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Major article

Data elements and validation methods used for electronic surveillance of health care-associated infections: A systematic review

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Background: We describe the primary data sources, data elements, and validation methods currently used in electronic surveillance systems (ESS) for identification and surveillance of health care-associated infections (HAIs), and compares these data elements and validation methods with recommended standards.
Methods: Using Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines, a PubMed and manual search was conducted to identify research articles describing ESS for identification and surveillance of HAIs published January 1, 2009-August 31, 2014. Selected articles were evaluated to determine what data elements and validation methods were included.
Results: Among the 509 articles identified in the original literature search, 30 met the inclusion criteria. Whereas the majority of studies (83%) used recommended data sources and validated the numerator (80%), only 10% of studies performed external and internal validation. In addition, there was variation in the ESS data formats used.
Conclusions: Our findings suggest that the majority of ESS for HAI surveillance use standard definitions, but the lack of widespread internal data, denominator, and external validation in these systems reduces the reliability of their findings. Additionally, advanced programming skills are required to create, implement, and maintain these systems and to reduce the variability in data formats.

For the past 3 decades, surveillance has been recognized as the cornerstone of effective infection prevention and control programs,[1] but traditional manual surveillance methods are labor intensive and limited by interobserver variability.[2] To address these issues, the infection prevention community has pursued the development of automated electronic surveillance systems (ESS). Whereas ESS using electronically available patient data have been found to be accurate and potentially save time,[3-5] their performance is not consistent across settings.[6] The performance of ESS often depends on implementation issues related to data sources and data capture.[7] This review uses an adapted framework[8] to describe primary data sources, data elements, and validation methods currently used in ESS for the identification and surveillance of health care-associated infections (HAIs), and compare these data elements and validation methods with recommended standards.

METHODS

Search strategies and information sources

Using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statement (http://www.prisma-statement.org/) as a guide, we conducted a systematic search of published literature that evaluated ESS for HAIs. The PubMed system was used to search for publications indexed by Medline from January 1, 2009, through August 31, 2014. Manual searches were also performed by scanning the bibliographies of eligible original research papers and systematic reviews.

Eligibility criteria and study selection

Selected articles had to describe an automated system that performed electronic HAI surveillance, relevant data sources used in the system, and any system validation performed. Studies that

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Table 1
Search term used for the PubMed query

Search term
((*cross infection* [All Fields] OR *Algorithms* [All Fields] OR *automated surveillance* [All Fields] OR *Automatic Data Processing* [All Fields] OR *Bacteremia/classification* [All Fields] OR *Infection Control* [All Fields] OR *Sentinel Surveillance* [All Fields] OR *Electronic Surveillance System* [All Fields] OR *Surgical Wound Infection* [All Fields] OR *Surgical site infection* [All Fields] OR *Population Surveillance/methods* [All Fields] OR *Hospital Information Systems* [All Fields] OR *Diagnosis, Computer-Assisted* [All Fields] OR *Data Collection/methods* [All Fields] OR *hospital acquired infection* [All Fields] OR *hospital associated infection* [All Fields] OR *healthcare associated infection* [All Fields] OR *Fields* [All Fields] OR *patient to patient infection* [All Fields] OR *nosocomial infection* [All Fields] OR *catheter related infection* [All Fields] OR CLABSI [All Fields] OR *BSI* [All Fields] OR *Urinary Tract Infections* [All Fields] OR *central line associated bloodstream infection* [All Fields]) AND *electronic health record* [All Fields] OR *EHR* [All Fields] OR EMR [All Fields] OR *electronic medical record* [All Fields] OR *computerized medical record* [All Fields]) AND *2009/01/01* [PDAT]: *2014/09/01* [PDAT]))

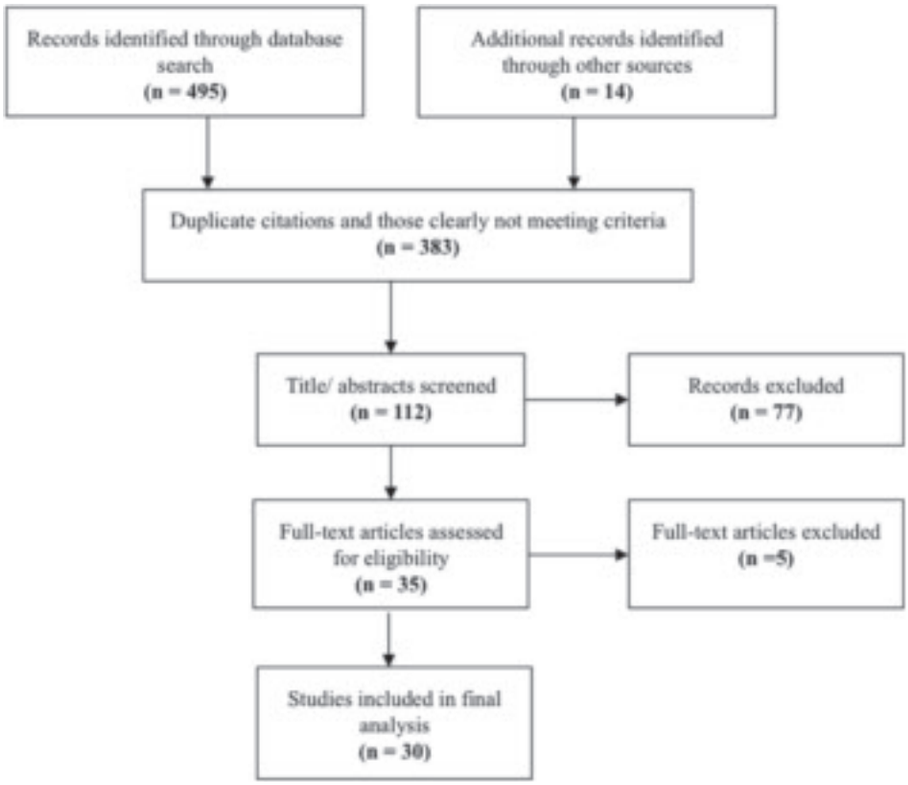

Fig 1. Flow chart used to identify articles examining automated health care-associated infection surveillance systems to ultimately select articles for inclusion in our analysis.

used the electronic health record as solely a means for conducting chart review were excluded, as were those that investigated predictive risk modeling for HAI. We used the filters *human*, *abstract*, and *English language* on all searches. Table 1 summarizes the PubMed search query.

Assessment of studies

To ensure articles matched the eligibility criteria, titles and abstracts were evaluated independently by each author and discrepant cases were settled by consensus. Full texts of the remaining articles were then reviewed independently by each author to verify that they met the inclusion criteria. After articles that met the inclusion criteria were identified, they were assessed using a modified framework originally developed by Woeltje et al.[8] The first 3 articles were independently assessed and then discussed by all 3 authors, and any discrepancies were resolved by consensus. The remaining articles were abstracted by 1 of the 3 authors using an assessment framework.

The assessment framework developed by Woeltje et al[8] has 2 main components. First, for each of 5 types of infection, recommended data elements for ESS were outlined based on National Healthcare Safety Network definitions for HAI surveillance (http://www.cdc.gov/nhsn/pdfs/pscmanual/17pscnosinfdef_current.pdf). These included central line-associated bloodstream infection, catheter-associated urinary tract infection, surgical site infection, ventilator-associated event, multidrug-resistant organism module, and *Clostridium difficile* module. We added bloodstream infection, urinary tract infection, ventilator-associated pneumonia, and pneumonia to the list of HAIs because these were also investigated in the articles we reviewed. Second, 4 key concepts for describing data validation were recommended: internal and external validation and validation of numerator and denominator.[8] Based on this framework, we evaluated each article to determine whether all recommended data elements were included and whether recommended validations were performed. The Woeltje et al[8] framework was modified only for surgical site infections, for which it was decided that an ESS would not require both procedure and diagnostic codes because there is considerable overlap between

Table 2
Data elements and validation used by electronic surveillance system studies

Group	Article	Study setting and size	Health care-associated infection type	Data sources used	Used recommended data sources[8]	Validation performed
	Benoit et al 2011[22]	34 Hospitals, 4,585 patients, 12 states	*Clostridium difficile*	Microbiology cultures, ADT	Yes	None
	Branch-Elliman et al 2014[20]	5 Acute care VA hospitals	MDRO	Microbiology cultures	No	None
	Choudhuri et al 2014[24]	Teaching hospital 136 patients	CAUTI	Microbiology cultures, ADT, vital signs, urinalysis	Yes	Internal, numerator, denominator
	De Bus et al 2014[26]	University hospital 14-bed MICU, 22-bed SICU, 876 admissions	UTI, BSI	Microbiology cultures, ADT, vital signs, urinalysis	Yes	Internal, numerator
	Dubberke et al 2012[3]	4 Hospitals	*Clostridium difficile*	Microbiology cultures, ADT	Yes	Numerator
	FitzHenry et al 2013[21]	6 VA hospitals, 33,565 patients	SSI	Microbiology cultures, ADT	Yes	Numerator
	Harron et al 2013[27]	109,654 Pediatric inpatient records	BSI	Microbiology cultures, ADT	Yes	Internal,numerator
	Herasevich et al 2010[38]	Academic medical center, 204-bed ICU	BSI	Microbiology cultures, ADT	Yes	Internal, numerator
	Inacio et all 2011[15]	Large HMO	SSI	Microbiology cultures, ADT, hospital procedure codes, hospital diagnosis codes	Yes	Numerator, denominator
	Klein et al 2014[16]	Tertiary referral centers, 2,080 patients	VAP, VAE	Microbiology cultures, ADT, vital signs, presence of endotracheal intubation device, laboratory (white blood cell count), ventilator settings (PEEP, FiO_2 antimicrobial use)	Yes	Numerator
	Knepper et al 2013[9]	Academic safety net hospital, 2,449 surgical procedures	SSI	Microbiology cultures, ADT, antibiotic administration, hospital procedure codes, hospital diagnosis codes	Yes	Numerator
	Leal et al 2010[4]	Regional hospital, 306 patients	BSI	Microbiology cultures, ADT	Yes	Numerator
	Leth et al 2010[18]	1,504 C-section cases	UTI	Microbiology cultures, ADT, vital signs, urinalysis	Yes	Numerator
	Lo et al 2013[28,39]	Tertiary care teaching hospital, 730-bed	CAUTI	Microbiology cultures, ADT, vital signs, urinary catheter present, urinalysis	Yes	Numerator
	Peterson et al 2012[28]	Health system, more than 300,000 patients	MDRO	Microbiology cultures, ADT	Yes	Numerator
	Schmiedeskamp et al 2009[19]	23,920 Inpatient discharges	*Clostridium difficile*	Microbiology cultures, ADT	Yes	Numerator
	Shepard et al 2014[12]	A 583-bed adult tertiary care center, 6,379 urine cultures	CAUTI	Microbiology cultures, ADT, vital signs, urinary catheter present, urinalysis	Yes	Numerator
	Venable et al 2009[40]	A 420-bed teaching hospital	CLABSI, CAUTI	Microbiology cultures, ADT, vital signs, urinary catheter present, urinalysis, central venous catheter presence	Yes	Numerator
	Wald et al 2014[29]	A 425-bed university hospital, 1,695 patient visits	CAUTI	Microbiology cultures, ADT, vital signs, urinary catheter present, urinalysis	Yes	Internal, numerator
	Woeltje et al 2011[30]	A 1,250-bed tertiary care teaching hospital	CLABSI	Microbiology cultures, ADT	No	Internal, numerator
National Taiwan University	Tseng et al 2012[14]	A 2,200-bed teaching hospital	MDRO	Microbiology cultures, ADT	Yes	Numerator
National Taiwan University	Tseng et al 2013[13]	A 2,200-bed teaching hospital	BSI	Microbiology cultures, ADT	Yes	Internal, numerator
National Taiwan University	Wu et al 2009[41]	A 2,200-bed teaching hospital	MDRO	Microbiology cultures, ADT	Yes	Internal, numerator
Columbia	Apte et al 2011[10]	Academic medical center, 28,956 hospital admissions	SSI	Microbiology cultures, ADT, antibiotic administration, hospital procedure codes	No	Internal, numerator, denominator
Columbia	Apte et al 2011[11]	Academic medical center 320,000 inpatient discharges	BSI, PNU, SSI, UTI	Microbiology cultures, ADT, urinary catheter present, urinalysis, central venous catheter presence, antibiotic administration, hospital procedure codes	No	None
Columbia	Landers et al 2010[17]	Academic medical center 33,834 hospital admissions	UTI	Microbiology cultures, ADT, urinalysis	No	None

MONI	Adlassnig et al 2009[23]	Teaching hospital 96 ICU beds	UTI, CAUTI, BSI, CLABSI	Microbiology cultures, ADT, vital signs, urinary catheter present, urinalysis, central venous catheter presence	Yes	None
MONI	Adlassnig et al 2014[5]	Teaching hospital, 87 adult ICU beds, 46 NICU beds	UTI, CAUTI, BSI,CLABSI	Microbiology cultures, ADT, vital signs, urinary catheter present, urinalysis, central venous catheter presence	Yes	None
MONI	de Bruin et al 2013[25]	Teaching hospital 75 ICU beds	BSI	Microbiology cultures, ADT, vital signs, urinalysis, biochemistry laboratory	Yes	Internal
MONI	Blacky et al 2011[42]	Teaching hospital 96 ICU patients in 12 ICUs	BSI, CLABSI, PNU, UTI	Microbiology cultures, ADT, vital signs, urinary catheter present, urinalysis, central venous catheter presence, antibiotic administration	Yes	Numerator

ADT, admission discharge transfer information; *BSI*, bloodstream infection; *CAUTI*, catheter-associated urinary tract infection; *FiO_2*, fraction of inspired oxygen; *HMO*, health maintenance organization; *ICU*, intensive care unit; *MDRO*, multidrug resistant organisms; *MICU*, medical intensive care unit; *MONI*, monitoring of nosocomial infections; *NICU*, neonatal intensive care unit; *PEEP*, positive end expiratory pressure; *PNU*, pneumonia; *SICU*, surgical intensive care unit; *SSI*, surgical site infection; *UTI*, urinary tract infection; *VA*, Veterans Administration; *VAE*, ventilator-associated events; *VAP*, ventilator-associated pneumonia.

the 2; thus, this data element was considered present if either type of code was used.

RESULTS

As Figure 1 illustrates, 509 articles were initially identified (Table 1 lists the full search text). After removing duplicate citations and limiting articles to those with available abstracts, 383 abstracts were screened. An additional 77 were excluded during title and abstract review, primarily because they did not pertain to automated ESS. Full-text assessment of 35 articles resulted in 30 final studies that met inclusion criteria.

Table 2 provides a summary of each study reviewed, which included an array of HAIs: bloodstream infection = 10 and central line-associated bloodstream infection = 5, urinary tract infection = 7 and catheter-associated urinary tract infection = 7, surgical site infection = 5, multidrug-resistant organisms = 3, any ventilator-associated events = 1 and pneumonia = 2, and *C difficile* = 3. The majority of studies, 83%, used the recommended HAI-specific data sources in their ESS.

The articles reviewed did not always report how clinical facts (eg, laboratory results, diagnosis, and medications) were annotated and the corresponding vocabularies used to format the related data. However, there was variation in data formats for the studies that did provide a detailed description of data used by their ESS. These formats varied from unstructured, noncoded, and institution-specific coded data to internationally and nationally adopted formats like ICD-9. To determine antibiotics administered, textual medication names[9-11] and institution-specific code[12-14] formats were used. ICD-9,[4,9-11,15-19] Systematized Nomenclature of Medicine—Clinical Terms,[20-22] and free text from notes were used to determine hospital billing diagnosis and procedures.[10,11,17,21] Microbiology results were formatted in institution-specific codes,[10,11,13,14,17] textual results,[3-5,9,12,16,18,22-30] and Logical Observation Identifiers Names and Codes.[22]

Validation performed

Validation of the numerator was performed most often (80%; 24 out of 30 studies). Checking of the actual data with an independent data source, also referred to as internal validation, was done in 33% of the studies (10 out of 30). External validation; for example, having an external organization validate the ESS findings, was not used in any of the studies in our sample. Ten percent of the studies (3 out of 30) reported having validated the denominator.

DISCUSSION

The ideal ESS would be fully automated and accurately identify infections without human input. The goal of our literature review was to assess the state of the science with regard to electronic surveillance of HAI (ie, how close we are to full automation). A number of themes emerged from the review relating to data availability, lack of standardized sources of data, the complexity of the ESS, and the lack of validation of the surveillance systems.

The increased number of data sources used in ESS reflects the fact that more electronic clinical data continue to become available.[6] However, the fact that 17% of the studies in our review did not use the recommended data suggests that availability of relevant data is still 1 gap that must be filled before fully automated surveillance of HAI is possible.

The fact that a majority of studies used the recommended data elements to define an HAI is encouraging. Still, it is important to note that, for example, although all of the ESS used microbiology laboratory results, there was great variability in the structure of the

actual results. This lack of standardization of data is an impediment to having ESS that can be implemented uniformly across settings. Furthermore, lack of uniformity in data input increases the complexity of the systems and the required resources to implement and maintain these systems.

In our review most of the studies were conducted in academic medical centers, Veterans Administration hospitals, and 1 large health maintenance organization. This finding reflects the fact that only institutions with considerable financial resources can afford to implement these systems. Moreover, ESS are complex and range in sophistication, but in general they require high-level programming and technologic support. Clearly, the specialized workforce that is required to support these systems is sorely lacking.[31,32] The creation, implementation, and management of ESS systems require individuals who understand the nuances of clinical data and analytical techniques and have the ability to extract and transform standard and nonstandard data sources.

None of the studies in our review met the criteria of having internal, external, denominator, and numerator validation. It is important to note that denominator validation is often not applicable and feasible to calculate for the HAIs that are applicable to an entire inpatient population. Whereas the logistics of accomplishing the task of validating the data are daunting, validation is vital and must be performed on these systems.[33] Research has indicated that ESS studies that have performed the requisite numerator, denominator, and/or external validation found high variability in sensitivity/specificity.[7,34] In addition, studies have also highlighted the lack of completeness[35] and bias[36,37] of electronic patient data.

Our literature review was limited by the inclusion of only articles written in English with abstracts, and the use of a single database with a limited number of search terms. Therefore, some articles pertaining to the topic could have been missed. Nonetheless, our findings present the state of the science in ESS research and point to important future directions for continued investigation. We recommend that future ESS HAI surveillance focus on obtaining high-quality data, employing dedicated programmers with advanced skills, and performing more thorough validation.

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