1   **Authors:**

2   **Summary Line**

3   An evaluation of the Centers For Disease Control and Prevention (CDC) "Influenza
4   Hospitalization Surveillance Network" (IHSN) following the most recent CDC guidelines for
5   evaluating a public health surveillance system.

6

7   **Abstract:**

8   The Influenza Hospitalization Surveillance Network (IHSN or FluSurv-NET) was evaluated
9   using the Centers for Disease Control and Prevention's (CDC) guidelines for evaluating a public
10 health surveillance system. The IHSN was evaluated for usefulness, simplicity, flexibility, data
11 quality, acceptability, sensitivity, positive predictive value, representativeness, timeliness, and
12 stability. The IHSN was found to utilize a broad range of sources for influenza surveillance
13 which can be openly accessed via the CDC's "FluView" online application. The IHSN is highly
14 adaptable with its capacity to accommodate additional data sources when needed. The over-
15 inclusiveness of different laboratory diagnostic methodologies was found to be detrimental to the
16 overall data quality of the IHSN in the form of variable sensitivity and positive predictive value
17 measures amongst the CDC's acceptable testing methods. Overall, the IHSN is a very robust
18 system that allows for timely access to influenza data by public health officials. However, the
19 inclusivity of the IHSN causes it to fall short when considering the importance of consistency in
20 data collection practices. The IHSN fails to take into account several factors that could either
21 artificially increase, or decrease case counts. We recommend the IHSN integrate a more
22 streamlined and reliable data collection process and standardize its expectations with all of its
23 reporting sites.

24 MESH/Index terms: Influenza, Human. Public Health Surveillance. Evaluation Studies as Topic.

25

26 **Title of Report:**

27 An Evaluation of the Influenza Hospitalization Surveillance Network

28 **Stakeholders:**

29   The Stakeholders of the Influenza Hospitalization Surveillance Network (IHSN) include
30 the Emerging Infections Program (EIP) and all of their affiliates, the United States Centers for
31 Disease Control and Prevention (CDC), the World Health Organization (WHO), local and state
32 health departments, educators, healthcare officials, and the general public.

33 **System Description:**

34 Importance

Annually, influenza disseminates worldwide causing widespread illness and in severe cases, death. In the 2014-15 season for the United States, laboratory confirmed influenza associated hospitalizations reached upwards of approximately 65 cases per 100,000 persons, 30 in 2015-16, 60 in 2016-17, and 102 in 2017-18.[1] Influenza associated hospitalization cases are organized by age, underlying medical conditions, virus subtype, and cumulative/weekly rates.[1,2] Severity is indexed by accumulating influenza-associated hospitalization case counts and calculating cumulative and weekly (unadjusted) incidence rates using population estimates from the National Center for Health Statistics (NCHS) to estimate hospitalization rates in the US.[1]

The inequities of influenza infection result in time away from work and other societal obligations. The economic losses from the effects of influenza are considerable and the cost of hospitalization due to influenza is substantial. A study published in June of 2018 estimated the average annual total economic burden of influenza to the healthcare system and society was $11.2 billion. Direct medical costs were estimated to be $3.2 billion, and indirect costs $8.0 billion.[3] Influenza infection can be largely, but not completely prevented by vaccination. CDC's 2017-2018 influenza season vaccine effectiveness study showed that for children between 6 months of age and 8 years old, there is 68% less influenza (subtype A or B) in those vaccinated compared to unvaccinated; While in the elderly population (>65 years) there was only a 17% reduction of influenza in those who were vaccinated compared to unvaccinated).[4] The contents (or viral subtype targets) of influenza vaccines are based on recommendations by the WHO that carefully analyze sentinel surveillance of viral genotyping each year.[5] Influenza can only be prevented through vaccinations, there is no cure for the infection outside of physician prescribed antiviral drugs and basic symptom management. Influenza surveillance benefits the public by outlining the severity of each influenza season in an approximation of real time to help drive intervention strategies of public health entities within the United States.

Purpose

The purpose of the IHSN within the Emerging Infections Program of the CDC, is to conduct population-based surveillance for laboratory-confirmed influenza associated hospitalizations.[5] The objectives of the IHSN are to determine the time and location of where influenza activity is occurring, track influenza-related illness, determine which influenza virus subgroups are circulating, detection of influenza virus mutation events, and to measure the influence influenza has on hospitalizations and deaths in the US population.[4]

IHSN gathered data is used to estimate age-specific hospitalization rates on a weekly basis and display characteristics of persons hospitalized with influenza. Cases are identified by reviewing hospital laboratory and admission databases and infection control logs for patients hospitalized during the influenza season with a documented positive influenza test (i.e., viral culture, direct/indirect fluorescent antibody assay (DFA/IFA), rapid influenza diagnostic test (RIDT), or molecular assays including reverse transcription-polymerase chain reaction (RT-PCR).[4] There is no legal requirement for the stats to submit influenza associated hospitalization

73   data to the CDC because it is not a nationally notifiable disease,[7] however participation is
74   conditional in order for each participating state to receive funding from the CDC. The IHSN
75   resides within the EIP sponsored by the CDC. The IHSN facilitates integration with other
76   systems by aggregating data collected from individual EIP state
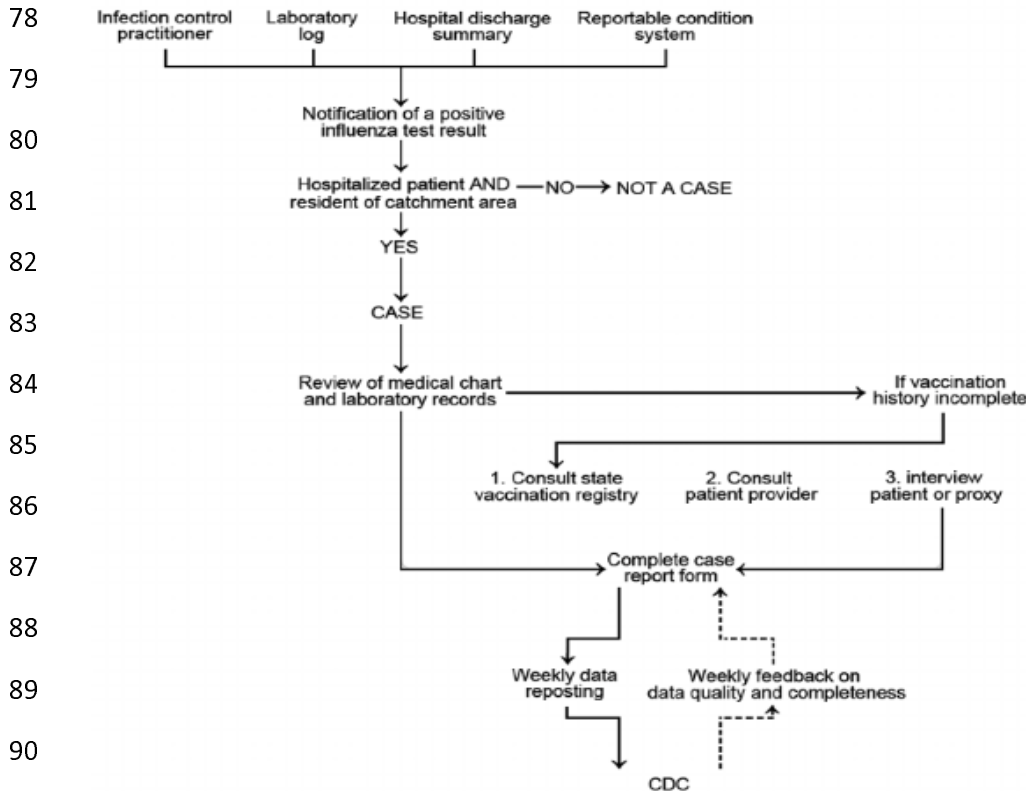77   surveillance systems (Figure 1).

Figure 1. The Influenza Hospitalization Surveillance Network data flow from site location, to the CDC where the data is then inputted into FluView for public use. Additional information from laboratory confirmed influenza cases provided to the CDC include: patient ID number, surveillance site, hospital admission date, patient DOB, influenza test methodology, and identified influenza subtype (A or B).[8]

93   The IHSN conducts surveillance on the individual populations of the 10 EIP participating
94   states. Data is collected annually and published weekly starting at the beginning of October and
95   ends as late as May. Each of the EIP states have designated counties that contribute data to the
96   IHSN.[4] Between the 10 states there are approximately 70 counties whose hospitals contribute
97   data to the IHSN. The IHSN accumulates data from 267 acute care hospitals and laboratories in
98   counties varying in socioeconomic status within the 10 EIP sites. All sites within the EIP are
99   geographically distributed throughout the United States, and encompass approximately 27
100   million people.[8] Surveillance officers (usually through EIP participating public health
101   departments) are trained to collect laboratory confirmed influenza cases from laboratory logs,
102   infection control practitioner logs, weekly calls to data collection sites (hospitals), or (depending
103   on the state) state reportable condition logs.[6] Data is then compiled and sent on a weekly basis to
104   the CDC for analysis and eventual input into the FluView application.[1,2] Patient information is

105 recorded with each case in all EIP participating states. This is because in contrast to the CDC's
106 notifiable conditions, laboratory confirmed influenza (subtype A) is a reportable condition in all
107 EIP states (Table 1) and that same information is required for use at the CDC (figure 1).
108 However, unique patient information (name, Date of Birth(DOB), patient ID) is encrypted and
109 securely sent, and is not published in weekly surveillance reports, nor is it inputted into the
110 FluView application.

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EIP participating State	Influenza reportable?	Reporting Window	Isolate sent?
California	yes	7 days	no
Colorado	yes	4 days	no
Connecticut	yes	12 hours	no
Georgia	yes (subtype A only)	7 days	not listed
Maryland	yes (subtype A only)	immediately	yes
Minnesota	yes	24 hours	yes
New Mexico	yes	24 hours	no
New York	yes	24 hours	not listed
Oregon	yes	immediately	yes
Tennessee	yes (subtype A only)	immediately	yes

Table 1. Displays a list of the 10 EIP reporting sites and their varying requirements for influenza reporting. "Influenza reportable?" indicates whether or not influenza is required to be reported to the state department. "Reporting Window" indicates the state allowable timeframe for reporting before a penalty incurred. And "Isolate sent?" indicates whether or not the laboratories that identified a positive case of influenza are required to send a specimen to the state health department for confirmation testing. [11,12,13,14,15,16,17,18,19,20]

Resources used

127 The IHSN is primarily financed by core funding for operation and personnel training
128 provided to the EIP by the CDC.[8,9]

Evaluation Design:

130 The overall purpose is to evaluate the performance of the IHSN (FluSurv-NET) by
131 assessing the reliability of laboratory confirmed influenza related hospitalizations in the United
132 States. The evaluation can be taken under consideration and used to drive improvement or
133 reinforce the IHSN strengths by the aforementioned stakeholders. Information gathered by the
134 evaluation can be utilized to highlight noted strengths and weaknesses of the IHSN and to

135 improve overall quality assurance of data collection. An evaluation of the IHSN will consider
136 whether or not the data collection methods require improvement, determine efficiency of case
137 report flow, identify any discrepancies between the 10 EIP participating sites, and determine any
138 implications of variable state level data accumulation. IHSN will be assessed by determining its
139 overall usefulness for detecting trends and associations of influenza occurrences and how they
140 can be used to prompt further research and prevention efforts. The IHSN will also be assessed by
141 investigating each individual system attribute and their levels of contribution to the overall
142 performance of the IHSN. System attributes will include: simplicity (structure and ease of
143 operation), flexibility (adaptability to evolution of information and public needs), data quality
144 (validity of gathered data), acceptability (participation rate of EIP states), sensitivity (ability to
145 identify cases and monitor changes), positive predictive value (confidence of reported cases
146 being "actual" cases), representativeness (accuracy of influenza occurrence and population
147 distribution), timeliness (turnaround time between data collection steps), and stability (overall
148 reliability of the IHSN).

149 **Credible Evidence:**

150 Usefulness:

151 Through the FluView Interactive application, the IHSN uses laboratory, hospital
152 admission database, and infection control logs to capture hospitalized cases with a documented
153 positive influenza test result during the regular influenza season.[1,2] This is a very comprehensive
154 approach for accumulating data. The IHSN addresses the variability of testing methods by
155 outlining the Food and Drug Administration (FDA) cleared, or The Clinical Laboratory
156 Improvement Amendment (CLIA) waived influenza testing method that includes but are not
157 limited to: viral culture, direct/indirect fluorescent antibody assays (DFA/IFA), rapid influenza
158 diagnostic tests (RIDT), or nucleic acid detecting molecular assays.[2]

159 **System attributes:**

160 Simplicity:

161 FluView application allows for real time data access and can differentiate cumulative
162 rates based on age group, EIP state, and influenza season. Data is gathered by weekly reports to
163 the CDC Influenza division by each EIP participating state (fig 1.). The 10 states participating in
164 the EIP that contribute data to the IHSN FluView application are: California, Colorado,
165 Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee.
166 Georgia, Maryland, and Tennessee only require influenza subtype A be reported to the state
167 health department. All other aforementioned states require all hospital confirmed influenza cases
168 be reported to their state health department authorities (subtypes A and B).[11,12,13,14,15,16,17,18,19,20]

169 Flexibility:

170   Influenza has the ability to undergo "antigenic drift," which are changes made (through
171   mutation) to its varying subtypes. Because of antigenic drift, previous vaccination targets
172   (subtypes) are then less effective at preventing infection in the population, making influenza
173   difficult to control each year.[21] Considering the unpredictable nature of influenza, The IHSP has
174   a high degree of flexibility between influenza seasons. The IHSP can adjust to each influenza
175   season by adding additional reporting sites outside of the EIP states (sites).[6] The 2009-2010
176   H1N1 pandemic prompted this change in the IHSP's surveillance capacity. Additionally, the
177   IHSP can also remove sites as needed. This has potential to compromise the longitudinal validity
178   of data gathering and analysis. Each EIP participating state has their own unique criteria for
179   reportable conditions (Table 1 which can also compromise the validity IHSN data. However,
180   aggregation of data at the CDC level is simplified due to their strict criteria for each case report
181   (figure 1).[8]

182   Data Quality:

183   Consistent surveillance officer training at EIP sites mitigates variability of the data
184   accumulation process at a state level. The IHSN uses NCHS data to form population estimates
185   used in rate calculations when calculating weekly and cumulative influenza associated
186   hospitalization rates.[1] However, each test method outlined within the CDC's "Information for
187   Clinicians on Influenza Virus Testing" have variable sensitivity and positive predictive value
188   measures (Table 2).[22] This variability has potential to compromise the overall reliability of rate
189   calculations used in the FluView application via underreporting due to inaccurate test results
190   (false negatives).

191   Acceptability:

192   In order for the IHSN EIP sites to receive funding from the CDC, they are required to
193   comply with basic reporting standards of the CDC's national notifiable conditions. By having
194   trained surveillance officers for collection of relevant information (and paying them to do so) this
195   allows EIP sites to participate in the IHSN ensuring as much data is provided as possible. With
196   the exception of three participating sites (Table 1), laboratory confirmed influenza (A and B
197   subtypes) is a state reportable condition ensuring compliance at a "site level." Failure to report a
198   "reportable" or "notifiable" condition by a hospital or physician office subjects them to potential
199   revocation of individual medical license or operating license revocation of the institution
200   (hospital) at fault.[23]

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Platform and/or Instrument	Influenza Virus Types Detected	Test Time	Methodology	Sensitivity		Positive Predictive Value	
				A	B	A	B
GeneXpert Xpress	Influenza A and B	approximately 30 min or less	nucleic acid detection	97.50%	93.80%	100.00%	96.80%
FilmArray® Film Array® Torch	Influenza A and B	1-2 hr	nucleic acid detection	90.00%	100%	99.8%*	100%
ABI 7500 Fast Dx	Influenza A and B	4 hr	nucleic acid detection	100%	100%	100%	100%
Sofia 2 FIA Analyzer	Influenza A and B	10-15 minutes	Antigen Detection	97.00%	90.00%	74.60%	84.20%
BD Veritor Reader	Influenza A and B	10-15 minutes	Antigen Detection	83.60%	81.30%	93.60%	93.30%
Alere Reader	Influenza A and B	10-15 minutes	Antigen Detection	84.30%	89.50%	83.10%	94.40%

Table2. A table comparing the turnaround times (test time), methodologies, analytical sensitivity, and positive predictive values (separated by influenza A and B subtypes) of 6 different randomly selected test methods selected from the CDC's "Available FDA-Cleared Rapid Influenza Diagnostic Tests"[22] and "FDA-cleared Nucleic Acid Detection Based Tests for Influenza Viruses"[24] tables found on the CDC website. Sensitivity and positive predictive values for each test were calculated individually using package insert clinical study data of each methodology.[26-31]

Sensitivity and Positive predictive value:

Table 2 includes a compilation of three tests each selected from the "Available FDA-Cleared Rapid Influenza Diagnostic Tests (Antigen Detection Only)" and the "FDA-cleared Nucleic Acid Detection Based Tests for Influenza Viruses" pages on the CDC's website,[22,24] and the sensitivity/positive predictive value calculations for each test. Test selections were made by numbering each test in each table and submitting them into a random number generator. Calculations were performed using "Nasopharyngeal Swab" sample type data.

Figure 2. Shows an example of a 2x2 table used to calculate sensitivity and positive predictive value (PPV). Test 1 is the method of interest and Test 2 is the method used for reference. The sensitivity calculation is: TP/(TP+FN) The positive predictive value calculation is TP/(TP+FP).[25]

TP-True Positive, FP-False Positive, FN-False Negative, TN-True Negative

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238   The clinical sensitivity of all three nucleic acid testing methodologies ranges from 90% to
239 100% while for antigen detection methods they range from approximately 84% to 97% for
240 influenza subtype A. The confidence that a detected positive value is actually positive within the
241 patient for nucleic acid testing methods are all almost universally 100% whereas antigen
242 detection tests only had a range of approximately 75%-93% confidence in positive values for
243 influenza subtype A.

244   The IHSN is heavily reliant on the accuracy of influenza testing methods at the individual
245 laboratories within the EIP states' participating counties. Sensitivity and positive predictive
246 values were determined at individual testing levels in order to address this at the IHSN level.
247 There are currently no criteria for confirming positive influenza tests within the IHSN.
248 Confirmation testing for positive results is left to the discretion of the EIP participating states.
249 Table 1 indicates only three EIP participating state health departments require confirmation
250 testing on all positive influenza tests. The lack of confirmation testing could lead to an inflation
251 of false positive test results on methods with a lower positive predictive value. Table 2 outlines
252 the differences in sensitivity and positive predictive values between the six selected tests. It is
253 noted that there is a lot of variability in sensitivity and specificity among the different test types.

254 <u>Representativeness:</u>

255   The IHSN has a high degree of representativeness in terms of geographic distribution of
256 counties within the EIP participating states and of the EIP states themselves. This allows for a
257 stratified approach to IHSP data collection, which helps published data to be more generalizable
258 to the rest of the United States.

259   A key challenge is accurate representation of a grossly underreported disease such as
260 influenza.[32, 33] CDC has struggled for decades to adjust and refine their models to determine
261 epidemic thresholds and determination of seasonal severity. This is due to changes in diagnostic
262 technology, access to diagnostics, and modeling techniques.[34-37] It is important to note that
263 population-based estimates of influenza are based on census data, which is also based on
264 statistical models that have evolved over the decades as well. The dichotomy of having more
265 cases reported may result in stimulating media reporting, which in turn stimulates patient
266 demand that stimulates healthcare providers to order influenza testing. Because of an increase in
267 influenza molecular testing options, increased access of testing options to physicians can cause
268 them to "over-screen," which can lead to an artificial inflation of positive influenza cases that
269 may or may not be contributing to patient hospitalizations.[38] The IHSN counts all

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270   hospitalizations that have a laboratory confirmed positive influenza test. Artificial inflation of
271   positive cases in the form of "over-screening" combined with the IHSN case definition can lead
272   to a misrepresentation of the population's influenza associated hospitalization rates. This raises
273   concerning questions regarding the scientific basis upon which we claim severity: is it based on
274   antigenic shift (i.e. a pandemic) or more accurate statistics for an underreported disease?

275   <u>Timeliness:</u>

276   Each EIP IHSN state has variable reporting conditions and timelines for influenza (Table
277   1). All participating states require all laboratory confirmed influenza cases be reported to the
278   state health department. The reporting timeframe for influenza in each state ranges from
279   immediate, to reporting "within 7 days" (Table 1) The CDC estimates there to be a median 7-day
280   lag time from the time a case is identified to when the CDC receives the report for the IHSN.[6] It
281   is unclear as to whether or not the IHSN inputs influenza cases using the identification date at the
282   laboratory level, or the date the CDC received the data. However, a 7-day lag time between
283   identification and reporting to the CDC is fairly rapid considering the geographical distribution
284   of EIP sites and frequency of influenza cases.

285   <u>Stability:</u>

286   There have been no significant events, or available evidence that suggest the stability of
287   the IHSP and their FluView application have ever been compromised in the past. The IHSP
288   provide weekly updates and there have been no notable delays in updates as of 2018.

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290   **Conclusions/Recommendations:**

291   The IHSN uses a broad range of sources to identify influenza associated hospitalization
292   cases. This, combined with a narrow case definition, affords the IHSN the benefit of having
293   reliable sources of data collection.[13] The added benefit of each EIP state having at least some
294   degree of required reporting for influenza (Table 1) and near identical reporting requirements
295   (figure 1), indicates that some effort has been made to mitigate underreporting from participating
296   EIP states. The FluView application is user-friendly and easily accessed by the public ensuring
297   widespread use of IHSN accumulated data.[13] Adaptability of the IHSN allows for timely and
298   appropriate reactions to the constant shifts in influenza activity between seasons. The IHSN data
299   quality can be both effective and ineffective depending on which data points are being
300   considered. It is also noted that the stability of the IHSN has been proven adequate in the past,
301   but must continue to remain vigilant in maintaining that security.

302   By using NCHS data, universal determination of population estimates from each
303   participating county within the EIP states allows for consistent population estimates for rate
304   calculations.[12] However, laboratory testing methodologies and individual physician testing
305   behaviors are not universal. Each reporting laboratory uses different testing methodologies that

306 vary in sensitivity and positive predictive value (Table 2). Certain testing methodologies are
307 more reliable than others in terms of sensitivity. Methodologies with lower sensitivity can
308 artificially decrease case counts. Testing platforms that have a lower positive predictive value
309 can artificially increase case counts. All of this can potentially confound "site specific" data and
310 lead to inaccurate predictions or comparisons when used for research. Lower rates in certain
311 areas could be a product of less accurate testing methods (eg RIDT) and not an accurate
312 reflection of the status of influenza in that area. Molecular testing has proven to the be one of the
313 most reliable methods of identifying influenza.[4] By incentivizing hospital laboratories to adopt
314 more molecular testing, for influenza identification, the IHSN can ensure a higher degree of
315 accuracy in its data sources. Furthermore, state health departments can address artificial
316 increases to case counts implementing more confirmation testing on positive influenza samples
317 that do not exceed a certain positive predictive value threshold.

318   The IHSN ensures EIP state participation by making weekly influenza case reporting
319 conditional for the receipt of funding from the CDC.[26] This further diminishes the likelihood of
320 cases not being reported to the state health departments for IHSN use. Population specific
321 socioeconomic status and demographics are well represented in the IHSN dataset. This is due to
322 a wide geographic distribution of participating counties and EIP states.[1,2] However, the IHSN
323 fails to take into account individual hospital policy on screening patients for influenza which is
324 made possible by the increasing number of affordable influenza testing methods on the market.[38]
325 Policies that favor "over-screening" can artificially increase case counts, deteriorating the quality
326 of IHSN rate estimates. This can potentially be addressed by narrowing the case definition so
327 that laboratory confirmed influenza associated hospitalizations only encompass hospitalizations
328 that are a result of influenza.

329   Each EIP state have varying reporting time frames for influenza. This can result in delays
330 of reporting and lower weekly case counts. This can be addressed by proposing a more universal
331 reporting timeframe amongst the EIP states. However, the IHSN is still able to provide weekly
332 updates to the FluView application which is fairly rapid considering the scope of the IHSN
333 (Table 1). The variability of influenza each year requires that the United States be vigilant in its
334 evaluation and improvement of influenza associated hospitalization surveillance in order to adapt
335 to the ever growing changes in severity, morbidity, and mortality of influenza.

336 **<u>Lessons Learned:</u>**

337   Overall, the Influenza Hospitalization Surveillance Network provides a fairly reliable
338 data source when considering its flexibility, usefulness, and timeliness. The IHSN's ability to
339 add states into its data pool based on need makes it highly adaptable to the unpredictability of the
340 influenza virus, but at the cost of introducing more variability into its dataset. IHSN data can be
341 used to establish incidence rates and trends over time. The FluView application that utilizes
342 IHSN data is able to stratify data based on age, underlying conditions, and viral subtypes to help
343 determine measures of association during each influenza season. Data is updated on a weekly

344 basis allowing for analysts and public health officials to implement control and prevention
345 measures in a timely manner. The IHSN is extremely stable and experiences little to no
346 (noticeable) system outages.

347   The IHSN data collection process requires a more streamlined and reliable approach.
348 Coupled with a lack of confirmation testing, variability in the clinical sensitivity and positive
349 predictive values of each test method deteriorates the overall reliability of data. Measures that
350 ensure confirmation testing for positive influenza results obtained by analytically unreliable tests
351 is paramount to enhancing overall quality of data. The representativeness of IHSN data can be
352 more accurately determined by comparing the influenza screening policies of individual hospital
353 based laboratories to differentiate volume of testing and potentially eliminate "over-testing" as
354 an inflation for cases in a future study.

355   The question remains of how to manage communications in the context of increased
356 accuracy in representing a historically underreported disease like influenza. There are ethical
357 considerations when interpreting data in the context of continually changing data collection
358 processes and assessment methods, all of which in the context of ongoing vaccine skepticism.
359 On the one hand, we are improving awareness of the importance of influenza as a potentially
360 serious disease for which early treatment can reduce cost of care, morbidity, and mortality. On
361 the other hand, overcalling severity without providing key disclaimers regarding changes made
362 over time to improve surveillance may impair credibility with patients and providers.

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373 Disclaimers:

374 The opinions expressed by authors contributing to this article do not necessarily reflect the
375 opinions of the Centers for Disease Control and Prevention or the institutions with which the
376 authors are affiliated.

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402   Antibiotic resistant microbes continue to be a major threat to both healthcare and community.
403   Healthcare associated infections (HAIs) have become increasingly difficult to manage. His
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