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Quality control of the surveillance programme of ICU-acquired infection (ENVIN–HELICS registry) in Spain

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SUMMARY

Background: Data validation is an essential aspect for the accuracy of a nosocomial infection surveillance registry.
Aim: To report the results of the first quality control programme in the national surveillance programme of intensive care unit (ICU)-acquired infection in Spain (ENVIN–HELICS registry).
Method: During 2008, of 13,824 records included in the database, 1500 (10.8%) registries from 20 ICUs were reviewed. These ICUs were selected at random and stratified according to the number of cases included in the registry. The proportion of infected patients, which was 9.6% [95% confidence interval (CI) 8.09–11.16], was maintained during the selection of cases for review. Two physicians were trained for the purpose of the study and undertook the review.
Results: Overall sensitivity, specificity and positive and negative predictive values of the ENVIN–HELICS registry for the identification of patients with any device-related infection acquired during their ICU stay were 86.0% (95% CI 80.0–92.0), 98.7% (95% CI 82.19–93.6), 87.9% (95% CI 82.19–93.6) and 98.5% (95% CI 97.8–99.2), respectively, with a kappa index of 0.85 (95% CI 0.79–0.92). Secondary bloodstream infection had the lowest sensitivity (59.3%), and intubation-associated pneumonia had the highest sensitivity (86.3%).
Conclusion: There was good correlation between data reported by the registrars and data validated by auditors, confirming the reliability of the ENVIN–HELICS registry.

Introduction

Surveillance of infections acquired in intensive care units (ICUs) is important to measure infection rates, assess the aetiology of the main infections related to invasive devices, and monitor the spread of multi-drug-resistant infections.[1–3] An active and efficient surveillance system for nosocomial infections is considered a quality criterion of inpatient care.[4] In Spain, a registry of ICU-acquired infections, named

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'Estudio Nacional de Vigilancia de Infecciones Nosocomiales en Unidades de Cuidados Intensivos' (ENVIN) (National Surveillance Study of Nosocomial Infections in Intensive Care Units) was developed in 1994 and has collaborated from its inception with the European registry 'Hospitals in Europe Link for Infection Control through Surveillance' (HELICS).[5,6] The ENVIN–HELICS registry is an ongoing, multi-centre data collection system, in which data are provided prospectively and participation is voluntary. It was designed to record infections related to invasive devices that developed during a patient's stay in an ICU. The registry includes information collected from admission to ICU discharge of patients admitted to participating Spanish ICUs. These ICUs account for approximately 55% of all ICUs in Spain. Although the registry includes safety systems to ensure the systematic recording of predefined basic variables and avoid the introduction of illogical values, external audits are recommended in order to guarantee the reliability of the results obtained, particularly those related to infections included in the registry.

Studies on the validity of nosocomial surveillance systems in critically ill patients admitted to ICUs have been reported in the literature.[7–9] An ideal or gold standard validation method is lacking because audits may be focused on very different aspects, such as checking the existence of patients included in the registry, the concordance of data recorded, or the adequacy of diagnostic criteria of infection.

This paper describes the results of the first audit or quality control of the ENVIN–HELICS registry. The aim of the study was to assess concordance between the information registered in the database and the information found in patients' medical records for data included in the registry in 2008, as well as to determine the sensitivity, specificity and positive and negative predictive values of the data recorded.

Methods

This was a retrospective review of randomly selected medical records of patients included in the ENVIN–HELICS registry in 2008. The main aim of the study was to evaluate agreement between the information retrieved from the registry and the information obtained from patients' medical records.

Characteristics of the registry

The ENVIN–HELICS registry includes data from patients admitted to the participating ICUs for more than 24 h between April and June each year. All adult ICUs participate on a voluntary basis. The participating ICUs are uniformly distributed throughout the country, and 87.1% are combined medical–surgical units. Surveillance infections include intubation-associated pneumonia, catheter-related urinary tract infection, primary bloodstream infection (BSI), BSI related to intravascular catheters and ICU-acquired BSI secondary to other foci. Data are collected using the ENVIN–HELICS software application located in a web-based server available at http://hws.vhebron.net/ENVIN–helics. The database (in SQL server) runs on the same server. A national report is published annually on the Internet, and each participating ICU has a daily update of their own data.

Audit methodology

Concordance of the information was assessed at each ICU by two physicians who were independent of the audited hospital. These physicians were specialists in intensive care medicine, familiar with the ENVIN–HELICS programme, and had received specific training in the surveillance of nosocomial infections. During the second quarter of 2009, they moved to the selected ICUs and reviewed the randomly selected medical records. The proportion of infected to non-infected patients was maintained in each ICU, but in some units where this was not possible (e.g. insufficient numbers of infected patients), this was compensated for by including a greater number of cases from another appropriately selected unit, which was similar in relation to the number of cases provided in the registry.

For each case, the following data were evaluated: case record identification number, age, date of admission to the hospital, date of admission to the ICU, date of discharge from the ICU, whether alive or dead at ICU discharge, underlying condition and ICU-acquired infections. Only infections associated with devices included in the ENVIN–HELICS registry were evaluated. Definitions of infections were those established in the HELICS European registry (http://helics.univ-lyon1.fr/protocols/icu_protocol.pdf) and included in the ENVIN–HELICS registry manual, available at http://hws.vhebron.net/ENVIN–helics/Help/Manual.pdf.

The auditor's assessment was considered final. Doubts were resolved by the auditing group assistant coordinators. Concordance of data was measured by evaluation of the clinical documentation for each patient and other complementary information, such as microbiology laboratory results and radiological studies. A deviation of one day from each recorded date was accepted. For ICU-acquired infections, a double assessment was performed; the concordance between the presence or absence of infection in the medical documentation and the individual registry for each patient, and the concordance for each of the infections controlled according to the pre-established diagnostic criteria. In all cases, reasons for discrepancies were discussed with the local physicians in charge of the ENVIN–HELICS registry.

The auditing process was approved by the ethics committees of two participating hospitals.

Sample size calculation

The total sample of 13,824 patients admitted to 118 ICUs from 109 hospitals in Spain accounts for approximately 55% of all Spanish ICUs. Two different ICUs from seven hospitals and three different ICUs from one hospital (that cares for patients with specific pathologies) participated in the ENVIN–HELICS registry. Thirteen ICUs with less than 50 cases registered were excluded, leaving 13,324 patients. Those ICUs that provided only 3.6% of the registries were arbitrarily excluded because of the low representation relative to the total number of patients, and the imbalance between the number of registries and the work load that may represent an audit in each unit. Based on the results of Zuschneid *et al.*,[7] the sample size was estimated for sensitivity of 66% and specificity of 99%. Precision was arbitrarily established at 8%, an intermediate number between 5% and 10%, with a 95% confidence interval (CI). Accordingly, the sample size of 1500 medical records (11.8% of the potentially evaluable population) was established. The