Evaluation of the surveillance of surgical site infections within the Dutch PREZIES network

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3

Validation of surgical site infection surveillance in the Netherlands

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Infection Control and Hospital Epidemiology 2007;28(1):36-41

ABSTRACT

Objective: To describe how continuous validation of data on surgical site infection (SSI) is being performed in the Dutch National Nosocomial Infection Surveillance System (Preventie Ziekenhuisinfecties door Surveillance [PREZIES]), to assess the quality and accuracy of the PREZIES data, and to present the corresponding outcomes of the assessment.

Design: Mandatory, 1-day validation visit to participating hospitals every 3 years. The process of surveillance, including the quality of the method of data collection, is validated by means of a structured interview. The use of SSI criteria is validated by review of medical records, with the judgment of the validation team as the criterion standard.

Setting: Hospitals participating in PREZIES.

Results: During 1999-2004, the validation team visited 40 hospitals and reviewed 859 medical charts. There was no deviation between reports of SSI by infection control professionals and findings by the PREZIES validation team at 30 hospitals and 1 deviation in each of 10 hospitals; the positive predictive value was 0.97, and the negative predictive value was 0.99. The validation team often gave advice to the hospital, aimed at perfecting the process of surveillance. On 2 occasions, data were removed from the PREZIES database after the validation visit revealed deviations from the SSI surveillance protocol that could have resulted in nonrepresentative SSI rate data.

Conclusions: PREZIES is confident that the assembled Dutch SSI surveillance data are reliable and robust and are sufficiently accurate to be used as a reference for interhospital comparison. PREZIES will continue performing on-site validation visits, to improve the process of surveillance and ensure the reliability of the surveillance data.

INTRODUCTION

Surgical site infection (SSI) is a common nosocomial infection that leads to increased morbidity and mortality, causes a longer hospital stay, and increases cost.[1-3] In the 1970s, the Study on the Efficacy of Nosocomial Infection Control showed that infection surveillance with feedback of the results to the staff reduces infection rates.[4] In a nosocomial infection surveillance system, infection rates are compared within and between hospitals. To ensure the quality and reliability of surveillance data, surveillance methods should be standardized, and a clear statement of the criteria used to analyze the patients, procedures and infection variables must be included.[5] Validation is the only independent means to determine the accuracy for surveillance data, and thus it is essential for determining the reliability of a SSI surveillance network in which data are aggregated from multiple data collectors and used for comparisons between hospitals.

In recent decades, national surveillance systems for detection of nosocomial infections have been set up in many countries. Data are being collected from several institutions and gathered in one national reference database in these multi-hospital surveillance systems, and ensuring the quality of surveillance data is the responsibility of both the participating hospitals and the organization managing the surveillance system. The accuracy of the data depends on the experience, qualifications, training and awareness of the surveillance staff,[6-8] and all staff must work according to the same protocol and use the same definitions accurately. Validation is necessary to get insight into the reliability of data. Furthermore, validation may identify difficulties within each hospital and within the surveillance program.[9]

Although many countries perform nosocomial infection surveillance, hardly anyone has reported about validation of data. Most of the few published studies regarding validation were performed in only one institution or hospital,[10,11] and often only the outcome was validated and not the process.[8,11-13] To our knowledge, no national surveillance system other than that in the Netherlands validates nosocomial infection data continuously. In Germany, Gastmeier et al.[7] performed a validation study of the prevalences of nosocomial infection among 14,966 patients at 72 hospitals. A remarkable difference in accuracy was found among the institutions. Because this was a prevalence study, many patients had to be included because of the low incidence of infection, and sometimes the presence of a SSI could not be assessed because laboratory test results were not yet available. The National Nosocomial Infection Surveillance system (NNIS) performed a validation study of surveillance for nosocomial infection in intensive care units,13 but the NNIS does not validate data on SSI surveillance. Their SSI data are considered reliable because all participating infection control professionals (ICPs) undergo surveillance training for 2 weeks and because standardized and validated data collection protocols are used. In addition, because the surveillance system is voluntary and confidential, ICPs are thought to have no incentive to provide incorrect estimates of their results. In the United States, 2 separate validation studies have been performed. The hospital-wide nosocomial infection surveillance at the University of Iowa Hospitals and Clinics was validated in 1987. The validation of SSI surveillance data for 953 patients revealed a sensitivity of 81%, a specificity of 98%, a positive predictive value of 75%, and a negative predictive value of

98%.[10] During 1990 and 1991, the Regional Medical Center at Memphis (Memphis, TN) validated SSI surveillance data for 925 patients and found a sensitivity of 84% and a specificity of 99.8%. Accuracy of the data seemed to be related to experience of the surveillance staff, and incisional SSIs appeared to be more difficult to identify than deep SSIs.[11]

In this article, we describe how continuous validation is being performed in the Dutch National Nosocomial Infection Surveillance (Preventie Ziekenhuisinfecties door Surveillance [PREZIES]). Furthermore, we give the results of our validation of the process of data collection and the interpretation of the criteria used to define SSI.

METHODS

SSI surveillance

PREZIES was set up in 1996 as a collaboration between the National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu), the Dutch Institute for Healthcare Improvement CBO, and participating hospitals.[14] Hospital participation in PREZIES is voluntary and confidential. Surveillance for SSI was the first component in the network, and since 1996 data have been collected from 64 of the 98 Dutch hospitals on 143,321 surgical procedures and 4,625 SSIs. Hospitals collect data prospectively according to a protocol that specifies the data to be recorded and the definitions to be used. The SSI definition used in PREZIES is based on the definition used by the Centers for Disease Control and Prevention,[15] with the additions that there must always be clinical symptoms and that diagnosis by only a surgeon or attending physician is not decisive. The method for data collection during the patient's hospital stay is not described in detail in the protocol; each hospital can organize this in a way that is optimal for their organization. Usually, data on surgical procedure and SSI are collected for each patient during ward visits by the ICP, which makes review of patient charts or reports and personal discussion with nurses or physicians possible. If an SSI is suspected, results of microbiologic analyses are also examined. Postdischarge surveillance is voluntary within PREZIES, but a method for postdischarge surveillance that is feasible to all Dutch hospitals has been recommended and is described in the protocol.[16] Currently, 50% of the participating hospitals perform postdischarge surveillance according to the recommended method and 20% according to another active postdischarge method.

On-site validation

Within the PREZIES network, a validation study was performed in 1997, comprising a process validation (involving 32 hospitals) and a prevalence study (involving 6 hospitals).[17] Voluntary on-site validation was implemented in 1999, and since 2002 validation has been mandatory for each participating hospital.

Validation of PREZIES data is a continuous process that includes investigating the quality of data collection (completeness and reliability) and interpretation of the criteria for assessing a SSI in accordance with the protocol. Each participating hospital is validated once every 3 years for every surveillance component that the hospital participates in. The hospital is visited by a validation

team, consisting of a PREZIES team member plus an ICP from a previously validated hospital. The validation visit takes 1 day. The process and the outcome of surveillance are examined. The process of surveillance is validated by means of a structured interview. The items that are discussed are shown in Table 1. For validation of the outcome data, the team aims to review the 20 most recently completed medical records of patients regardless of SSI status and the 5 most recently completed medical records of patients who received a diagnosis of SSI from the hospital ICP. In addition, the ICP can present 5 doubtful diagnoses to the validation team. The team assesses whether an SSI was present and, if present, whether it was a superficial, deep, or organ/space infection. The judgment of the validation team is considered the "gold standard". The results of the validation team are compared and discussed with those of the ICP of the hospital undergoing validation. By doing this, the ICP's interpretation and use of the criteria for diagnosing SSI can be evaluated.

Since 2005, an epidemiologist of the PREZIES team makes a prevalidation report in advance of each validation visit. The goal of the report is to improve the validation team's preparedness and enable its members to ask more-specific questions during the validation visit. The prevalidation report gives information about the surgical procedures under surveillance, the infection rate per procedure (relative to the reference rate), the method for postdischarge surveillance, the number of missing data for some important variables, and the distribution of American Society of Anesthesiologists physical status (ASA) classification and wound contamination class (relative to national data) reported by the hospital for which a validation visit is scheduled. So far, this prevalidation report has proven to be very practical, with supplemental value for both the validation team and the validated hospital.

Table 1. Checklist for interviews to validate the process of surveillance.

General
Actuality of registration plan, software, and protocol of PREZIES
Is use of patient data for surveillance mentioned in patient brochure?
Is privacy of patients guaranteed?
Is surveillance announced to the Dutch Data Protection Authority?
Process related
What type of procedures are included and why?
Method for including patients in the surveillance
Are selection criteria used for including patients?
Are responsibilities of all participating people recorded (eg, who delivers which data, who collects the data, who imports data into computer)?
Method for tracing SSIs
Feedback and application of surveillance results
Is internal validation performed (eg, check whether anesthesist reports correct ASA score and whether surgeon reports correct wound contamination class)?
Is postdischarge surveillance performed, and how?
Items from the prevalidation report (eg, completeness of the data)
Outcome
Application and interpretation of criteria for risk factors and SSI by reviewing medical records

ASA, American Society of Anesthesiologists; *PREZIES*, Preventie van Ziekenhuisinfecties door Surveillance (Dutch National Nosocomial Infection Surveillance System).

Within 2 weeks after the validation visit, the PREZIES team member writes a validation report in which all discussed items are reported. This report is sent to the hospital's ICP, who discusses it with other members of the surveillance staff.

If the validation team finds that the hospital does not follow the protocol in detail (eg, the ICP instead of the surgeon records the wound contamination class) or has not organized the surveillance in an optimal way, it will advise improvements. If major deviations from the protocol are observed (eg, excluding pediatric patients from surveillance), the data will be retrospectively adjusted, if possible. If this is impossible or too time-consuming, the data will be excluded from the national database. In addition, the hospital will be validated again within 1 year. These actions are also taken if the criteria for SSI are not used properly by the surveillance staff (eg, reporting SSI for a patient with a positive culture result but no clinical symptoms).

Analysis

From the results of the hospitals that were validated, we tried to assess the nondifferential misclassification of disease by the ICP. Possible tools for this purpose include the positive predictive value (ie, the proportion of patients for whom the ICP reported SSI who truly had SSI), the negative predictive value (ie, the proportion of patients for whom the ICP did not report SSI who truly did not have SSI), the sensitivity (ie, the proportion of patients who truly had SSI and also had SSI reported by the ICP), and the specificity (ie, the proportion of patients who truly did not have SSI and also did not have SSI reported by the ICP).

If all medical charts were selected on the basis of whether a patient truly had SSI, it would be possible to calculate the sensitivity and specificity. However, patient selection for the validation study is (partly) based on SSIs reported by the ICP, and such patients may not truly have SSI. Therefore, only the positive and negative predictive values could be assessed. Because the SSI rate in the sample undergoing validation is likely artificially higher than the overall rate in the database, calculating the sensitivity and specificity from these data would be incorrect.

We calculated 95% confidence intervals for the positive and negative predictive values, using the quadratic equation described by Fleiss.[18]

RESULTS

During 1999-2004, the validation team reviewed 859 medical charts from 40 hospitals. Table 2 shows the results of the validation of the outcome, including a positive predictive value of 0.97 (ie, 97% of the 149 patients who had SSI diagnosed by the ICP, truly had SSI) and a negative predictive value of 0.99 (ie, 99% of the 710 patients who had no SSI diagnosed by the ICP, truly had no SSI). In 30 hospitals, no disagreement occurred. In each of the remaining 10 hospitals, the opinion of the ICP regarding the presence of SSI differed on one occasion from that of the validation team, resulting in 4 false-positive diagnoses and 6 false-negative diagnoses. The results include the diagnoses that the ICP thought were doubtful.

Table 2. Validation results for surgical site infection (SSI) diagnoses reported in 859 medical records from 40 hospitals in the Dutch national nosocomial infection surveillance system, 1999-2004.

	No. of records		
	Diagnosis by validation team[a]		
Diagnosis by hospital ICP	SSI	No SSI	Total
SSI	145	4	149
No SSI	6	704	710
Total	151	708	859

The positive predictive value was 0.97 (95% confidence interval, 0.95-0.999).
The negative predictive value was 0.99 (95% confidence interval, 0.98-0.998).
ICP, infection control professional.
[a] The "gold standard" for this comparison.

The validation team often gave advice to the hospital, aimed at perfecting the process of surveillance. The most common advices was to perform internal validation more often (*see* Discussion), communicate the surveillance results more widely within the hospital, use the PREZIES criteria for defining SSI, choose procedures for which improvement is possible or procedures done by surgeons who are willing to participate, perform postdischarge surveillance, and avoid limiting surveillance to certain patients and to certain surgical procedures, because such restrictions are not allowed (eg, excluding children or excluding patients with a hospital stay of less than 24 or 48 hours).

Since we started validating the SSI surveillance, data have been removed from the database twice, because of outcomes of the validation visits. Selection bias was evident at one hospital, because surveillance data after hallux valgus procedures were only reported for patients with a hospital stay of at least 48 hours. No differences in assessment of SSI by the ICP and the validation team were observed. In another hospital, the validation visit revealed a substantial lack of information about surgical wound healing in patient medical charts, which potentially led to severe underreporting of infections. During this latter validation visit, assessments of medical charts by both the validation team and the ICP did not reveal any SSI. Retrospective review and correction of the data at each hospital was not possible. Exclusion of these data from the overall results shown in Table 2 would not change our estimation of the positive and negative predictive values.

DISCUSSION

The primary goal of validation is to ensure the quality of data. Results of the ongoing validation study within PREZIES showed that the process of data collection was accurate in 38 of 40 hospitals and that the overall accuracy of SSI assessment by ICP's was high. Validation of the outcome parameter (presence of SSI) showed that the opinion of of the ICP differed from the gold standard in only 10 (1%) of the 859 reviewed medical charts, which resulted in a positive predictive value of 0.97 and a negative predictive value of 0.99. At the time of writing, data have had to be removed from the national database on 2 occasions. The validation findings within PREZIES showed that validating must include the outcome as well as the surveillance process, to discover possible deviations from the PREZIES protocol, such as patient selection. As a result of our ongoing validation results,

PREZIES is confident that the assembled Dutch SSI surveillance data are reliable and robust and are sufficiently accurate to be used as a reference database for interhospital comparison. Data for other Dutch surveillance parameters (central-line associated sepsis, ventilator-associated pneumonia, and SSI after heart surgery) are also validated, but the number of participating and validated hospitals is currently too small for analysis.

The outcomes of the validation visits revealed high positive and negative predictive values. In fact, these may even be slightly higher than we report, because the cases of SSI indicated as doubtful by the ICP were also included in the estimation. If we analyzed the 25 most recent medical charts for validation, without specifically selecting 5 medical charts in which ICPs reported SSI, we would be able to calculate the sensitivity and specificity of the SSI data. However, in the current analyses we cannot exclude the charts in which SSI was reported by the ICP or charts with a doubtful diagnosis, because the reason for inclusion of each chart in the validation was not available. In addition, to evaluate the correct use of SSI criteria, one needs enough patients with and enough patients without true SSI. Our experience has shown that it is possible to validate 25 medical charts during a 1-day validation visit. As the SSI incidence is low in the Netherlands (3.2% overall), 25 medical charts would on average include 1 SSI, resulting in unreliable estimates of the sensitivity, the specificity, and the positive and negative predictive values. Therefore, it was decided that the validation should include 5 medical charts in which SSI was reported by ICPs.

We have chosen to perform the first validation visit during the first year after the hospital starts surveillance, so that, if necessary, surveillance methods can be improved and faulty data can be adjusted retrospectively. Because employees involved in surveillance within a hospital may change quite often, it is necessary to organize validation visits on a regular basis. Regular validation visits are also necessary because a hospital may change the types of procedures under surveillance (eg, from orthopedic surgery to general surgery), which involves other personnel. We think, therefore, that performing validation visits not only once but continuously is necessary to ensure the accuracy of the data. To our knowledge, no other country validates their national nosocomial infection surveillance data continuously. We realize that validation studies are often technically difficult and costly. The validation method used by PREZIES also requires substantial effort and cost, but it is feasible for the Dutch nosocomial surveillance system, mainly because the Netherlands is a small country. Currently, only 55 of 98 hospitals in the Netherlands participate in PREZIES, which means that 20-30 validation visits are needed every year; the visits, including traveling, can be done within a day.

Despite training and instructions, the validation visits revealed minor deviations from the protocol, but overall, surveillance was usually performed accurately. Some deviations from the protocol were caused by lack of knowledge; for example, one ICP did not realize that excluding outpatient or emergency procedures could bias results. Other deviations developed as a result of poor cooperation of personnel; for example, one ICP documented the ASA classification and wound contamination class because the anesthetist and surgeon did not record those items. In addition to detecting defections, a validation visit also offers the opportunity to improve surveillance by giving the ICP advice (eg, how to improve internal validation) or by advising the ICP to switch the

surveillance to other types of surgical procedures. Furthermore, visits improve the communication between the PREZIES team and the participating hospitals, decrease the threshold for the hospitals to ask questions, and increase PREZIES team's insight into the daily routine of surveillance at the hospitals.

In addition to on-site validation visits, several other factors contribute to the optimization of the Dutch surveillance data. First, all ICPs in the Netherlands have finished a 1.5-year education program that includes courses in surveillance and basic epidemiology. Second, data received by PREZIES are checked for obvious mistakes by software that is especially developed for this purpose. For example, the wound contamination class must be between 1-4, the date of birth must be before date of surgery, and values of mandatory variables must be recorded. In addition, each year, before the national surveillance data are reported, review of the aggregated database is conducted, including confirmation that no men are reported as having had gynecological surgery performed, that no duplicate records are present, and that no SSIs were detected later than 30 days after surgery (or 365 days after surgery, for patients who received a nonhuman implant). Third, during yearly meetings for network participants, methodological points are discussed, participants' experiences exchanged, and SSI case studies are presented and discussed. Since 2003, PREZIES has also organized a 1-day workshop for ICPs and other surveillance staff who are planning to start surveillance. During the workshop, PREZIES provides general information and tips about how to set up the surveillance. Fourth, PREZIES has a Web site on which general information, protocols, reference data, and news items are published. Surveillance staff can review SSI definitions by analyzing case studies that are published on the PREZIES Web site every 2 months. Fifth, PREZIES often publishes surveillance-related articles in the primary Dutch journal for ICPs (*Tijdschrift Voor Hygiëne en Infectie Preventie*). Finally, experiences are shared among participating hospitals through discussions on best practices, and PREZIES introduces ICPs from different hospitals in order to exchange knowledge.

Generally, several people are involved in collecting data and tracing and determining SSIs. Data are derived from various hospital information systems, and several disciplines from different departments are involved. In some organizations, a secretarial department is responsible for data entry. In PREZIES, one person – usually the ICP - is responsible for surveillance data. When part of the surveillance is done by other personnel, this person must ensure that everyone works according to the protocol, using the correct definitions for all recorded variables and SSIs. The responsible person should, therefore, perform internal validation by periodically reviewing the process, confirming that definitions are being applied correctly, and confirming that data entry accords with established protocol. Performance of internal validation is recommended in PREZIES, and guidelines for performing internal validation are described in an article published in *Tijdschrift Voor Hygiëne en Infectie Preventie*.[19] The advised method for internal validation is very similar to that for external validation, except that internal validation concerns not only the presence of SSI but also correct use of the definitions of other variables (eg, wound contamination class, ASA classification, and culture findings). Internal validation can be done regularly within a hospital after the start of data collection, especially after a change in the surgical procedures undergoing

surveillance or after changes in surveillance staff. We have observed an increase in the use of internal validation at participating hospitals, which contributes to accuracy of surveillance data.
In conclusion, to facilitate interhospital comparisons within a national surveillance network, data integrity is essential. Validation of the data from the Dutch nosocomial surveillance network PREZIES is included as an important aspect of the surveillance system. PREZIES will proceed with this strategy to keep in touch with daily surveillance practice within the hospitals, to improve the process of surveillance, and to ensure reliability of the surveillance data.

ACKNOWLEDGEMENTS

We thank all PREZIES participants who have contributed to the improvement of the network by means of active participation in the validation visits, both on the receiving and visiting end. We gratefully acknowledge all PREZIES hospitals that contribute to the aggregated PREZIES database.

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