Impact of Hospital Care on Incidence of Bloodstream Infection: The Evaluation of Processes and Indicators in Infection Control Study

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The Evaluation of Processes and Indicators in Infection Control (EPIC) study assesses the relationship between hospital care and rates of central venous catheter-associated primary bacteremia in 54 intensive-care units (ICUs) in the United States and 14 other countries. Using ICU rather than the patient as the primary unit of statistical analysis permits evaluation of factors that vary at the ICU level. The design of EPIC can serve as a template for studies investigating the relationship between process and event rates across healthcare institutions.

Comparing Clinical Performance

Health-care organizations are increasingly expected to provide clinical outcomes data as measures of clinical quality to accreditation bodies, purchasers, and the public, under the premise that outcome variations indicate quality differences across organizations. Variation in clinical performance can result from variation in any number of factors, some relevant to improving the quality of care but many not. The best-studied source of variation in clinical performance measures is patient characteristics. Hospitals differ widely in the severity of illness and extent of coexisting illnesses in their patients, and much research has been devoted to developing risk adjustment methods to permit interhospital comparisons not confounded by patient characteristics (1). Hospitals also differ in methods of data abstraction and data management (2). Even subtle differences in definitions can introduce measurable variation in clinical performance (3).

Variations in patients, data collection, and definitions distract from collecting comparative data for quality improvement. To be useful, an indicator must be linked to measurable variation in clinical performance (4). To be useful, an indicator must be linked to measurable variation in clinical performance (4).

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focus is bloodstream infections, specifically those in intensive-care unit (ICU) patients.

Because hospital epidemiology is a mature discipline, infection control indicators offer excellent opportunities to demonstrate how processes of care relate to infectious disease outcomes. Hospital epidemiology has long addressed surveillance techniques, disease definitions, patient risk factors, and process factors that may influence disease rates (5-7).

**EPIC Study Design**

EPIC is two investigations under one name. The first investigation is designed to answer the following question: do the relative rankings of hospitals change, with indicators of bloodstream infection used for comparison? The design is relatively straightforward. With the assistance of the Centers for Disease Control and Prevention's Hospital Infections Program, the project identified six vendors offering different bloodstream infection indicators. A sample of 36 hospitals is collecting the data necessary to calculate these six indicators. When completed, the relative rankings of the hospitals across the set of indicators will be compared. The second investigation is designed to answer the following question: can variation in hospital care process explain variation in bloodstream infection rates across a sample of ICUs? The design for answering this question differs considerably from traditional epidemiologic designs (e.g., cohort and case-control designs).

**Patient Risk vs. Unit Rates**

EPIC relates process performance to variation in bloodstream infection rates across ICUs. Traditional epidemiologic designs focus on the prediction of disease risk for the individual patient. In a traditional cohort study, the processes of care under scrutiny would be documented in ICU patients with central venous catheters. Primary bloodstream infections are relatively rare, even in this vulnerable population; however, this rarity presents practical problems in study design. Given an average 3% risk to each patient, prospective cohorts would have to include approximately 2,500 patients to have 80% power to detect as statistically significant a twofold relative risk associated with an exposure common to 25% of ICU patients. The case-control design was developed to address situations in which the outcome under study is uncommon; however, case-control studies establish exposure status after the disease has occurred. Therefore, not all varieties of exposure can be studied. In hospital epidemiology, exposures that are reliably documented in the medical record (coexisting diseases, for example) can be studied by a case-control approach. However, relevant aspects of the process of care are not always documented (e.g., the experience of the central venous catheter inserter or the number of attempts at insertion) and may be difficult to establish retrospectively.

Even if all relevant process factors could be documented in advance, some factors cannot be studied within a single ICU or even across a small number of ICUs. In many instances, process exposures are mandated by hospital, ICU, or infection control policy. In this situation, all patients within an ICU may have catheters inserted with specific types of barriers or have a similar skin preparation before catheter insertion. If there is no variation in the process under study within an ICU, that process cannot be evaluated by examining patients within that ICU. One would need to examine many ICUs with varied processes to relate the process to disease risk.

Ultimately, traditional designs cannot address the variation in unit rates because they focus on the wrong unit of analysis, i.e., the patient rather than the ICU. To study variation in ICU bloodstream infection rates, the ICU is the appropriate unit of analysis. The ICU rate is an aggregate measure that represents the average risk for bloodstream infection. Strong but infrequent determinants of patient risk have relatively little influence on the unit rate. A certain process factor, like gross contamination at the insertion site, may be related to a marked increase in bloodstream infection risk for individual patients but may occur so rarely that the overall rate of infection is not noticeably influenced. Even if a strong determinant of risk were relatively common, it would not necessarily be an important determinant of differences in bloodstream infection rates across ICUs. For an exposure to affect variation in rates between ICUs, two criteria must be met. First, the condition must be common enough to influence the bloodstream infection rate, i.e., it must have a fairly high attributable risk. Second, there must be variation between ICUs in the proportion of patients affected. Even a strong factor will not explain differences if every ICU has the same proportion of patients affected. Conversely, a relatively modest determinant of patient risk could account for a substantial proportion of the variation between ICU infection rates if ICUs varied greatly in the proportion of patients exposed. The average patient and average process determine the ICU infection rate since the ICU rate is a function of the average patient risk. The difference between individual risk and population rates has been extensively explored elsewhere (8).

When the ICU is the unit of analysis, important difficulties in evaluating process can be resolved. First, factors that vary at the level of the ICU can be studied appropriately. Factors not routinely charted can also be studied efficiently. Since the goal of the evaluation is to relate the average process to the ICU rate, only data sufficient to adequately characterize the average process are required. Therefore, every insertion in an ICU does not have to be followed; a random sample of insertions allows characterization of typical performance. On the other hand, many ICUs must be studied, since the sample size of the project is not the number of patients in ICUs but the number of ICUs being compared.

**EPIC Process Assessment Design**

In 1998, the membership of SHEA and other interested persons were solicited to support participation of their respective hospitals in the study. Initially, 58 hospitals volunteered to participate (Table) (four were added later and eight withdrew). Data collection began in November 1998 and continued through January 2000, and data from 54 ICUs have been forwarded to the coordinating unit. The number of ICUs was determined by the willingness of epidemiologists and infection control personnel to participate in the study. However, the sample size is sufficient to evaluate important determinants of variation in ICU bloodstream infection rates. With a sample of 54 ICUs, a factor that explains 7% of the variance in the ICU rates would be statistically significant (alpha=0.05).

Because of its precise definitions and long history of use in the field, the National Nosocomial Infections Surveillance...
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References


