

The study period included 2 consecutive influenza seasons. By definition, the influenza season began the first day of 2 weeks with 2 or more positive influenza cultures per week and ended the last day of the second week with fewer than 2 positive influenza cultures in hospital and research laboratories of Vanderbilt University Medical School.<sup>5</sup> For the 2 study years, this included the periods from January 28 to April 8, 2003, and December 1, 2003, to January 31, 2004.

Study days were randomized to rapid test or no rapid test days using blocks of 4 and 6. Block size and determination of which days the rapid test was performed were determined by a random number generator by Stata version 8.1 (Stata Corp, College Station, Tex). This study had 80% power to detect a 15% difference in diagnostic testing with 185 children in the rapid test group and the no rapid test group with an  $\alpha$  of 0.05.

## INFLUENZA VIRUS DETERMINATION

## Culture

Nasal and throat swabs were obtained from each enrolled child, combined into a test tube of veal-infusion broth transport medium, and inoculated onto primary rhesus monkey kidney cells. Cultures were incubated at 35°C and initially identified by cytopathic effect and hemadsorption. Cultures without cytopathic effect and hemadsorption were screened by immunofluorescent assay at 10 days.<sup>6</sup> A specimen was considered culture positive if either influenza A or B was identified.

#### **Polymerase Chain Reaction**

For reverse transcription–PCR (RT-PCR) testing, aliquots of the sample were placed in lysis buffer and the RNA was extracted and frozen at –70°C.<sup>7</sup> Duplicate aliquots of extracted RNA were tested by RT-PCR with previously described oligonucleotide primers and probes for influenza A and B viruses using colorimetric microtiter plate systems.<sup>8</sup> A specimen was considered PCR positive if both PCR determinations were positive for influenza A or B.

# **Criterion Standard**

Influenza infection was defined as any sample with either a positive viral culture for influenza A or B or 2 consecutive positive PCRs for influenza A or B.<sup>8</sup> Approval to perform point-of-care rapid influenza testing was obtained from the Tennessee Medical Laboratory Board, and all study nurses completed formal training using the QuickVue Influenza Test. Laboratory proficiency tests from the American College of Pathologists were performed by the study nurses 3 times each year. Positive and negative controls were confirmed prior to use of each kit of 25 rapid influenza tests. A study nurse obtained a nasal swab with the QuickVue Influenza Test applicator, placed it in a test tube, and mixed it with kit reagent. The test was performed and interpreted at the point of care according to the manufacturer's instructions.

## STATISTICAL ANALYSIS

To measure the impact of the QuickVue Influenza Test, the primary study outcome was the proportion with any diagnostic tests, except a rapid influenza test, ordered by the treating physician in the performance and no performance of the rapid test groups using  $\chi^2$  analysis. Secondary outcomes evaluated the performance of individual tests, including complete blood cell count and/or blood culture, urinanalysis and/or urine culture, and chest radiograph, which were compared using  $\chi^2$  or Fisher exact tests. Antibiotic or antiviral prescriptions were also compared using  $\chi^2$  or Fisher exact tests. Demographic variables (race and age) were analyzed using  $\chi^2$  tests, and continuous variables were analyzed using a t test. Because excluding 10 children in the emergency department and 1 in the acute care clinic who were younger than 1 month of age did not change the statistically significant results, these 11 children were included in the study population. High-risk medical conditions were those conditions for which the influenza vaccine is specifically recommended according to the 2003 Red Book.9 Stata version 8.1 was used for all analyses.

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#### Table 1. Demographics of Study Population by Clinical Setting

Characteristic	No. (%)							
	Emergenc	y Department	Acute	e Care Clinic				
	Rapid Test (n = 135)	No Rapid Test (n = 170)	Rapid Test (n = 70)	No Rapid Test (n = 93)				
Sex								
Male	66 (49)	84 (49)	33 (47)	51 (55)				
Female	69 (51)	86 (51)	37 (53)	42 (45)				
Age, mo*								
0-5	33 (24)	49 (29)	10 (14)	11 (12)				
6-23	57 (42)	74 (44)	27 (39)	48 (52)				
24-59	45 (33)	47 (28)	33 (47)	34 (37)				
Race			<b>、</b>	( , , , , , , , , , , , , , , , , , , ,				
Black	73 (54)	80 (47)	45 (64)	52 (56)				
White	46 (34)	64 (38)	14 (20)	27 (29)				
Other	16 (12)	26 (15)	11 (16)	14 (15)				
High risk	29 (21)	34 (20)	13 (19)	13 (14)				

\*Percentage sum might not equal 100% because of rounding.

The performance characteristics of the QuickVue Influenza Test were determined by comparing its results with that of the criterion standard. Intrarater and interrater reliability for 2 study nurses were ascertained by obtaining a second reading of 102 randomly selected test strips that were scanned and printed in color on the enrollment day.

## RESULTS

# PARTICIPANTS

Enrollment included 305 (92%) of 333 and 163 (84%) of 195 eligible children approached in the emergency department and acute care clinic, respectively. On days randomized to performance of the rapid test, 205 (89%) of 230 eligible children were enrolled. For each clinic setting, demographic characteristics of children enrolled on performance of rapid test days were similar to those on no rapid test days (**Table 1**). Demographic characteristics of children enrolled in the emergency department and the acute care clinic were similar with the exception that children in the emergency department were significantly younger than those in the clinic. Eighty-nine enrolled children (19%) had high-risk medical conditions and 71 (80%) had asthma.

Common presenting symptoms of enrolled included fever (77%) and cough (88%). Overall, the median symptom days prior to presentation was 3, and 38% of children had had symptoms for 2 or fewer days. Children with influenza infection by criterion standard had a mean of 3.9 symptom days prior to presentation to both the emergency department and the acute care clinic. None of the children enrolled in the clinic were subsequently hospitalized as compared with 41 children (13%) in the emergency department (P<.001). The mean number of diagnostic tests per child performed in the emergency department was significantly higher than in the clinic (1.1)vs 0.2, P < .001). Because of the significant difference in diagnostic test ordering between the 2 clinical settings, we analyzed the impact of the rapid test on clinical care for each clinical setting separately.

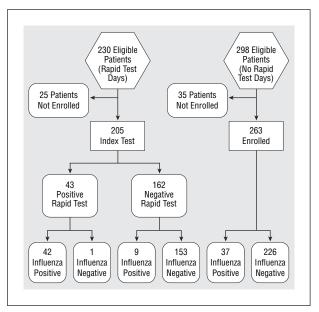


Figure. Flow diagram of children enrolled on days randomized to rapid influenza test and no rapid influenza test in emergency department or acute care clinic.

## **RAPID INFLUENZA TEST CHARACTERISTICS**

The nasal swab for the rapid influenza test and the nasal and throat swab for the criterion standard were obtained at enrollment and prior to any treatment. No adverse events were experienced with the performance of the rapid influenza test or criterion standard.

Because test characteristics were similar and the prevalence of influenza was 19% for both the emergency department and clinic settings, the data from both were combined to evaluate the diagnostic accuracy of the pointof-care rapid influenza test. Of 88 criterion-standard influenza infections, 87 (99%) had influenza A and 1 (1%) had influenza B. Of children enrolled on the performance of rapid test days, 51 (25%) were influenza positive by criterion standard and 43 (21%) were influenza positive by the point-of-care rapid test (**Figure**). Of 102

Diagnostic Test	Overall			Influenza Positive*		
	No. (%)			No. (%)		
	Rapid Test (n = 135)	No Rapid Test (n = 170)	<i>P</i> Value†	Rapid Test (n = 28)	No Rapid Test (n = 29)	<i>P</i> Value†
Any diagnostic test						
Yes No	53 (39) 82 (61)	88 (52) 82 (48)	.03†	9 (32) 19 (68)	12 (41) 17 (59)	.47
Chest radiograph	× /	× /			(	
Yes	31 (23)	56 (33)	.06	3 (11)	7 (24)	.18
No	104 (77)	114 (67)		25 (89)	22 (76)	
Blood count/culture	. ,				· ,	
Yes	14 (10)	31 (18)	.05	1 (4)	3 (10)	.61
No	121 (90)	139 (82)		27 (96)	26 (90)	
Urinanalysis/culture	, , , , , , , , , , , , , , , , , , ,	· · /				
Yes	18 (13)	27 (16)	.53	3 (11)	3 (10)	1.00
No	117 (87)	143 (84)		25 (89)	26 (90)	
Antibiotics	. ,				· ,	
Yes	43 (32)	49 (29)	.57	4 (14)	5 (17)	1.00
No	92 (68)	121 (71)		24 (86)	24 (83)	
Antivirals				. ,		
Yes	1 (1)	0	.44	1 (4)	0	.49
No	134 (99)	170 (100)		27 (96)	29 (100)	

\*Influenza positive was determined by viral culture or reverse transcription-polymerase chain reaction.

 $\uparrow \chi^2$  or Fisher exact tests are statistically significant at *P*<.05.

rapid test results read twice by research nurses, the intrarater and interrater reliability were excellent ( $\kappa$ =0.98, SE 0.02, for both). Using the criterion standard, the Quick-Vue Influenza Test had a sensitivity of 82% (95% confidence interval, 69%-92%), specificity of 99% (95% confidence interval, 96%-99.9%), positive predictive value of 98% (95% confidence interval, 88%-99.9%) and negative predictive value of 94% (95% confidence interval, 90%-97%). The positive and negative likelihood ratios, which are measures of discriminatory power, were 126 and 0.18, respectively.

# IMPACT ON CLINICAL CARE

In the emergency department, fewer children in the rapid test group, whether the rapid test had positive or negative results, had any diagnostic test ordered than those in the no rapid test group (39% vs 52%, P=.03, **Table 2**). Interestingly, fewer children without influenza infection had any diagnostic test ordered than those in the no rapid test group (41% vs 53%, P=.046). Although no one diagnostic test accounted for the differences in testing between the rapid and no rapid test groups, there was a trend for fewer chest radiographs and fewer blood cultures and/or complete blood counts in the rapid test group. Only 1 (5%) of 21 children who were positive for influenza met criteria for (symptoms for 1 or 2 days and at least 12 months of age) and was prescribed an antiviral medication; this child had a positive point-of-care rapid influenza test result. Overall, 13% of children in both the rapid and no rapid test groups were admitted to the hospital. In contrast to the emergency department, the performance and no performance of the rapid test groups did not differ in rates of diagnostic testing or antibiotic or antiviral prescribing in the acute care clinic setting (Table 3).

COMMENT

To our knowledge, this is the first study to evaluate the impact of a rapid diagnostic test in an emergency department and an outpatient clinic using viral culture and PCR as the criterion standard. The QuickVue Influenza Test performed by trained nurses at the point-of-care in children younger than 5 years of age with fever or acute respiratory symptoms was sensitive, specific, and reliable. In addition, 12.5% fewer children in the emergency department had any diagnostic test performed in the rapid test group than in the no rapid test group; among children without influenza infections, those in the rapid test group had fewer diagnostic studies than those in the no rapid test group. There were no differences in diagnostic testing noted in the acute care clinic.

The point-of-care rapid influenza test characteristics in this report were very similar to those reported in earlier studies in children.<sup>8,10-12</sup> Although previous studies differed in age of population, sample collection methods, time between sample collection and test performance, influenza season, influenza strain, and the criterion standard, the QuickVue Influenza Test had comparable performance characteristics with sensitivity ranging from 37% to 96% (mean±SD, 75±18%) and specificity ranging from 81% to 98% (mean ± SD,  $^{1}88 \pm 10\%$ ).  $^{3,8,10-17}$  Given the fact that younger children have higher viral titers, the sensitivity of the test is greater in the younger age groups.<sup>8,17</sup> Studies using frozen specimens or specimens delayed in testing have reported more false-positive results and thus a lower specificity.13-17

Two earlier studies in pediatric emergency departments found that children whose physicians were aware

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Diagnostic Test	Overall			Influenza Positive*		
	No. (%)			No. (%)		
	Rapid Test N = 70	No Rapid Test N = 93	<i>P</i> Value†	Rapid Test N = 23	No Rapid Test N = 8	<i>P</i> Value†
Any diagnostic test						
Yes	12 (17)	12 (13)	.45	2 (9)	1 (13)	1.00
No	58 (83)	81 (87)		21 (91)	7 (87)	
Chest radiograph						
Yes	6 (9)	5 (5)	.42	2 (9)	0	1.00
No	64 (91)	88 (95)		21 (91)	8 (100)	
Blood cell count/culture	· · ·			· · /	· · · ·	
Yes	3 (4)	3 (3)	1.00	2 (9)	1 (13)	1.00
No	67 (96)	90 (97)		21 (91)	8 (100)	
Urinanalysis/culture	. ,				. ,	
Yes	5 (7)	3 (3)	.29	2 (9)	0	1.00
No	65 (93)	90 (97)		21 (91)	8 (100)	
Antibiotics	. ,				. ,	
Yes	18 (26)	26 (29)	.75	6 (26)	3 (38)	.54
No	52 (34)	67 (71)		17 (74)	5 (62)	
Antiviral						
Yes	0	0		0	0	
No	70 (100)	92 (100)		23 (100)	8 (100)	

\*Influenza positive was determined by viral culture or reverse transcription-polymerase chain reaction.

 $\dagger \chi^2$  or Fisher exact test was used to determine *P* value.

of a positive rapid influenza test ordered fewer blood tests and urine tests as compared with physicians unaware of a positive rapid influenza test.<sup>18,19</sup> However, our study differed from these studies in 2 ways. First, we used an independent criterion standard instead of the results of the rapid influenza test to define influenza infection, which allowed us to account for the fact that rapid influenza tests are not 100% sensitive. Second, we evaluated the impact of the rapid influenza test in both the acute care clinic and the emergency department. In our study, fewer children in the emergency department had diagnostic tests ordered in the rapid test group compared with the no rapid test group. Although no differences between the groups in diagnostic testing were noted in the acute care clinic, this is likely due to the fact that fewer tests are ordered in the clinic than in the emergency department.

This study has some limitations. First, it was designed to evaluate the impact of the rapid influenza test on diagnostic testing and medication use. However, other factors such as alleviation of parental anxiety might have been impacted by the test and were not measured. Although the specific results of the diagnostic tests do dictate further evaluation and treatment, this study focused on whether 1 or more diagnostic studies were performed because ordering tests is associated with longer evaluation times. With increasing pediatric emergency department volumes and with long wait times due to overcrowding, especially during the respiratory season, factors influencing the performance of diagnostic testing are important. The sample size calculation was computed prior to the determination that the testing characteristics in the emergency department and acute care clinic were different. Although the acute care clinic study population had insufficient power to detect a difference in test ordering, this population would detect a significant difference only if 185 children were randomized to each group and the no rapid test group had a 22% higher rate of test ordering than the rapid test group. The impact of the rapid testing may vary by influenza season and between the beginning and end of each season. Finally, our results will likely be influenced by media coverage, pediatric influenza vaccination rate, and inherent prescribing practices of physicians.

Although 24% of all children with influenza infection met the criteria for antiviral treatment, the only child given antiviral medications was one who had a positive point-of-care rapid test. With effective antiviral agents, confirming influenza may be one major role for pointof-care tests. Persons who may benefit from antiviral therapy include individuals 12 months of age and older who arrive within 1 to 2 days of symptom onset of influenza infection or exposed family members and can be identified with rapid tests in a timely fashion. It is interesting to note that nearly 20% of children who tested positive for influenza from both study groups received antibiotics. Rapid influenza testing may provide timely data for influenza surveillance and impact public health decisions, including the decision to close schools during large outbreaks. Finally, with the expanding pediatric influenza vaccination recommendations, identifying children with influenza infections may impact the perceived value of influenza vaccinations for the child and family members.

In summary, point-of-care rapid influenza tests are readily available. A few studies have shown that positive rapid influenza test results impact clinical decision making in the pediatric emergency department. This study evaluated the impact of performing rapid influenza tests (both positive and negative results) on clinical decision making in a pediatric emergency department and an acute care clinic and used independent laboratory testing to define influenza infections.

We confirmed that the point-of-care QuickVue Influenza Test when performed by trained nurses was sensitive, specific, and reliable in young children who present to the outpatient setting with acute respiratory symptoms during the influenza season. The rapid influenza test results influenced the likelihood that a child had an influenza infection with positive and negative likelihood ratios of 126 and 0.18, respectively. The point-ofcare rapid influenza test reduced unnecessary diagnostic testing in the emergency department by 12.5% among all children with respiratory symptoms during the influenza season when emergency department overcrowding is a common problem. Further assessment of the impact of rapid influenza testing is warranted.

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