A surveillance system model for central line-associated bloodstream infections (CLABSI) coordinated at the regional level: a pilot feasibility study

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SUMMARY

We describe the methods used to define a surveillance model to incorporate into activities aimed at preventing central line-associated bloodstream infections (CLABSI) in non-critical care units (NCCUs) and designed to be implemented at the regional level.
In 2015 we conducted a pilot feasibility study in three NCCUs based in hospitals of the Regional Health System of Emilia Romagna to evaluate the feasibility of the proposed model and to test its accuracy and cost-effectiveness in terms of resources needed to maintain the system.
Our results indicate that the system is feasible at the regional level by using the available sources and instruments to collect data in clinical practice context. Observation of device utilization for at least three months in all NCCU wards is needed in order to prioritize the medical area on which to focus costs for surveillance prior to implementing it on a regular basis.

Keywords: surveillance, healthcare-associated infections, catheter-related bloodstream infections, infection control indicators.

INTRODUCTION

The complexity of patients in hospital settings is increasing due to the emergence of multidrug resistant organisms (MDROs), increasingly immunocompromized patients and a growing number of individuals requiring aggressive treatments and invasive procedures. The risk of complications increases as patients become more complex. In particular, healthcare-associated infections (HAIs) represent the most common complications affecting hospitalized patients [1]. These infections are also considered a safety issue as they are the main contributor to significant adverse events in healthcare, by causing higher morbidity and mortality and having immediate and future implications for the individual, the healthcare system, and the community [2-13]. In a recent prevalence study, Magill et al. reported that 14% of HAIs were bloodstream infections (BSI) and that all BSIs identified were central line-associated bloodstream infections (CLABSI) [14]. As CLABSIs have been shown to increase the length of stay in hospital by 10 to 20 days, they also represent one of the highest costs attributable to HAIs [6,15]. Although a decrease in the rate of CLABSIs has been observed in intensive care units (ICUs) thanks to the use of prevention strategies, a substantial number of CLABSIs continue to occur in other hospital settings [16].
It is estimated that up to 70% of HAIs are prevent-

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able and there is evidence that the frequency of these events could be reduced by incorporating surveillance systems into infection prevention and control activities (IPAC) [17].
Surveillance represents an essential function of infection prevention programs in that it is useful to monitor IPAC effectiveness and patient safety [18]. Previous studies have shown positive changes in HAI rates following the introduction of surveillance [19-21].
Current best practices in infection prevention and control programs sustain that coordinated regional, provincial and national surveillance systems as more effective in managing HAIs in hospitals than local surveillance approaches [22].
Although in the region of Emilia-Romagna there are several positive multiyear regional experiences on surveillance systems coordinated by the Regional Health Care Agency such as Surgery Site Infections, MDROs, Carbapenemase-Producing Enterobacteriaceae (CPE) Infections, a regional CLABSI surveillance system for non intensive care settings in hospitals is still lacking [23-25]. We thus decided to conduct a pilot feasibility study in three public hospitals of the Emilia Romagna region. The primary objective of the pilot study was to propose a surveillance model based on a standardized method to measure the performance of healthcare organizations in preventing central line-related infections (common indicators; case definition and criteria, minimum data set, supportive instruments to validate cases). Secondary objectives comprised the evaluation of the feasibility of the proposed model in a clinical context using available sources and instruments to collect data; estimation of its cost-effectiveness in terms of resources needed for surveillance and to ensure system accuracy; and exploration of the acceptability of the proposed system by organizations and possible barriers for its implementation on a regional basis.

MATERIALS AND METHODS

Research team description
The research team involved in the study was composed of the following healthcare professionals: an infectious disease specialist, two epidemiologists, a medical expert in the implementation of clinical governance instruments and two infection control nurses (ICNs). All team members play key roles in infection prevention and control in Regional Public Health System hospitals.

Step 1
Definition of performance indicators for CLABSI prevention
The group agreed that at least two indicators were needed to measure hospital performance in relation to CLABSI prevention:
- Central line device utilization (CLDU) ratio
- CLABSI rate in specific medical wards.

Rationale
The first indicator is essential to identify the priority areas of non critical care units (NCCUs) in which to implement CLABSI surveillance at the regional level.
The second represents the direct indicator of a unit's performance in preventing CLABSIs. The definitions of central line (CL), CLDU ratio, CLABSI rate, case definition and criteria used by our group were based on 2015 Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) definitions and were endorsed by all research team members for use in the feasibility studies [26]. Consensus regarding the minimum data set to collect during the pilot feasibility study was then reached. Each participating center, in accordance with its Healthcare Administration and ward coordinators, selected the ward and a one-month period for the CLABSI surveillance study.

Minimum data set
The information needed to measure the two identified indicators represented the minimum data set required for CLABSI surveillance.
The following formula was used to measure the CLDU ratio indicator [26]:

$$\text{CLDU ratio} = \frac{\text{Number of CL device-days}}{\text{Number of patient-days}}$$

The data required to measure the CLDU ratio consisted of:
- patients admitted to the ward at a specific time each day during the survey period;
- patients with at least one central line at a specific time each day during the survey period;
- additional information about type of central line in place (temporary or permanent).

The following formula was used to measure the CLABSI ratio [27]:

$$\text{Central line-associated BSI (CLABSI) rate} = \frac{\text{Number of central line-associated BSIs}}{\text{Number of central line-days}} \times 1000$$

The data required to measure the CLABSI rate indicator consisted of:

a) Laboratory data
- number of blood samples drawn from each body site within a 24-hr timeframe during the CLABSI window period;
- positive blood cultures sampled from patients with central line during the CLABSI window period;
- the presence of cultures sampled from other body sites during the CLABSI window period;

Type of bacteria isolated from the blood sample and from any other samples;

b) Clinical information
- information needed to identify the CLABSI window period, *e.g.* 3rd day, 4th day etc, of the CL being in place in the same medical unit;
- temperature >38°C, hypotension, chills;
- other clinical information relating to signs and symptoms of infection excluding secondary bloodstream infections (BSI) and mucosal barrier injury/laboratory-confirmed bloodstream infections (MBI-LCBI).

Data required to read and interpret indicators - facility and location information:
c) Hospital identification
d) Teaching hospital status
e) Medical area of the participating unit
f) Number of unit beds
g) Bed occupancy rate

Cost-effectiveness evaluation
The costs required to maintain the system were evaluated by taking into consideration the instruments used, the professionals involved and the *person-time* taken to collect data. The efficacy of the surveillance system was assessed by estimating the ability of each single data collection method used to detect and confirm the cases of CLABSI.

Step 2
Data collection
The instruments available in each participating center were used for data collection. Data relating to admitted patients and to the number of these with one or more central lines were collected at the same time each day during the study period. This information was collected by ICNs *electronically* in one of the participating centers and *manually* in the other two. Data were then registered in a dedicated encrypted database which was subsequently integrated with laboratory and clinical data relating to CLABSIs. Clinical data were retrospectively extracted manually by ICNs from vital sign records, treatment schemes, nursing and medical diaries. The final database was anonymized by deleting the identity of patients and other sensitive information and by assigning a unique numerical code to each individual.

Ethical considerations
The study was approved by the Healthcare Administration of each participating center and by the Independent Scientific Board of the coordinating center. When using retrospectively extracted and anonymized data for healthcare planning and clinical governance, studies are exempt from formal ethics review and specific written consent is not required to use patient information stored in hospital databases.

Step 3
CLABSI case detection and validation
We simultaneously collected laboratory data and clinical information to identify CLABSI cases. On the basis of laboratory data, patients with at least one central line in place whose blood cultures were performed during the CLABSI window period and for whom at least one recognized pathogen or the same commensal organism was isolated from at least two blood cultures on separate occasions within a 24-hour period were considered as suspected cases to be confirmed or excluded.
On the basis of clinical information, patients with at least one central line in place who showed signs and symptoms of systemic infection (fever, chills or hypotension) during the CLABSI window period were considered as suspected cases to be confirmed or excluded. Combined methods consisting in laboratory data integrated with clinical information were used to verify whether suspected cases met at least one of the CLABSI criteria, thus

confirming true cases of CLABSIs and excluding false-positive cases. Unconfirmed suspected cases represented false positives. A group meeting was held to validate and confirm or not suspected CLABSI cases. Figure 1 shows the algorithm used by our group to validate CLABSI cases.

RESULTS

The units taking part in the study, all based in hospitals in the region of Emilia Romagna, were two internal medicine wards and one onco-hematology ward (Unit 1 - Internal Medicine Ward of the Health Trust Hospital of Imola; Unit 2 - Internal Medicine Ward of the Health Trust Hospital of Fidenza; and Unit 3 - Onco-Hematology Ward of Istituto Scientifico per lo Studio e la Cura dei Tumori di Romagna, respectively). Table 1 shows facility characteristics and CL devices in place in patients hospitalized in the study units. The surveillance period lasted for one month in each participating center and was performed in June 2015. Table 2 shows the sources used for data collection in the 3 participating units. Electronically collected data showed some advantages over data collected manually, *e.g.* less time was needed to measure the CLDU indicator: 3 minutes/bed/month in Unit 1 vs. 6.5 (Unit 2) and 8 minutes (Unit 3). In addition, the electronic data collection modality proved feasible at any time, even retrospectively, and could be performed by the ICN alone, in contrast to manual data collection that required the involvement of other healthcare professionals. We observed different device utilization rates between units, *i.e.* 3% in Unit 1, 13% in Unit 2 and 54% in Unit 3. Consistent with this result, the person-time required on a monthly basis for surveillance per hospital bed increased as the device utilization rate increased: 11.4 minutes in Unit 1, 21 minutes in Unit 2 and 60 minutes in Unit 3 (Table 3).

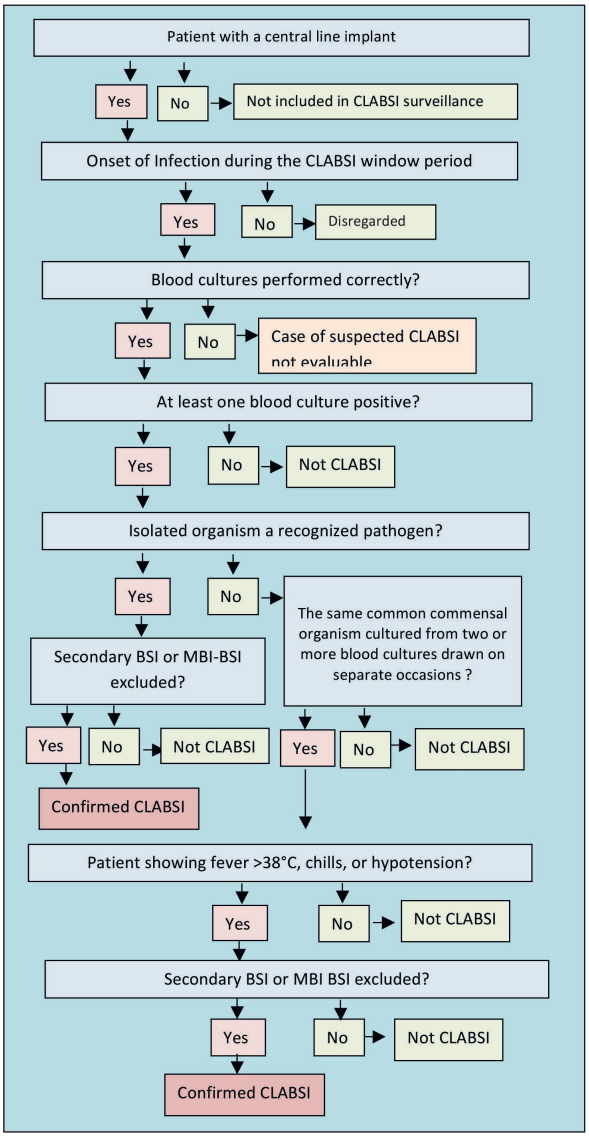

Figure 1 - CLABSI case support algorithm.

We identified 12 suspected cases of CLABSI using clinical information alone, 10 of which were also identified by laboratory data. In order to confirm or exclude infections present at admission (POA), secondary BSIs or MBI-LCBIs (*e.g.* neutropenia, infections from other body sites, mucositis), we combined the two information sources. Four cases of CLABSI were confirmed using the combined methods, representing 33% and 40% of suspected cases, respectively. Thus, a single source of information was not capable of confirming or excluding any suspected case of CLABSI (Table 4). One suspected case remained unconfirmed because of insufficient information. The patient in question had a central line in place and showed signs and symptoms of systemic infection but not of ongoing infection in other body sites in the CLABSI period window. Only one set of blood samples for culture had been taken from this patient over a period of 24 hours and a common commensal organism had been isolated. However, at least one more set of blood samples per site taken at a dif-

Table 1 - Device utilization and facility information.

Hospital characteristics	*Unit 1* No. patients*	*Unit 2** No. patients*	*Unit 3*** No. patients*
No. hospitalized patients	108	191	145
No. patients with CL in place	5	25	59
No. hospital beds under surveillance	42	46	36
No. hospital days under surveillance	1178	1405	913
Type of CL device in place during surveillance period			
Peripherally-inserted central catheter	1	4	54
Tunneled central venous catheter	-	1	11
Femoral line	-	2	3
Other central line	4	18	3

*Unit 1 = Internal Medicine Ward, Santa Maria della Scaletta Hospital, Imola, Italy
**Unit 2 = Internal Medicine Ward, Fidenza Hospital, Fidenza, Italy
***Unit 3 = Oncohematology Ward, Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori, Meldola, Italy

Table 2 - Instruments and resources used for data collection.

Indicator	*Required Information*	*Data source Unit 1**	*Person-time required per hospital bed on a monthly basis*	*Data source Unit 2***	*Person-time required per hospital bed on a monthly basis*	*Data source Unit 3****	*Person-time required per hospital bed on a monthly basis*
Device utilization rate	Patients with central lines	Electronic screening of patient records	3 minutes	Manual	6.5 minutes	Manual	8 minutes
	Central line days						
	Admitted patients	Electronic Admission Database					
CLABSI rate	Laboratory data: • Blood sample positivity • Isolated organism • Other body site cultures • Other laboratory data	Electronic screening of laboratory records during CLABSI window period	8.4 minutes	Electronic laboratory reports for the survey period	14.4 minutes	Electronic screening of laboratory records for all patients with device during CLABSI window period	52 minutes
	Clinical information	Total chart/ medical record review only for suspected patients		Total chart/ medical record review only for suspected patients		Total chart/ medical record review only for suspected patients	

*Unit 1 = Internal Medicine Ward, Santa Maria della Scaletta Hospital, Imola, Italy
**Unit 2 = Internal Medicine Ward, Fidenza Hospital, Fidenza, Italy
***Unit 3 = Oncohematology Ward, Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori , Meldola, Italy

Table 3 - CLABSI indicators and resources required for surveillance

	Unit 1	*Unit 2*	*Unit 3*	*Total*
CLDU (central line device utilization)	0.03	0.13	0.54	-
CLABSI rate	0	5.3	5.9	-
Bed-occupancy rate	95%	98%	88%	-
Person-time per hospital bed on a monthly basis	11.4 minutes	21 minutes	60 minutes	-
Central line days Suspected CLABSIs Confirmed CLABSIs	40 2 0	189 2 1	508 8 3	737 12 4

Table 4 - Ability of single data collection methods to detect and confirm CLABSI cases

	Laboratory data	*Clinical information*	*Combined methods*
Suspected cases	10	12	12
Confirmed cases (true positives)	Single method not capable of confirming cases	Single method not capable of confirming cases	4
False negatives	0	0	0
False positives	6	6	0
True negatives	79	77	87

ferent time within the same 24 hours would have been needed to confirm whether or not the second CLABSI criteria had been fulfilled.

DISCUSSION

Surveillance systems coordinated at the regional or national level are recommended by best practice documents [22]. In particular, the implementation of CLASBI surveillance in NCCUs is now considered of primary importance due to the increasing use of central line devices in these healthcare settings [16]. As far as we know, ours is the first study to investigate the feasibility of a NCCU-based surveillance system for CLABSIs coordinated at the regional level in Italy. The methods used for this study will enable us to implement a standardized regional surveillance system based on performance indicators, CDC CLABSI case definition criteria, a minimum data set, and a decision support algorithm to validate CLABSI cases. Such surveillance will help us to create an epidemiology of CLABSIs and to avoid variations in surveillance practices over time. It will also provide data that are comparable with international CLABSI rates in specific medical areas [18, 28].

The small number of cases and patients and the short observation period represent limits to the evaluation of secondary objectives, especially in relation to the assessment of the system's accuracy. There was also a risk of overestimating the number of catheter related BSIs, which is an accepted intrinsic risk of all CLABSI surveillance systems [29]. The primary objective of this pilot study was to propose a surveillance model, and the study design and methods used allowed us to evaluate its feasibility in clinical practice. Our study highlighted differences between the instruments used in the 3 hospitals involved, especially with regard to the level of computerization of medical and nursing records, resulting in different person-time costs incurred to monitor the indicator of device utilization among wards of the same medical specialty. At the same time, device utilization rates in specific medical areas influence person-time costs incurred on a monthly basis for CLABSI surveillance per hospital bed and such information is needed to identify areas in which to invest resources and maintain surveillance.
Limitations of our study were the small number of medical wards involved and the short duration of the surveillance period. Although we have no historical data on CLDU or CLABSI rates in medical

wards for comparison purposes, our findings suggest that onco-hematology wards may be a priority area in which to implement and maintain CLABSI surveillance. Manual data collection for at least three consecutive months is necessary in all NCCUs to identify priority areas requiring surveillance [30]. Furthermore, in medical wards where electronic data collection is possible, both data collection methods should be performed simultaneously to validate the accuracy of the computer-based data.
We observed one case in which it was not possible to confirm CLABSI because of insufficient information, suggesting that medical wards may differ in their clinical approach to patients with central line in place showing signs and symptoms of systemic infection. In such patients there must be clear indications about when to perform blood culture and the number of blood sample sets to collect for each site over a period of 24 hours.
Differences in the level of computerization of clinical records and in clinical approaches to patients with central line among hospitals represent the main barriers to implementing a surveillance system coordinated at the regional level.

CONCLUSIONS

The findings from the present study indicate that the instruments available in our region would permit a standardized CLABSI surveillance system to be successfully implemented. Our research group proposes the following strategy for adopting the studied model:

- NCCU patients with a central line should be monitored for signs and symptoms of infection on a daily basis and clinical data must be registered in medical records;
- For patients with a central line in place for at least 48 hours showing signs and symptoms such as fever >38°C, chills, or hypotension, we recommend drawing at least two blood sample sets per site at different time during a period of 24 hours;
- To define priority areas for surveillance, we recommend collecting data relating to device utilization manually and, where possible, also electronically, for at least three consecutive months. On the basis of device utilization rates, the Regional Health Care Agency, in accordance with Hospital Healthcare Administrations, will select medical areas in which to implement CLABSI surveillance;
- Each hospital implementing our surveillance system will be required to guarantee a minimum data set defined to monitor and evaluate performance indicators;
- The decision support algorithm should be used for CLABSI case validation.

Finally, we believe that the methods used for this feasibility study could also be applied in other surveillance system studies in the Italian context.

Conflict of interest
The authors have no conflicts of interest to disclose.

Statement of authorship
All authors designed the study and contributed to the definition of the surveillance model, the methods and the feasibility study. All authors contributed to the drafting of the manuscript and approved the final version for submission.

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