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Outbreak of Influenza and Rhinovirus Co-circulation Among Unvaccinated Recruits, U.S. Coast Guard Training Center Cape May, NJ, 24 July–21 August 2016

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Military and Coast Guard recruits are particularly susceptible to respiratory infections. Although seasonal influenza vaccinations are mandatory for recruits, the vaccine expires annually in June. On 29 July 2016, the U.S. Coast Guard Training Center Cape May, NJ, identified an increase in febrile respiratory illness (FRI) among recruits. During 24 July–21 August, a total of 115 recruits reported symptoms. A total of 74 recruits tested positive for respiratory infections: influenza A (H3) (n=34), rhinovirus (n=28), influenza/rhinovirus co-infection (n=11), and adenovirus/rhinovirus co-infection (n=1), while 41 recruits had no laboratory-confirmed specimen but were considered suspected cases. Only one recruit reported receiving the seasonal influenza vaccine within the previous 12 months. Influenza predominated during 24 July–6 August, whereas rhinovirus predominated during 7 August–20 August. Most (92.2%) cases were identified in four of 10 recruit companies; incidence rates were highest among recruits in weeks 2–4 of an 8-week training cycle. Key factors for outbreak control included rapid detection through routine FRI surveillance, quick decision-making and streamlined response by using a single chain of command, and employing both nonpharmaceutical and pharmaceutical interventions.

In 2016, respiratory infections affected more than 250,000 U.S. service members and comprised approximately 22% of medical encounters among military recruit populations.^{1,2} Seasonal influenza and rhinovirus are two of the leading respiratory pathogens of major military concern in terms of incidence and operational impact.³ Although incidence of seasonal influenza typically peaks during the winter and spring months in the Northern Hemisphere, illness caused by rhinovirus remains a persistent threat throughout the year among recruit trainee populations.⁴

Military recruits are highly susceptible to respiratory infections. This susceptibility

is largely attributed to factors associated with a shared, closed environment; greater-than-usual social proximity; and physical and mental stress during training.^{3,5,6} To mitigate these factors, mandatory vaccinations, including seasonal influenza, are administered routinely to all incoming recruits in addition to other active duty personnel.⁷ However, variations in seasonal influenza vaccine effectiveness and coverage can lead to gaps in immunity. Additionally, the vaccine expires each year in June, while the following season's vaccine is not available until late summer;⁷⁻⁹ therefore, incoming recruits who begin training during summer months do not receive the

seasonal influenza vaccine. Currently, there are no licensed vaccines for rhinovirus.³ Although proper hygiene and routine disease prevention measures should be instituted year-round, additional mitigation and control strategies, such as chemoprophylaxis and nonpharmaceutical interventions, can mitigate outbreak severity when implemented during an outbreak even in the absence of a vaccine.^{3,10,11}

The U.S. Coast Guard (USCG) Training Center Cape May (TCCM), NJ, is the only USCG recruit training center and the fifth largest USCG installation. Training cycles typically last 8 weeks, and approximately 4,250 recruits graduate each year. During any given week, approximately 700 recruits in seven to eight companies are present at the training center. TCCM is overseen by one commander with a single chain of command for the various functions, including the facilities division, administrative support division, training division, and medical division, to ensure mission success. The on-site health clinic includes a 21-bed patient care unit for recruits requiring overnight treatment.

TCCM participates as a Department of Defense febrile respiratory illness (FRI) sentinel surveillance site.¹² The training center collects nasal swab specimens for FRI patients and sends them for laboratory testing and characterization at the Naval Health Research Center (NHRC) in San Diego, CA. TCCM typically reports three to four FRI patients per week, and isolation protocols have been established for controlling disease spread. On 29 July 2016, the clinic identified an increase in the number of recruits presenting with FRI. This report characterizes the outbreak and containment measures implemented at TCCM during 24 July–21 August 2016.

METHODS

During the outbreak, two case classifications were used: 1) FRI cases, defined as persons with a fever of 100.4°F or greater and respiratory symptoms; and 2) upper respiratory illness (URI) cases, defined as persons with a temperature between 98.6°F and 100.4°F and respiratory symptoms. Documented signs and symptoms were based on a combination of self-reports and medical examinations, and included pneumonia, sore throat, cough, shortness of breath, congestion, headache, pink eye, body aches, and fever.

Clinic logs from TCCM and laboratory results from NHRC were used to analyze case information collected during 24 July–21 August 2016, the period during which case numbers increased above the baseline rate of 0.4 FRI cases/100 trainees/week to a rate of 2.8 cases/100 trainees/week. Individuals presenting with FRI or URI who had a positive laboratory specimen by polymerase chain reaction (PCR) were classified as confirmed cases, while those without a positive laboratory specimen (either no specimen collected or no pathogen detected) were classified as suspected cases.

The following variables were analyzed: specimen collection date, clinic admission and discharge dates, final laboratory diagnosis, training company assignment, seasonal influenza vaccination status, sex, and symptom types. Seasonal influenza vaccination status was based on self-reports of vaccination within the previous 12 months because influenza vaccination records were often unavailable. The training week (1–8) at the time of specimen collection or admission date was determined for each case. Lost duty time was assessed using duration of clinic admission, and light duty time was assessed using days of restricted training following medical discharge.

Average weekly recruit populations were calculated for each company and training week. The total numbers of confirmed and suspected cases were divided by the average weekly recruit populations to calculate incidence rates by company and by training week. Incidence rates also were calculated using only confirmed cases.

Quantitative and qualitative data regarding outbreak response activities were collected from TCCM staff using email and unstructured interviews. Outbreak interventions were classified as either pharmaceutical or nonpharmaceutical. The number of persons who were screened for symptoms and received prophylaxis through a point-of-dispensing (POD) was determined by using available paper documentation from two PODs implemented on 5 and 16 August 2016.

RESULTS

Data were analyzed for 115 confirmed and suspected cases detected during the outbreak period during 24 July–21 August 2016. Of these, 74 (64.3%) were classified as confirmed cases and 41 (35.7%) were classified as suspected cases. Among confirmed cases, nearly half of the laboratory specimens tested positive for influenza A (H3) (n=34; 45.9%), followed by rhinovirus (n=28; 37.8%), influenza A (H3) and rhinovirus co-infection (n=11; 14.9%), and rhinovirus and adenovirus co-infection (n=1; 1.4%). Gene sequencing of the positive influenza specimens showed that the circulating influenza strain belonged to the subclade 3C.2a, which was not included in the 2015–2016 influenza vaccine composition.¹³ Among suspected cases, 22 (53.7%) had no pathogen detected and 19 (46.3%) had no specimen available for laboratory testing.

No cases were identified among non-recruits, and only one of the 73 (1.4%) confirmed cases who had available seasonal vaccine status information had received the vaccine within the previous 12 months. A total of 16 (13.9%) patients were female, which is consistent with the distribution of the recruit population (**data not shown**). Overall, the outbreak resulted in at least 373 person-days of lost duty time in addition to 91 person-days of light duty time (**data not shown**).

Overall, the outbreak showed a bimodal distribution, with a peak during 31 July–6 August and a smaller peak during 14–20 August (**Figure 1**). However, influenza A (H3) infections predominated

during 24 July–6 August, particularly in Companies B and C, whereas rhinovirus predominated during 7 August–20 August, particularly in Companies D and E (**data not shown**). Additionally, 91.6% of co-infections occurred during 24 July–6 August (**Figure 1**).

Seven of 10 (70.0%) recruit companies reported either confirmed or suspected cases, and five companies (50.0%) reported at least one confirmed case (**Table 1**). Company C accounted for the most cases (n=41) and had the highest overall incidence rate (46.1%), followed by Companies B (25.0%) and E (22.9%); however, incidence rates for confirmed cases only were highest among Companies B and C.

Incidence rates were highest among recruits in training weeks 2–4 (**Table 1**). Similarly, the highest proportion of influenza A (H3) infections, rhinovirus infections, co-infections, and suspected cases, respectively, were among recruits in these training weeks. Conversely, no confirmed cases and only two suspected cases were among recruits in training weeks 6–8.

Among cases with available information (n= 95), the following symptoms were identified through self-report or medical examination upon presentation at the clinic: cough (87 of 95, 91.6%), sore throat (87 of 95, 91.6%), congestion (83 of 94, 88.3%), fever (75 of 106, 70.8%), headache (56 of 94, 59.6%), nausea (27 of 95, 28.4%), shortness of breath (18 of 94, 19.1%), conjunctivitis (5 of 93, 5.4%), and diagnosed pneumonia (2 of 95, 2.1%).

Table 2 details the nonpharmaceutical and pharmaceutical interventions that were implemented to control the outbreak, encompassing three main components: 1) screening and isolation, 2) enhanced hygiene and social distancing, and 3) treatment and prophylaxis. **Figure 2** depicts the timeline of these interventions, along with key events pertaining to laboratory diagnostic testing. Screening and isolation and enhanced hygiene and social distancing measures were implemented within the first 24 hours upon recognition of the outbreak, even before the receipt of positive rapid influenza diagnostic test results. Tamiflu® (oseltamivir) treatment (75 mg twice daily for 5 days) was initiated immediately, and

TABLE 1. Numbers of confirmed and suspected cases and incidence rates, by recruit company and training week, U.S. Coast Guard Training Center Cape May, NJ, 24 July–21 August 2016

	Average weekly recruit population	Total cases		Confirmed cases						Suspected cases	
		No. cases N=115	Incidence rate ^a	Influenza A (H3) N=34		Rhinovirus N=28		Co-infection ^b N=12		N=41	
Recruit company	N	N		N	%	N	%	N	%	N	%
Company A	78	1	1.3	0	0.0	0	0.0	0	0.0	1	2.4
Company B	120	30	25.0	14	41.2	3	10.7	6	50.0	7	17.1
Company C	89	41	46.1	17	50.0	9	32.1	5	41.7	10	24.4
Company D	104	11	10.6	0	0.0	3	10.7	1	8.3	7	17.1
Company E	105	24	22.9	3	8.8	11	39.3	0	0.0	10	24.4
Company F	98	3	3.1	0	0.0	1	3.6	0	0.0	2	4.9
Company G	97	1	1.0	0	0.0	0	0.0	0	0.0	1	2.4
Company H	109	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Company I	71	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Company J	89	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Other ^c	53	4	7.5	0	0.0	1	3.6	0	0.0	3	7.3
Recruit training week ^d											
Week 1	103	3	2.9	2	5.9	0	0.0	0	0.0	1	2.6
Week 2	99	33	33.3	16	47.1	7	25.9	1	8.3	9	23.7
Week 3	101	40	39.6	3	8.8	15	55.6	4	33.3	18	47.4
Week 4	106	31	29.2	13	38.2	4	14.8	7	58.3	7	18.4
Week 5	99	2	2.0	0	0.0	1	3.7	0	0.0	1	2.6
Week 6	89	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Week 7	83	2	2.4	0	0.0	0	0.0	0	0.0	2	5.3
Week 8	81	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

^aRate per 100 persons. Calculated for any patients meeting the confirmed or suspected case definitions.

^bCo-infection with influenza A (H3) and rhinovirus or adenovirus and rhinovirus

^cIncludes recruits not assigned to a training company

^dBy date of specimen collection or admission; four cases were not assigned a training week.

prophylaxis (75 mg once daily for 10–20 days) for the entire recruit regiment and staff was initiated within 48 hours of receiving positive influenza A (H3) and rhinovirus PCR test results.

EDITORIAL COMMENT

The influenza/rhinovirus outbreak at TCCM during 24 July–21 August 2016 occurred in a recruit population that was unvaccinated against seasonal influenza as a result of the annual vaccine's expiration. The lack of vaccination, coupled with close social proximity in a high-stress environment along with a continuous influx of

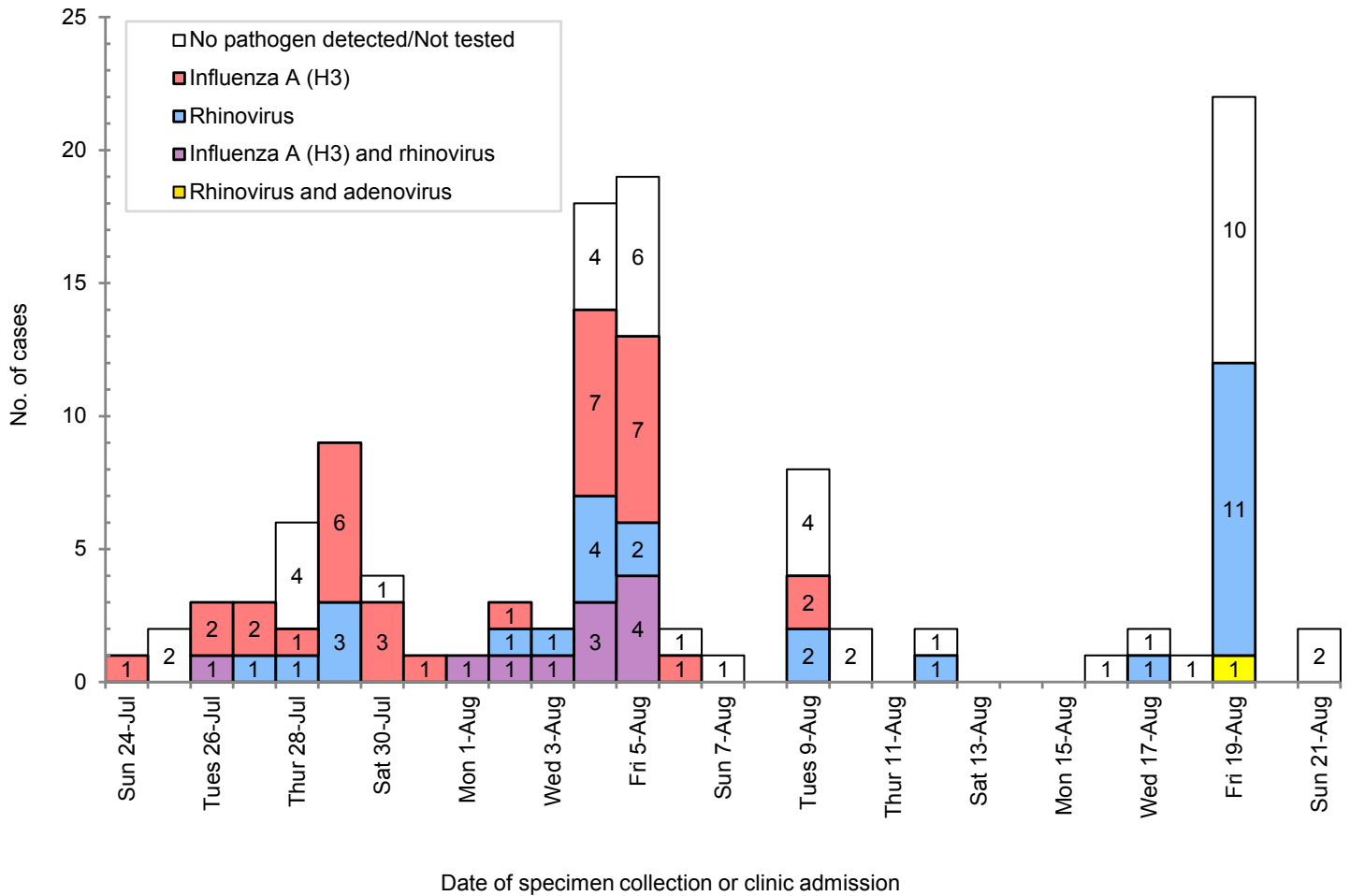
new recruits, likely led to lower immunity and increased risk of person-to-person transmission of both influenza and rhinovirus in this susceptible population.

The first half of the outbreak was dominated by influenza A/H3 circulation, particularly in Companies B and C. These companies were housed on different floors within the same barracks, which may have increased the chances for respiratory infections to spread. The decline in cases during 7–13 August suggested that Tamiflu and other nonpharmaceutical measures likely controlled influenza transmission (**Figure 1**). Rhinovirus infections subsequently increased during 14–20 August, and primarily occurred within companies with incoming recruits. A total of 22 suspected

cases did not have a pathogen detected, which may be related to diagnostic testing sensitivity or may occur if the specimen was collected more than 72 hours after the onset of symptoms.

Overall, most ill recruits were identified in training weeks 2–4 and no cases were confirmed among recruits in training weeks 6–8. This timing supports historical findings indicating that new recruits experienced higher incidence of acute respiratory disease,¹⁴ potentially due to inexperienced immune systems and high stress levels, although this may vary by pathogen. Other possibilities include that the index case was in early training and had less contact with recruits in advanced training weeks, or that recruits in advanced

FIGURE 1. Numbers of outbreak-associated cases (confirmed and suspected), by laboratory diagnosis and date of specimen collection or admission, U.S. Coast Guard Training Center Cape May, NJ, 24 July–21 August 2016



training weeks were vaccinated against seasonal influenza before the vaccine expired and received some cross-protection against the circulating 3C.2a strain.

Although the outbreak significantly affected operations at TCCM, including lost duty time as well as procedural changes, a timely and comprehensive response resulted in successful containment of the outbreak within 5 weeks. Several key factors were identified as having contributed to this success. First, TCCM's participation as a FRI sentinel surveillance site enhanced its ability to quickly detect an increase in FRI patients and to request expedited laboratory testing results through established communication channels. Second, the cooperation of TCCM leadership and

its single chain-of-command structure allowed for rapid decision-making and a streamlined outbreak response. This structure allowed for the operationalization of a POD for Tamiflu prophylaxis the same day that release of the stockpile was authorized, after which only three new cases of influenza were identified. Third, the immediate implementation of nonpharmaceutical interventions likely prevented widespread disease transmission at the training center and to the neighboring community, evidenced by the fact that no nonrecruits or civilians were identified as cases. Furthermore, these interventions were nonspecific to a particular etiologic agent, and presumably helped to control infections caused by multiple pathogens.

Given the potential for adverse reactions and antiviral resistance, the Centers for Disease Control and Prevention (CDC) does not recommend the widespread or routine use of Tamiflu.¹⁵ Furthermore, targeted use of chemoprophylaxis with neuraminidase inhibitors, such as Tamiflu, is not routinely recommended for outbreaks by U.S. military officials,³ although its use should be considered under particular circumstances. CDC guidelines for the control of influenza outbreaks in institutional settings recommends the use of antiviral chemoprophylaxis for all residents for a minimum of 2 weeks and up to 1 week after the last known case was identified.¹⁵ In this case, TCCM had the available resources and proper justification to

TABLE 2. Nonpharmaceutical and pharmaceutical outbreak interventions, U.S. Coast Guard Training Center Cape May, NJ, 24 July–21 August 2016

Interventions	
Nonpharmaceutical	
Screening and isolation	Established separate FRI and URI wards to isolate cases.
	Conducted twice-daily temperature screenings per company (and encouraged self-reporting illness), initially within Company C and expanding to additional companies; ill recruits were sent to FRI or URI wards for isolation.
	Ensured a febrile status off medications for 24 hours prior to return to company.
	Utilized masks to prevent droplet spread.
Enhanced hygiene and social distancing	Delivered meals to FRI and URI ward patients.
	Cancelled swim, off-site liberties, reversions, ^a and motivational program. ^b Off-site liberties were replaced with alternative on-site recreational activities.
	Cancelled watch standing duties outside of assigned barracks and mandated watch standing within assigned halls/barracks to prevent transmission.
	Arranged beds in alternating head-to-toe orientation and distanced beds by 3 feet.
	Educated all recruits and staff on preventive hygiene measures.
	Instituted extra handwashing and routine use of hand sanitizers.
	Increased frequency of disinfection and sanitation of halls and facilities, as well as laundry regimen.
	Eliminated close physical contact during training and team-building activities.
Pharmaceutical	
Treatment and prophylaxis	Requested and received authorization for prophylactic use of Tamiflu® stockpile supply within 24 hours.
	Administered Tamiflu as treatment (75 mg twice daily for 5 days) for patients with symptom onset <72 hours.
	Established a closed point-of-dispensing to conduct temperature screenings and provide Tamiflu prophylaxis (75 mg once daily for 10–20 days) for recruits, staff, and the neighboring community (n=162).
	Provided Tamiflu prophylaxis (75 mg once daily for 10–20 days) to all incoming recruits during the outbreak period and conducted mop-ups for missed recruits.
<p>FRI, febrile respiratory illness; URI, upper respiratory illness ^aReassigning a recruit to an earlier training week for disciplinary purposes ^bRecruit Aptitude and Motivation Program used for disciplinary purposes</p>	

provide chemoprophylaxis to all residents; however, the duration of prophylaxis varied for individuals and may have been less than the 14-day minimum. Careful consideration should be given to the use of Tamiflu for chemoprophylaxis during outbreaks, and decisions should be made on a case-by-case basis following the appropriate guidelines.

Use of nonpharmaceutical interventions for disease control can be applied to future outbreaks, particularly in recruit populations where outbreaks are likely to

occur and when a vaccine is not available or has expired. Additionally, prudent use of chemoprophylaxis may be considered. Finally, this outbreak highlights the importance of routine disease surveillance on military installations to rapidly detect and respond to disease threats.

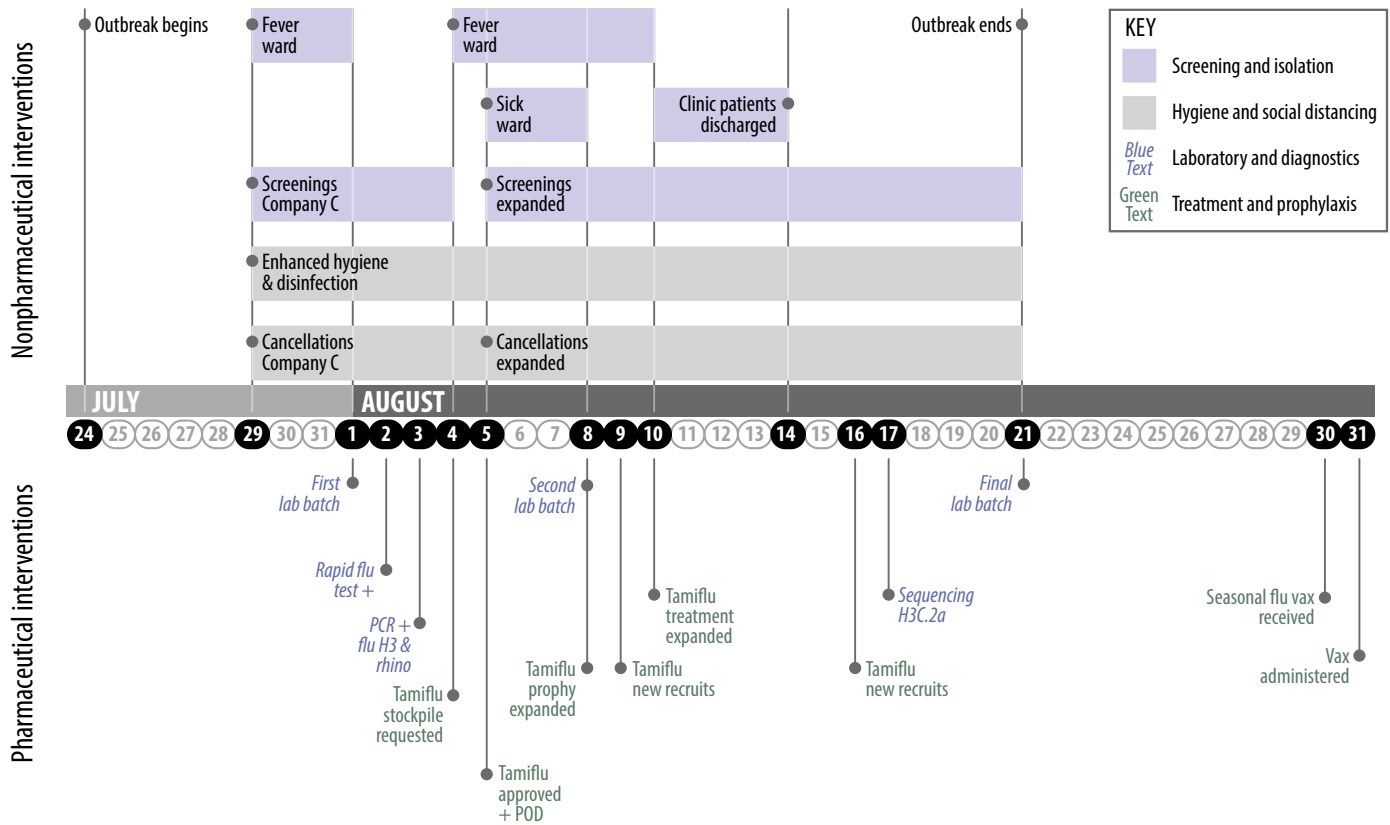
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FIGURE 2. Timeline of pharmaceutical and nonpharmaceutical interventions, U.S. Coast Guard Training Center Cape May, NJ, 24 July–21 August 2016



the United States Government.” Title 17, U.S.C. §101 defines a U.S. Government work as work prepared by an employee of the U.S. Government as part of that person’s official duties.

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Department of Defense Global, Laboratory-based Influenza Surveillance Program's Influenza Vaccine Effectiveness Estimates and Surveillance Trends for 2016–2017 Influenza Season

Lisa A. Shoubaki, MPH

Each year, the Department of Defense (DoD) Global, Laboratory-based Influenza Surveillance Program performs surveillance for influenza among service members of the DoD and their dependent family members. In addition to routine surveillance, vaccine effectiveness (VE) studies are performed and results are shared with the Food and Drug Administration, Centers for Disease Control and Prevention, and the World Health Organization for vaccine evaluation. This article will discuss in detail the annual surveillance trends for the 2016–2017 influenza season and the end-of-season VE results.

METHODS

The Influenza Surveillance Program conducts respiratory surveillance at 95 sentinel sites for active duty service members and their dependents with influenza-like illness (ILI).¹ ILI is defined as an illness marked by the presence of a fever (100.5°F or greater) and either a cough or sore throat within 72 hours of ILI symptom onset, or physician-diagnosed ILI. Respiratory specimens are sent to the Epidemiology Laboratory at Wright-Patterson Air Force Base, OH, and are tested using reverse transcription polymerase chain reaction (RT-PCR) and viral culture. Specimens that test negative for influenza also may be tested on a multiplex respiratory panel, which can detect up to 20 different respiratory pathogens. A patient questionnaire containing pertinent demographic, clinical, and vaccination information is submitted with each specimen.

An influenza VE study was performed at the end of peak influenza season to

determine how well the vaccine prevented medically attended, laboratory-confirmed influenza among DoD dependents. A test-negative, case-control study design was used to analyze the DoD dependent surveillance data. Cases were defined as those who tested positive for influenza on RT-PCR or viral culture. Controls were those who tested negative for influenza. Vaccination status was determined from medical records when such information was available, and otherwise from patient questionnaires. Individuals who were vaccinated at least 14 days before illness onset were considered vaccinated. Individuals who were vaccinated less than 14 days before illness onset were excluded from the study. Multivariable logistic regression was performed to calculate adjusted odds ratios (AORs), accounting for month of illness, age, and geographic region. VE estimates were calculated as $(1 - \text{AOR}) \times 100$. Peak influenza season was defined by those weeks during which at least 10% of respiratory specimens tested positive for influenza virus among cases and controls. Respiratory specimens within this time frame were included in the VE analysis. VE was calculated separately for children, adults, and overall for all dependents, as well as by influenza subtype (influenza A(H3N2) and influenza B). All active duty members were excluded from the VE calculation due to the high vaccination rate in that population.

RESULTS

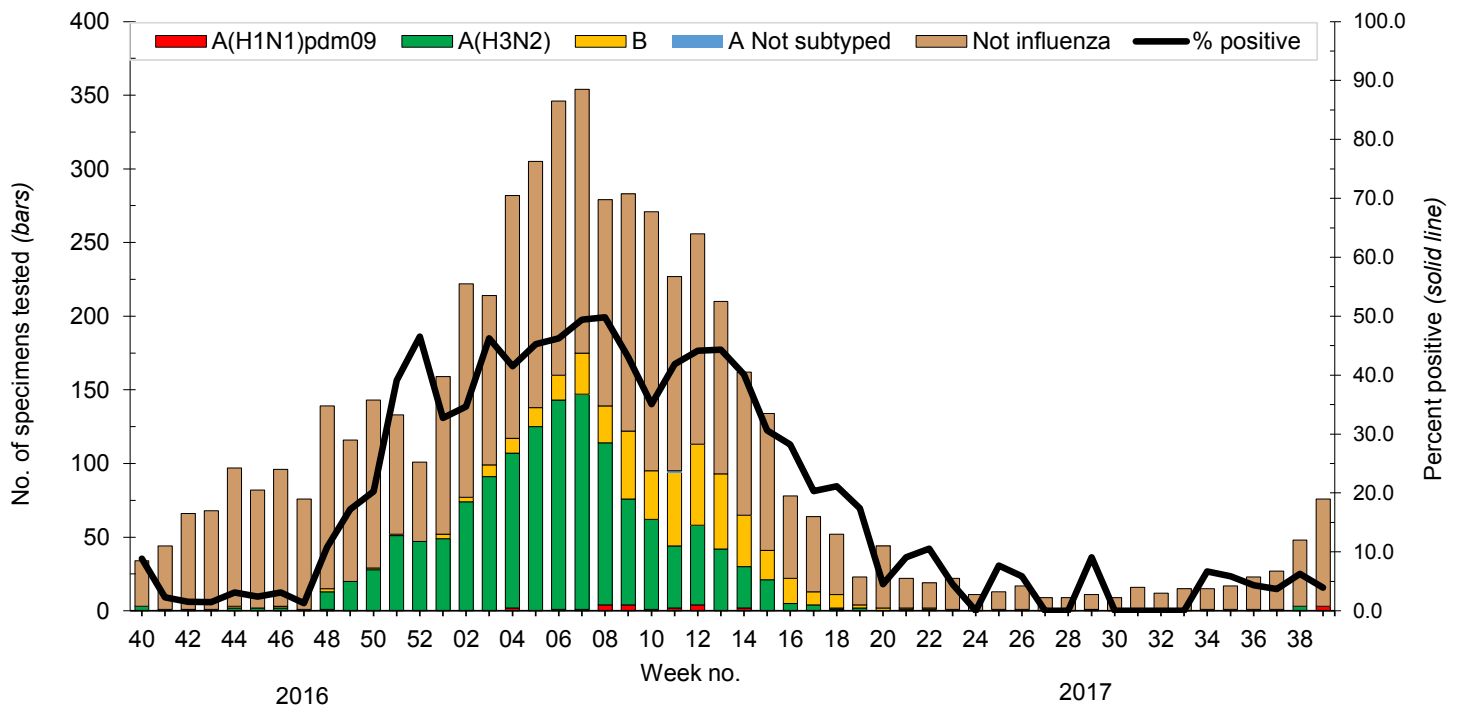
During the 2016–2017 influenza season, a total of 5,555 specimens were tested from 84 locations. Of the specimens that were tested, 1,382 (24.9%) tested positive

for influenza A; 443 (8.0%) tested positive for influenza B; 1,093 (19.7%) tested positive for other respiratory pathogens; 151 (2.7%) tested positive for co-infections; and 2,486 (44.7%) tested negative. The predominant influenza strain was A(H3N2), representing 73.8% of all circulating influenza. Sequence analysis of circulating influenza A(H3N2) showed that genetic clade 3C.2a was most predominant and shared a protein homology of 96.9%–99.3% when compared to the 2016–2017 vaccine component. Of influenza B strains detected, 60% were B/Yamagata and 40% were B/Victoria. Few respiratory specimens tested positive for influenza A(H1N1)pdm09 (n=29). Influenza activity was steadily increasing during weeks 51–14 (18 December 2016–8 April 2017), with influenza activity peaking in week 7 (12–18 February 2017) for influenza A(H3N2) and week 12 (19–25 March 2017) for influenza B (Figure).

Among non-influenza respiratory pathogens detected, rhinovirus/enterovirus was the most common (33.8%). Other common respiratory pathogens included respiratory syncytial virus (16.4%), parainfluenza (18.6%), coronavirus (11%), human metapneumovirus (8.7%), and adenovirus (7.0%). Most specimens did not test positive for influenza virus (n=3,722). The specimens tested for all pathogens were from children (n=2,383), active duty members (n=1,981), and all other dependents (n=1,191).

During weeks 48–18 (27 November 2016–6 May 2017), there were 1,069 cases and 1,274 controls. The adjusted VE for all dependents against all influenza types was 48% (95% CI: 37%–56%). The adjusted VE against all influenza types was 51% (95% CI: 39%–61%) for children and 42% (95% CI: 21%–56%) for adults. The adjusted VE

FIGURE. Numbers and percentages of respiratory specimens positive for influenza viruses, and numbers of influenza viruses identified, by type, by surveillance week, Department of Defense healthcare beneficiaries, 2016–2017 influenza season



against influenza A(H3N2) was 45% (95% CI: 33%–54%) overall, 50% for children and 36% for adults. For influenza B, the adjusted VE was 55% (95% CI: 39%–66%) overall.

EDITORIAL COMMENT

The influenza vaccine reduced the odds of medically attended, laboratory-confirmed influenza by 48% among all dependents. The VE for this season was slightly lower than for the 2015–2016 season, which had a 63% (95% CI: 53%–71%) adjusted VE. Several factors could explain the lowered VE for this season. During the 2016–2017 season, the predominant

influenza strain was A(H3N2), which differed from the 2015–2016 season when influenza A(H1N1)pdm09 predominated. Also, the live attenuated influenza vaccine (LAIV) was found to be ineffective during the 2015–2016 season. Therefore, the Advisory Committee on Immunization Practices did not recommend the use of LAIV during the 2016–2017 season.

In summary, the 2016–2017 season had a predominant influenza strain of A(H3N2) and peaked at week 7 for A(H3N2). The adjusted VE for the 2016–2017 season was 48% protective against all types of influenza. The limitations of the VE analysis have been described elsewhere.¹

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Assessment of 12 Influenza-like Illness Case Definitions Using Department of Defense Global, Laboratory-based Influenza Surveillance Program Data, 2011–2014

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Despite the growth in influenza surveillance programs, standardization of a globally accepted influenza-like illness (ILI) case definition remains difficult. With 2011–2014 Department of Defense Global, Laboratory-based Influenza Surveillance Program (DISP) data, 12 case definitions were evaluated using a combination of ILI case definitions from the Centers for Disease Control and Prevention, World Health Organization, and the DISP. The sensitivity, specificity, positive and negative predictive values, and odds ratios for each case definition were calculated. Additionally, area under the curve (AUC) was calculated for a receiver operating characteristic (ROC) curve to compare the case definitions. Between 2 October 2011 and 27 September 2014, 52.3% (5,575 of 10,662) of respiratory specimens submitted met the inclusion criteria. The case definition for the DISP had a sensitivity of 54.6% and specificity of 63.7%. Case definitions should be selected according to the objectives of the surveillance system and resources available. Sensitive case definitions capture a larger proportion of cases but at the cost of testing more specimens. Definitions with higher specificity result in fewer false positives but may miss more cases.

Acute respiratory illnesses have the potential to cause high morbidity among military personnel and undermine mission readiness.¹ Differentiating between influenza and other respiratory pathogens is difficult, but important, as it could bring forth changes in individual and population level management strategies. Numerous studies have evaluated the usefulness of specific signs and symptoms for detecting influenza. One study found that the most important symptoms are cough, fever, myalgia or fatigue.² The Department of Defense (DoD) Global, Laboratory-based Influenza Surveillance Program (DISP) has established an accepted influenza-like illness (ILI) case definition to identify ILI trends in the military population and to guide ILI specimen submission and testing protocols, but

the performance of this case definition has not been empirically evaluated with recent data and has remained unchanged for 12 years. By using influenza test-positive and test-negative results along with surveillance questionnaires over a 3-year period, this study compares the DISP case definition with 11 other case definitions using a combination of definitions from the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO).^{3–5}

METHODS

The DISP is a sentinel-based surveillance program with more than 80 (varying across study period) U.S. military installations across all services selected as sentinel

sites. Each site is requested to submit six to 10 nasal wash (or nasopharyngeal swab) inpatient or outpatient specimens per week that meet the DISP's ILI case definition of fever (100.5°F or greater) with cough and/or sore throat within 72 hours of symptom onset. Specimens are sent with a patient questionnaire that contains demographic, clinical, and vaccination information.⁴

Although DISP requests specimens that meet the program's ILI case definition, the laboratory will test any respiratory specimen that arrives within the correct temperature and transport media regardless of whether it meets the ILI case definition. The study included specimens submitted to the DISP for testing and collected between 2 October 2011 and 27 September 2014 from a population of service members and their dependents.

Gold standard influenza detection tests were used to confirm an influenza infection, with methodologies varying over the study period, including: Lab-developed Test Human Influenza Real-Time RT-PCR Diagnostic Assay (A/B typing and A subtype kit, 2011–2014), CDC Human Influenza Real-Time RT-PCR Diagnostic Panel (A/B typing and A subtype kit, 2014), viral culture (2011–2014), and FilmArray® (2013–2014). A specimen was considered positive for influenza if it was positive on any one of these testing platforms.

Case definition performance was based on surveillance questionnaire data using measures of sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). These data were used to analyze the 12 case definitions, all of which comprised components of the DISP, CDC, and WHO ILI case definition criteria (Table 1). Case definition performance was evaluated using receiver operating characteristic (ROC) curve analysis. The area under the curve (AUC) was used as a summary estimate of test predictive

TABLE 1. Test characteristics of 12 influenza-like illness (ILI) case definitions using Department of Defense Global, Laboratory-based Influenza Surveillance Program data (N=5,575): 2011–2014

Name/case definition	Sensitivity	95% CI	Specificity	95% CI	PPV	95% CI	NPV	95% CI	AUC	95% CI
CDC ILI										
≥100°F measured at home or in clinic—cough AND/OR sore throat	78.9	77.1–80.6	42.4	40.8–44.0	44.0	42.4–45.6	77.7	75.9–79.6	0.61	0.59–0.62
Cough										
Cough	95.5	94.6–96.4	24.9	23.5–26.3	42.2	40.8–43.6	90.5	88.7–92.4	0.60	0.59–0.61
Cough and reported/measured fever										
≥100.5°F measured at home or in clinic AND cough	70.5	68.5–72.5	57.1	55.4–58.7	48.5	46.7–50.3	77.1	75.5–78.7	0.64	0.63–0.65
DoD Influenza Surveillance Program ILI (measured fever in clinic or reported from home)										
≥100.5°F measured at home or in clinic—cough AND/OR sore throat—and collection within 72 hours of symptoms	54.6	52.5–56.8	63.7	62.1–65.3	46.4	44.4–48.4	71.0	69.4–72.5	0.59	0.58–0.61
DoD Influenza Surveillance Program ILI (measured fever in clinic only)										
≥100.5°F measured in clinic—cough AND/OR sore throat—and collection within 72 hours of symptoms	32.1	30.0–34.1	81.4	80.1–82.7	49.8	47.1–52.5	67.6	66.2–69.0	0.57	0.56–0.58
Measured or reported fever										
≥100.5°F measured at home or in clinic	73.4	71.5–75.3	41.4	39.8–43.0	41.8	40.2–43.5	73.0	71.1–75.0	0.57	0.56–0.59
Measured fever										
≥100.5°F measured in clinic	41.5	39.4–43.6	71.6	70.1–73.1	45.6	43.4–47.9	68.1	66.6–69.6	0.57	0.55–0.58
Sore throat										
Sore throat	74.6	72.7–76.5	31.3	29.8–32.9	38.4	36.9–39.9	68.2	66.0–70.5	0.53	0.52–0.54
Sore throat and cough										
Sore throat AND cough	72.0	70.1–74.0	45.4	43.7–47.0	43.1	41.4–44.8	73.8	72.0–75.7	0.59	0.57–0.60
Sore throat—cough—and reported/measured fever										
≥100.5°F measured at home or in clinic—cough AND sore throat	53.3	51.1–55.5	69.6	68.1–71.2	50.2	48.1–52.3	72.2	70.7–73.7	0.61	0.60–0.63
Sore throat and reported/measured fever										
≥100.5°F measured at home or in clinic AND sore throat	54.8	52.7–57.0	60.4	58.8–62.0	44.3	42.4–46.3	70.0	68.3–71.6	0.58	0.56–0.59
WHO ILI										
≥38°C measured in clinic only—cough and collection within 10 days	37.4	35.3–39.5	80.9	79.6–82.1	52.9	50.3–55.4	69.2	67.8–70.6	0.59	0.58–0.60

CDC, Centers for Disease Control and Prevention; WHO, World Health Organization; PPV, positive predictive value; NPV, negative predictive value; AUC, area under the curve

performance, taking values from 0.5 (chance) to 1.0 (perfect discrimination). A p value of .05 was used to determine whether there were statistically significant differences between the AUCs of the three main ILI case definitions: DISP, CDC, and WHO. Odds ratios (ORs) and the corresponding 95% confidence intervals (CIs)

were computed for individual symptoms and a combination of symptoms to identify whether any single symptom alone, or a combination of symptoms, was associated with an increased risk of influenza infection. Analysis was performed using SAS® SAS/STAT version 9.3, (2011, SAS Institute, Cary, NC).

RESULTS

Between 2 October 2011 and 27 September 2014, DISP received 10,662 respiratory specimens. A total of 5,575 specimens from 115 sites met the inclusion criteria. A total of 5,087 (47.7%) specimens were

TABLE 2. Odds ratios for case definition/symptoms for influenza-positive and -negative tests using Department of Defense Global, Laboratory-based Influenza Surveillance Program data, 2011–2014

Case definition/symptom	Odds ratio	95% CI
DoD Influenza Surveillance Program ILI (measured fever in clinic or reported from home)	2.11	1.89–2.36
CDC ILI	2.75	2.42–3.12
WHO ILI	2.52	2.23–2.85
Cough and reported/measured fever	3.18	2.83–3.57
Cough	6.99	5.60–8.73
DoD Influenza Surveillance Program ILI (measured fever in clinic only)	2.07	1.82–2.34
Measured or reported fever	1.95	1.73–2.20
Measured fever	1.79	1.59–2.00
Sore throat	1.34	1.19–1.51
Sore throat and reported/measured fever	1.85	1.66–2.07
Sore throat and cough	2.14	1.90–2.40
Sore throat, cough, and reported/measured fever	2.62	2.34–2.93

DoD, Department of Defense; CDC, Centers for Disease Control and Prevention; WHO, World Health Organization; ILI, influenza-like illness

excluded from the study, with the majority having a missing or partially completed patient questionnaire. Other reasons for exclusion included: specimens submitted for molecular sequencing only, test results pending or test not performed, and specimens submitted from Europe (because of a change in formal guidance over the years). Of those specimens included in the study, 2,034 (36%) tested positive for influenza virus.

Performance measures of sensitivity, specificity, PPV, NPV, and AUC were calculated for each case definition for the entire time period (Table 1). Additionally, the on (peak) and off (non-peak) season performance measures were calculated for each case definition, but due to small sample size in the off season, the on/off season results were not displayed. Cough, sore throat, and fever (100.5°F or greater, measured at home or recorded in clinic) were the three main case definition symptom components of influenza being evaluated. Among the individuals who submitted specimens, 83% had cough, 71% had sore throat, and 64% had fever (data not shown). When looking only at influenza-positive specimens, cough, sore throat, and fever were all more common at 95.5%, 74.6%, and 73.4%, respectively (data not shown). Time from symptom

onset to collection date varied with 94.6% of specimens being collected within 10 days. Among those, 75.5% were collected within 3 days of symptom onset (data not shown). ORs were calculated to determine which symptom(s) were associated with an increased risk of a test-positive result for influenza. Cough had the highest OR at 6.99 (95% CI: 5.60–8.73), while cough and reported/measured fever had the second highest OR at 3.18 (95% CI: 2.83–3.57). A recent study showed that sore throat was negatively associated with influenza infection; however, the analysis presented here showed a positive, yet weak, association of 1.34 (95% CI: 1.19–1.51) (Table 2).⁶ Demographic data on the study sample are presented in Table 3.

The case definition for the DISP (with temperature measured at home or recorded in clinic) had a sensitivity of 54.6% and a specificity of 63.7%. When modified to include fever only recorded at the clinic, the sensitivity dropped to 32.1% and the specificity improved to 81.4%. The CDC's sensitivity and specificity differed from those of the DISP, with a sensitivity of 78.9% and a specificity of 42.4%. The Figure shows the performance of all case definitions and the trade-off between sensitivity and specificity on a ROC curve. Results for the on/off

season are not displayed, but the on season closely followed the results for the entire time period (data not shown).

Of all the case definitions, cough and reported/measured fever had the highest AUC, indicating that these symptoms are able to appropriately discriminate risk of true infection 63.8% of the time. That is, for any pair of specimens where one tested positive for influenza and the other did not, there was a 63.8% predicted likelihood of cough and fever appropriately distinguishing these specimens. The minimum AUC was considered a chance level (i.e., 50%).⁷ Pairwise comparisons of the AUCs for the DISP, CDC, and WHO ILI case definitions showed a statistically significant difference between the DISP and CDC case definitions only. Additionally, the AUC for cough and fever was significantly higher than that for the DISP ILI case definition ($p=0.0004$), indicating that this combination of symptoms performed better than the DISP ILI case definition (Figure).

PPVs predict probability of disease in an individual and do not rise above 52.9% for any case definition at any point in the season. According to this study, the case definitions can only predict up to 52.9% of positive influenza tests during the on season and 12.0% of positive tests during the off season (data not shown).

EDITORIAL COMMENT

Methods of influenza surveillance differ depending on the data available and the objectives of the surveillance program. Google Flu Trends, which relies on Google data mining and social media, has evaluated their methods against the CDC's traditional laboratory and clinical surveillance system, reporting at a population level. Over time, Google's surveillance system has matched the CDC's ILI estimates; however, it has also performed less accurately.^{8,9} The military has previously reported on the performance of multiple case definitions based on medical diagnoses using ICD-9 codes among those with laboratory testing for influenza.¹⁰ This analysis also compared multiple case definitions based on underlying signs and

TABLE 3. Demographic characteristics of study population using Department of Defense Global, Laboratory-based Influenza Surveillance Program data, 2011–2014

	Patients with laboratory-confirmed influenza		Patients who tested negative for influenza	
	N	%	N	%
Surveillance season				
2011–2012	253	25.6	734	74.4
2012–2013	967	41.1	1,383	58.9
2013–2014	814	36.4	1,424	63.6
Gender				
Male	1,072	37.8	1,765	62.2
Female	840	38.4	1,348	61.6
Unknown	122	22.2	428	77.8
Age group				
0–5	160	25.8	460	74.2
6–9	185	47.9	201	52.1
10–17	242	46.2	282	53.8
18–24	236	24.8	715	75.2
25–44	912	39.1	1,421	60.9
45–64	262	42.3	358	57.7
65+	36	28.6	90	71.4
Unknown	1	6.7	14	93.3
Beneficiary status				
Active duty	853	33.3	1,709	66.7
Child	601	38.5	962	61.5
Spouse	412	39.9	621	60.1
Retiree	127	42.2	174	57.8
Other	40	35.7	72	64.3
Unknown	1	25	3	75.0
Service affiliation				
Air Force	1,251	35.3	2,288	64.7
Army	416	39.5	636	60.5
Navy	226	35.9	403	64.1
Coast Guard	51	37.8	84	62.2
Marine Corps	51	40.8	74	59.2
Other	38	42.2	52	57.8
Unknown	1	20	4	80.0
Total	2,034	36.5	3,541	63.5

symptoms that contributed to a clinical diagnosis among those with specimens submitted through DISP.

These results should be interpreted in light of their strengths and limitations. The study population was diverse

geographically and demographically (Table 3), drawing from specimens submitted at sentinel sites throughout the world (excluding Europe), with the assumption that there were not any demographic differences in those specimens excluded from

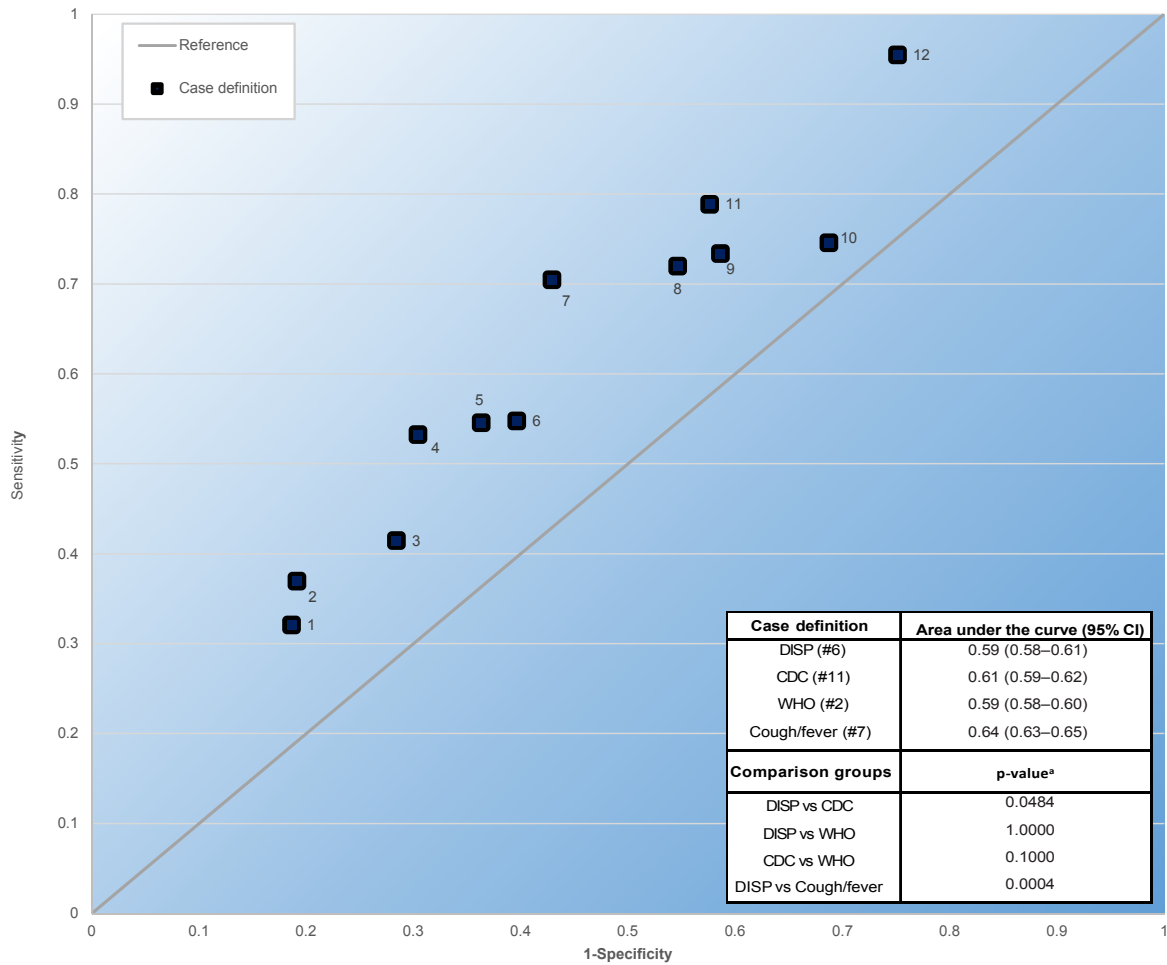
the analysis. Signs and symptoms were measured using a standardized patient questionnaire, which is subject to the patient's recall bias while enabling consideration of subjective variables commonly used in a clinical setting. An age-stratified analysis was not performed and would be warranted in comparing case definition performance across different age populations. This analysis was able to compare case definitions based on fever reported at home or in the clinic and showed a change in sensitivity and specificity in the expected directions (Figure). These comparisons help identify how variation in fever definitions can substantially change test characteristics. Additionally, all subjects were drawn from the same healthcare system, but utilization factors, including vaccination and antipyretic use, were not considered in assessing symptom severity or case status. In addition, the gold standard testing was another strength of this analysis, but it is possible that specimen collection and testing were unable to detect influenza among some of the cases.

Sensitivity and specificity are not good indicators to determine probability of disease in an individual. Predictive values may be used to estimate this, but rely heavily on the prevalence of disease in the population and cannot be generalized to a population with a different disease prevalence.¹¹ When disease prevalence is low, PPV will be low even with a high sensitivity and specificity. The low PPVs for specimens collected during the off season demonstrate that this principle and should be interpreted with caution.

The metrics presented here were calculated only among subjects who were being tested for influenza. Any bias in selecting patients for testing (i.e., symptom severity, timing during the influenza season, facility) may affect the results. Therefore, the results presented here are only applicable to individuals who present for care with at least one ILI symptom.

Balancing sensitivity and specificity is important and case definitions should be selected according to the objectives of the surveillance program, the resources available, and other contextual factors. The DISP requires a case definition that is adequate for surveillance across multiple years

FIGURE. Receiver operating characteristic (ROC) curve for 12 influenza-like illness case definitions using Department of Defense Global, Laboratory-based Influenza Surveillance Program data, 2011–2014



ROC curves describe the trade-off between the true positive rate (sensitivity) of a test and the false positive rate of a test (1-specificity). The better the performance of the test, the closer the value is to the top left corner. The area under the ROC curve, also described as a c-statistic, measures the accuracy of the test, with 1.0 representing a perfect test and 0.5 indicating a worthless test.

^aBecause there were four pairwise comparisons made, the Bonferroni correction factor was used to adjust the p value.

1. DoD Influenza Surveillance Program ILI (measured fever in clinic only)
2. WHO ILI
3. Measured fever
4. Sore throat, cough, and reported/measured fever
5. Sore throat and fever
6. DoD Influenza Surveillance Program ILI (reported/measured fever) - (DISP)
7. Cough and reported/measured fever
8. Sore throat and cough
9. Reported or measured fever
10. Sore throat
11. CDC ILI (reported/measured fever)
12. Cough

despite changes in influenza incidence and virulence over time (antigenic drift), and that is also suitable for calculations of influenza vaccine effectiveness. The DISP may benefit from altering the case definition to cough and fever (reported or measured); however, other aspects of the surveillance program may be affected. This study provides sufficient empiric support to keep the

current DISP case definition and further discussion would be warranted if the case definition were altered. The current results suggest that incorporating cough and fever into the case definition would optimize detection and characterization of influenza and also increase the number of specimens submitted (affecting the program budget) and lower the number of controls

available for vaccine effectiveness studies. The present data demonstrate the strengths and weaknesses of various case definitions within the DoD population that should be validated in other populations. By taking advantage of empirically supported definitions, influenza surveillance programs can optimize their contribution to this national security function.

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