Data requirements for electronic surveillance of healthcare-associated infections

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Data Requirements for Electronic Surveillance of Healthcare-Associated Infections

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Electronic surveillance for healthcare-associated infections (HAIs) is increasingly widespread. This is driven by multiple factors: a greater burden on hospitals to provide surveillance data to state and national agencies, financial pressures to be more efficient with HAI surveillance, the desire for more objective comparisons between healthcare facilities, and the increasing amount of patient data available electronically. Optimal implementation of electronic surveillance requires that specific information be available to the surveillance systems. This white paper reviews different approaches to electronic surveillance, discusses the specific data elements required for performing surveillance, and considers important issues of data validation.
present is decided solely by an objective computer algorithm rather than by an IP manually reviewing raw data.

The vast majority of programs in use by infection prevention programs today are semi-automated electronic surveillance systems in which the user must still make the ultimate call as to whether an HAI is present. The LDS system described above is one such example: the user receives alerts of interest but must perform additional tasks (eg, medical record review) to classify an alert as an HAI. Semi-automated electronic surveillance systems filter vast amounts of data from laboratory, pharmacy, and admission/discharge/transfer (ADT) systems. They require substantial user input and do not replace the need for chart review. This type of system is valuable in reducing the amount of time IPs need to spend on surveillance, but it is still subject to differences in case finding as a consequence of human factors. An ideal semi-automated electronic surveillance has a very high negative predictive value (ie, reliably eliminates from consideration an alert as a consequence of human factors. An ideal semi—automated surveillance in its entirety and do not require IP case review. Trick et al\(^\text{10}\) first described successful automation of central line—associated bloodstream infection (CLABSI) surveillance through an in-house developed algorithm in 2004. Several years later, the scalability of this algorithm was demonstrated at 4 medical centers.\(^\text{11}\) Subsequently, the authors have made all information, including the algorithm, available free to the public (http://bsi.cchil.org/index.html). A similar system that is able to capture data on central venous catheter (CVC) use electronically has been implemented at a large Midwestern health system.\(^\text{12}\) Analogous systems have also been constructed for automated notifiable disease detection and reporting,\(^\text{13}\) and systems incorporating diagnosis codes have been described.\(^\text{14,15}\)

**Basic Considerations**

Most HAI surveillance criteria, like those developed by the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN), include clinical signs and symptoms (eg, fever and suprapubic tenderness), medical procedure details (eg, duration of surgery), and medical device exposure data (eg, ventilator) in addition to laboratory and microbiological test results. The success of electronic HAI surveillance therefore often depends on the accuracy, consistency, and timeliness of data on these signs and exposures. Strategies to improve the quality of data collection include minimizing free text data entry and streamlining documentation into highly structured, discrete fields. In addition, cultivating an institutional culture that embraces technology and views change positively is also likely to improve data quality.\(^\text{16}\)

**Denominator Capture**

An essential component of expressing accurate infection rates is valid enumeration of at-risk patients, procedures, and/or days. There are underappreciated complexities to this process. For example, for surgical site infections (SSIs), these denominator data are derived from the number of procedures. Accurate assessment of these data may be a challenge because of competing coding systems (eg, current procedural terminology [CPT] vs International Classification of Diseases, 9th Revision [ICD-9], codes) that lack a 1:1 mapping. Another example is device-related infections, for which denominators are expressed in terms of “device-days.” For CLABSI, the current standard is to tally 1 device-day if any CVC is present in a patient, regardless of how many lines are present. For manual surveillance, the count is typically done at the same time each day. Electronic surveillance could yield different results, especially if a device-day is tallied using evidence of the presence of any line in a 24-hour time frame (rather than at a specific hour of the day, as with a manually tally). To minimize error, documentation in an EHR needs to be constructed to remove ambiguity. For example, rather than simply selecting a checkbox for “central line yes/no,” the actual device and anatomic site should be captured as discrete data. IP involvement in the design of electronic documentation is critical to the success of accurately and consistently enumerating device-days. With adequately detailed records, programmers can minimize discrepancies between electronic and manual device counts. In addition, capturing detailed information on each device will help institutions prepare for future changes in surveillance definitions (eg, in the future a patient with 2 catheters in place might count for 2 line-days, not one). Some devices, namely ventilators, are capable of electronically transmitting data with precise information regarding patient exposures. Surveillance systems that are capable of accepting electronic device data may dramatically improve the efficiency and accuracy of denominator calculations. Finally, in determination of device-associated utilization rates, the ability to capture patient-days by unit is an essential requirement in general.

**Numerator Determination**

With traditional surveillance, IPs typically consult detailed bedside records and/or treating clinicians to provide clinical...
context. In contrast, electronic systems make determinations with relatively sparse data. Although access to the fully clinical chart and treating clinicians’ impressions is alluring, these sources can be problematic, because there is the potential for interinstitutional differences in data availability, differences in reviewer intensity of record review, biases in finding data to support a presumed result, and variability in interpreting the data. Consulting clinicians can be especially pernicious, because they tend to advocate their subjective clinical gestalt rather than assessing whether a patient meets formal surveillance definition criteria.

In considering which data elements to include in the numerator for electronic surveillance, one must consider data availability, data accessibility, and how these additional data impact accuracy and reliability. Data availability speaks to whether workflow and electronic documentation processes are consistent across institutions. For example, blood culture results are highly available, and their methods of collection are relatively consistent across institutions. In contrast, catheter tip cultures are highly dependent on local practices and are thus an example of low data availability. Data accessibility refers to whether data are stored in an easy-to-access format. For example, most microbiology data feeds include the organism as a discrete element. Records that are not readily computable and rely on processing of text to extract the desired data elements are examples of low-accessibility data.

Discrete Data

Patient information can be captured in EHRs in many ways and in many locations. To be reliable and effective, electronic algorithms require discrete data with well-defined meanings. These data are most readily captured in the EHR by constraining the entry choices (eg, by requiring checkboxes [multiple choices allowed], radio buttons [only a single choice allowed], or drop down lists). One concern with this approach, however, is that, by constraining choices, clinically significant nuances will no longer be captured in the documentation. This risk can be addressed by allowing the option of free text notes to accompany discrete data whenever this makes clinical sense. Natural language processing tools that can transform complex free text into discrete data are constantly improving and offer promise for the future, but they are not yet readily available for nonexpert users.

Recommendations

EHRs should be designed to maximize the breadth and flexibility of data export capabilities. Healthcare organizations should commit to effective change processes during system implementation to ensure widespread adoption and the resultant potential benefits of more consistent, accurate, and reliable documentation. The extraction and application of data, commonly in the form of data warehousing, should be part of the organization’s commitment to IT.

DATA NEEDS FOR ELECTRONIC HAI SURVEILLANCE

CLABSI

Much of the initial work on semi-automated electronic surveillance and fully automated electronic surveillance for HAI has been completed using CLABSI.\textsuperscript{3,7,10-12} As noted above, capturing denominator data for CLABSI requires the collection of the presence of a CVC in a discrete format to determine “line-days.” In our experience, the workflow for recording the presence of a central line is better suited for daily accounting rather than enumerating line-days through insertion and removal dates.

For numerator data, the sine qua non for a CLABSI is the presence of a positive blood culture result. This has become a relatively easy event to capture electronically. However, the specific organism must also be captured and compared with other cultures to assess whether the organism represents a skin contaminant rather than a pathogen.\textsuperscript{17} Semi-automated electronic surveillance and fully automated electronic surveillance systems currently rely on positive cultures of specimens from body sites other than blood to help assess whether a positive blood culture result represents a secondary infection.\textsuperscript{10,12} Because cultures from possible primary sites (eg, intra-abdominal abscesses) may not be available or may not have positive results, some secondary BSIs may be incorrectly classified as CLABSIs. In addition, patients with mucositis and neutropenia may have translocation of gut microorganisms into the bloodstream,\textsuperscript{18} leading to incorrect classification of these bacteremias as CLABSIs. Future surveillance definitions may take these confounding clinical conditions into consideration when determining whether a culture represents a CLABSI. Currently, determining the presence of such conditions from discrete data can be quite difficult. As the maintenance of accurate and comprehensive patient problem lists becomes more accepted as standard practice when documenting care in an EHR, more reliable information may be available electronically, and incorporating such information into future algorithms may improve specificity. Semi-automated electronic surveillance and fully automated electronic surveillance algorithms intended for widespread use must consider whether the necessary data elements are widely available from hospital EHR systems.

Recommendations

The presence of CVCs, including catheter type and anatomic site, should be documented in a structured manner within the EHR. Either daily documentation of the presence of the CVC or insertion and removal dates could be used; the selected method will depend on local workflow and documentation practices. At a minimum, positive microbiology culture results, including specimen site and species identification (to the extent performed by the laboratory) and susceptibility
testing, should also be available and retrievable as discrete data elements.

As definitions change over time (eg, the recent inclusion of criteria for a mucosal barrier injury laboratory-confirmed bloodstream infection), additional information will be required to realize fully automated electronic surveillance. The mucosal barrier injury definition requires evaluating whether a patient received an allogeneic stem cell transplant within the past year, their white blood cell (WBC) count, and the presence and severity of graft versus host disease. It will be a challenge for most systems to electronically capture the data needed to fully automate the mucosal barrier injury determination.

Urinary Tract Infection (UTI)

In 2009, NHSN revised the catheter-associated UTI (CAUTI) definitions to divide UTIs into symptomatic and asymptomatic infections. Asymptomatic infections without a second-ary bacteremia are no longer reportable. Infection rates are reported as symptomatic UTIs per 1,000 urinary catheter-days.

For denominator determination, as with CVC catheter-days, electronic capture of urinary catheter-days requires unambiguous documentation in the EHR. To enable semi-automated electronic surveillance and fully automated electronic surveillance, patient-level device data is essential, because only infections in patients with urinary catheters within defined time frames are subject to the measure. In the context of CAUTI, the ability to capture patient-days by unit is not only important from a device utilization measurement standpoint, but may also become important if alternative denominators become standard.

For numerator capture, data elements that describe patients’ clinical symptoms are essential to apply the NHSN definitions. These include age, temperature, urgency, frequency, dysuria, suprapubic tenderness, and costovertebral angle pain or tenderness. For children 1 year of age or younger, additional data elements are required. Although age and temperature are generally relatively easy data points to capture in a structured manner, the remaining criteria are more subjective and generally more difficult to extract and interpret from electronic medical records. Ideally, these data elements should be part of a nursing assessment and could be documented as discrete data within assessment flow sheets. Because of the challenges of using subjective clinical information in case definition, future definitions of CAUTI may shift away from subjective elements. In any surveillance system, variations in practice regarding ordering urinary cultures can have dramatic effects on reported rates.

Discrete laboratory data elements are also required for algorithmic detection of CAUTIs. These include urine cultures, leukocyte esterase and nitrate results, microscopic pyuria (urine specimen with 10 or more WBC/mm³ or 3 or more WBC/high-power field of unspun urine), and Gram stains. Current NHSN criteria do not accept cultures with 3 or more organisms and require differential symptom assessments depending upon whether the culture has 10³ or more or 10⁵ or more colony-forming units per milliliter. Therefore, both the number of distinct species recovered per culture and the quantity reported are necessary data elements for algorithmic identification of CAUTI.

Recommendations

At a minimum, urinary catheter data, quantitative microbiology data, and urinalysis data should be captured discretely to develop semi-automated electronic surveillance for CAUTI. Additional work is needed to define more specific algorithms for semi-automated electronic surveillance or, ideally, fully automated electronic surveillance. To the extent that subjective symptoms continue to be part of the definition, they should also be captured in a structured manner whenever possible.

Ventilator-Associated Pneumonia/Ventilator-Associated Conditions

NHSN released new surveillance definitions for ventilator-associated events (VAEs) in January 2013. These new definitions were designed to overcome many of the weaknesses of traditional ventilator-associated pneumonia definitions, including their complexity, subjectivity, and inaccuracy. The new definitions shift the focus of surveillance from pneumonia alone to complications of mechanical ventilation in general. This shift is a more accurate description of the diagnostic limitations of routine surveillance, is an opportunity to broaden the focus of prevention from pneumonia alone to multiple complications of critical care, and facilitates simple and objective surveillance definitions that are amenable to automation. Notably, the new definitions do not include radiographic criteria, because they are difficult to interpret, prone to substantial disagreement between observers, and difficult to parse electronically.

VAE surveillance begins with identifying patients with “ventilator-associated conditions” (VACs). VAC is defined as a sustained increase in ventilator settings after a period of stable or improving ventilator settings. Additional criteria define a subpopulation of VAC as “infection-related VAC” (IVAC) and further subpopulations of IVAC as “possible pneumonia” or “probable pneumonia.” VAC and IVAC are the anchors for the new surveillance paradigm and the only 2 measures that the CDC proposes to be considered for public reporting.

Recommendations

The new surveillance definitions for VAEs are amenable to semi-automated electronic surveillance and fully automated electronic surveillance. To accomplish this, the following data must be captured in an electronically usable form: daily minimum positive expiratory end pressure (PEEP), daily mini-
mum FiO₂, daily minimum and maximum temperature, daily minimum and maximum WBC count, and antibiotic start and stop dates. To apply the possible and probable ventilator-associated pneumonia definitions, Gram stain neutrophil and epithelial cell counts (absolute or semiquantitative), and pulmonary culture results (quantitative or semiquantitative) are also necessary. Monthly ventilator-days (device-days) can be imputed from this data stream as the sum of all daily minimum PEEP values per unit per month.

**SSI**

Unlike denominators for device-related infections, for which aggregate device data are used, denominators for SSIs require that specific data elements be gathered at the individual patient level for all individuals undergoing surgery so that cases can be appropriately risk adjusted. Although earlier risk adjustment used fairly basic data, such as wound class, American Society of Anesthesiologists score, and duration of surgery, more recent NHSN risk adjustment models require more patient information. To submit denominator data electronically, hospitals must format and store these data in a manner amenable to electronic extraction. Attention must also be paid to data validity. Although a surgical information system may capture wound class, operating room (OR) staff may preferentially enter the most common value as the default value (e.g., “clean” for a cardiac procedure) for all cases. Organizations need to clearly define documentation expectations and procedures to respond to events occurring during the case that would change the wound class to ensure that this information is captured.

Because of the complexity in defining SSIs, fully automated electronic surveillance for numerator capture will be difficult. However, semi-automated electronic surveillance can aid in case finding and thereby reduce the overall work of surveillance. Combinations of administrative data (codes for SSIs) plus other data (readmission and antibiotic administration) are known to improve case finding for SSI.25-29 Although a positive culture result is not a prerequisite for diagnosing an SSI, having a wound culture ordered for a postoperative patient may also be a signal for case finding. Likewise, re-admission within 30 days of a surgical procedure (or within 90 days of a surgical procedure with an implant) may also be an indicator of possible infection. Using different algorithms for different kinds of surgical procedures helps to optimize sensitivity and specificity.

**Recommendations**

EHRS and/or surgical information systems should be designed to identify all patients undergoing target surgeries as well as data required for patient-specific risk adjustment (e.g., wound class, surgery duration, antibiotic administration, basal metabolic index, and selected comorbidities). Billing codes (ICD-9, ICD-10, and CPT codes) can be used to classify surgical procedures into NHSN categories (mapping from available codes to the CDC-defined codes is not trivial, but it is beyond the scope of this white paper). Wound culture information, antibiotic administration, readmission information, and administrative codes are increasingly recommended for numerator determination. For postdischarge surveillance, access to EHR or claims data from physician outpatient offices would be of great use. Additional work is needed to define sensitive algorithms for electronically assisted surveillance that optimize case finding while reducing the surveillance burden.

**VALIDATION**

HAI surveillance has moved beyond the realm of hospital quality improvement. With public reporting, HAI rates may affect a hospital’s reputation, and with concomitant shifts in reimbursement to “pay-for-performance” models, HAI rates may also affect a hospital’s finances.30,31 Validation is the process by which infection surveillance is vetted for quality.32 The human element in “judging” infection is inherently variable from person-to-person,33,34 and validation has traditionally been focused on improving human reliability. In the current context, it means that the products of electronic surveillance (whether semi-automated electronic surveillance or fully automated electronic surveillance) are compared against a reference standard (usually manual surveillance, although potentially an independent, fully automated surveillance could also serve this role).

For the purpose of this white paper, validation can be categorized into 2 types: internal validation, which refers to self-assessment performed by the reporting facility itself, and external validation, which refers to an assessment conducted by an agency outside the facility (e.g., health department). Validation is an iterative process that should be repeated on a scheduled basis, particularly when new databases or software are implemented. The following internal and external validation recommendations are adapted from the NHSN Validation Guidance and Toolkit 2012.35 Both numerator and denominator values will need validation, because these num-

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### Table 1. Key Concepts for Describing Data Validation

<table>
<thead>
<tr>
<th>Validation</th>
<th>Description</th>
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<tbody>
<tr>
<td>Internal</td>
<td>Active efforts by a reporting facility to assure completeness and accuracy of data</td>
</tr>
<tr>
<td>External</td>
<td>Survey and audit process by external agency (e.g., public health department) to assure quality of surveillance and reporting</td>
</tr>
<tr>
<td>Numerator</td>
<td>Primarily performed by external audit, by sampling candidate patient charts from a line list of positive microbiologic culture results</td>
</tr>
<tr>
<td>Denominator</td>
<td>Primarily performed by internal audit, by comparing electronically derived device counts with manual (hand) counts</td>
</tr>
</tbody>
</table>

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Device counts are within 5% of manual counts. Such validation efforts previously discussed.

Table 1 summarizes key validation concepts.

### Internal Validation

**Denominator validation.** The CDC-recommended approach for denominator validation in facilities that electronically collect such data is to ask the facility to validate that electronic device counts are within 5% of manual counts. Such validation is required for 3 months at the beginning of electronic count installation, and ongoing validation is recommended for 1 month per year. To assist in this activity, electronic surveillance systems should be able to produce “validation reports” of device count data at a patient level, so that IPs can review and troubleshoot discrepancies.

**Numerator validation.** IPs are asked to investigate all positive microbiologic cultures for possible HAIs. To facilitate such review, electronic surveillance systems should be able to produce a summary line listing of positive microbiologic cultures by source type, stratified by location (eg, all blood cultures from the intensive care unit [ICU] for 1 year). The electronic system should then form the basis of a workflow for the IPs to review each positive culture, document their decisions, and generate summary reports. It is worth noting that the optimal approach to numerator validation is not clear for some types of hospital-acquired infections for which cultures are sometimes negative or not performed (such as SSIs). This will require future guidance from the CDC.

### External Validation

**Denominator validation.** Electronic surveillance systems should also be able to produce the data needed for external validation activities. Most external validation currently focuses on numerator validation; denominator validation, if performed by external auditors, would mirror the internal validation efforts previously discussed.

**Numerator validation.** External auditors will typically request a list of all positive microbiologic culture results from a specific source and location (eg, all positive blood culture results from the ICU for 1 year). Auditors typically specify that the information come directly from the primary source of data (ie, laboratory information management system). Usual fields required for such reports include: (1) unique laboratory accession number, (2) specimen collection date, (3) primary organism genus and species identity, (4) specimen collection location (eg, medical ICU), (5) medical record number, (6) first name, (7) last name, (8) patient birth date, and (7) hospital admission date.

Of note, some laboratory information management systems continuously update the facility location field as a patient moves through a facility; thus, even if a blood sample for culture is drawn in the medical ICU, if the patient is then transferred to the medical ward, the facility location is changed accordingly. Such dynamic location fields impair the ability of microbiology laboratories to perform location-based queries based on collection location. We recommend that laboratory information systems retain the collection location as a static data element that is distinct from a dynamic patient “current location” field.

For semi-automated electronic surveillance, the current reference standard is the determination by a trained auditor using NHSN criteria. For fully automated electronic surveillance systems, there is no established auditing system in place.

### Table 2. Key Data Elements Necessary for Electronic Surveillance of Healthcare-Associated Infections

<table>
<thead>
<tr>
<th>NHSN surveillance metric</th>
<th>Key electronic data elements</th>
<th>Barriers to fully automated electronic surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central line–associated line infection</td>
<td>Microbiology cultures (blood and non-blood sites), ADT, central venous catheter presence</td>
<td>Current definition requires judgment regarding the origin of the blood pathogen</td>
</tr>
<tr>
<td>Catheter-associated urinary tract infection</td>
<td>Microbiology cultures (urine only), urinalysis, ADT, vital signs (fever), urinary catheter presence</td>
<td>Current definition requires assessment of patient symptoms</td>
</tr>
<tr>
<td>Surgical site infection</td>
<td>Microbiology cultures (superficial or deep wound cultures), procedure billing codes (eg, CPT codes), hospital billing codes (eg, ICD-9), ADT (to detect readmissions), antibiotic administration (optional)</td>
<td>Current definition requires judgment as to whether infection occurred, since not all infections have a positive culture; designation of depth of infection is often very nuanced</td>
</tr>
<tr>
<td>Ventilator-associated event (VAC, IVAC)</td>
<td>Ventilator settings (PEEP, FiO2), presence of endotracheal intubation device, ADT, antimicrobial use, vital signs (temperature), laboratory (white blood cell count), microbiology culture results</td>
<td>None</td>
</tr>
<tr>
<td>MDRO module</td>
<td>Microbiology cultures, ADT</td>
<td>None</td>
</tr>
<tr>
<td><em>Clostridium difficile</em> module</td>
<td>Microbiology (C. difficile), ADT</td>
<td>None</td>
</tr>
</tbody>
</table>

**Note.** ADT, admission/discharge/transfer system; CPT, current procedural therapy; FiO2, fraction inspired oxygen; ICD-9, *International Classification of Diseases, 9th Revision*; IVAC, infection-related VAC; MDRO, multidrug-resistant organism; NHSN, National Healthcare Safety Network; PEEP, positive expiratory end pressure; VAC, ventilator-associated condition.
although a manual verification of fully automated electronic surveillance outcomes using raw microbiologic and ADT data is a likely method of validation for the future.

Future validation efforts will likely add more advanced risk adjustment and automated benchmarking to identify facilities with potentially faulty surveillance. Future risk adjustment may include external requests for patient-level data, such as patient acuity of illness at the time of admission as well as patient comorbidities. Future benchmarking may also include either crude surrogates of device-related infections (eg, device-independent nosocomial bacteremia rate as a benchmark for CLABSI) or more advanced algorithms that estimate device-related infection rates based on probabilistic modeling.\(^ {40}\)

**Discussion**

Although still in the early stages, electronic surveillance for HAI s is clearly here to stay. Indeed, the current NHSN LabID surveillance for *Clostridium difficile* infections and MRSA bacteremia required by CMS can easily be implemented (and often are) as fully automated electronic surveillance systems, although they may not be recognized as such. One compelling reason for transitioning from traditional manual surveillance methods to fully automated electronic surveillance is that traditional methods are susceptible to variability caused by differences between IPs and hospitals in their intensity of surveillance as well as individual biases in interpretation. Variability and bias compromise reliability, and poor reliability undermines the validity of interinstitutional comparisons. Given the current environment, in which States are mandating reporting of infection rates to the public, valid interinstitutional comparisons are essential. Although rigorous training, episodic audits, and retraining make it theoretically possible to achieve acceptable reliability, the manpower to realize this level of performance across different device-associated infections, in a wide array of different ICU types, and across thousands of hospitals seems like an improbable if not insurmountable task. Even with heroic efforts to improve reliability, it seems that electronic rules and algorithms will be more reliably applied across institutions, and even if slightly less specific, such highly reliable systems can still be superior for interinstitutional comparison of infection rates.\(^ {41}\)

Perhaps an even stronger incentive driving a transition to fully automated electronic surveillance is the promise of reducing the substantial amount of time required for an IP to identify and categorize putative infections. From the hospital perspective, allowing IPs to devote their time to implementing and maintaining infection prevention interventions provides more value to the institution than counting events.

There are several challenges and limitations of fully automated electronic surveillance. One limitation is that traditional methods allow for a deeper understanding of the clinical context. However, if HAI rates are high in a given area, additional investigation can provide such context; otherwise, having this information adds little. A major challenge is the considerable start-up and maintenance costs associated with building interfaces to aggregate and organize raw clinical data, analyze them for events of interest, and present them to IPs in an actionable format. These costs are likely to diminish over time as hospitals increasingly adopt EHRs and transform these records to meet meaningful use requirements.

As an infection prevention and control community, it is time for us to embrace objective electronic definitions amenable to fully automated surveillance. Table 2 lists current NHSN surveillance measures along with elements needed to shift toward electronic surveillance. Shifting to objective definitions and developing electronic systems to automate the extraction, analysis, and presentation of these data not only will make surveillance more efficient but holds the promise of allowing us to direct ever more of our limited resources toward preventing, rather than just counting, infections.

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