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Use of statistical process control charts in the epidemiological surveillance of nosocomial infections

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ABSTRACT

Objective

To monitor occurrence trends and identify clusters of nosocomial infection (NI) using statistical process control (SPC) charts.

Methods

Between January 1998 and December 2000 nosocomial infection occurrence was evaluated in a cohort of 460 patients admitted to the Pediatric Intensive Care Unit of a university hospital, according to the concepts and criteria proposed by the National Nosocomial Infection Surveillance System of the Centers for Disease Control, in the United States. Graphs were plotted using Poisson statistical distribution, including three horizontal lines: center line (CL), upper warning limit (UWL) and upper control limit (UCL). CL was the arithmetic mean NI rate calculated for the studied period; UWL and

UCL were drawn at 2 and 3 standard deviations above average NI rates, respectively. Clusters were identified when NI rates remained above UCL.

Results

Mean NI incidence was 20 per 1,000 patient days. One urinary tract infection cluster was identified in July 2000, with an infection rate of 63 per 1,000 patient days, exceeding UCL and characterizing a period of epidemic.

Conclusions

The use of SPC charts for controlling endemic levels of NI, through both global and site-specific evaluation, allowed for the identification of uncommon variations in NI rates, such as outbreaks and epidemics, and for their distinction from the natural variations observed in NI occurrence rates, without the need for calculations and hypothesis testing.

Keywords

Epidemiological surveillance. Cross infection. Infection control. Endemic diseases. Statistical graphs. Incidence. Inpatients. Intensive care units, pediatric. Hospitals, university.

INTRODUCTION

Traditionally, three different categories of risk factors associated with nosocomial infection (NI) acquisition have been described: factors inherent to patient, to invasive procedures and to hospital environment. The study of these factors can guide the selection, implementation, and evaluation of control measures for this type of infection.

One of the goals of epidemiological surveillance and of NI control programs is to establish the endemic rates of this type of infection. Consequently, the continuous monitoring of endemic levels can identify increases in baseline NI rates, which, in a small proportion of cases, may be significant, constituting outbreaks or epidemics.[8,9]

Variations in nosocomial infection incidence rates are common. In order to demonstrate significant differences in NI occurrence during different time periods, statistical models that include tests for means, variance, and proportions, among others, are usually employed. [3,11,12] However, if frequent analyses of clustered data are to be carried out, repetitive hypothesis testing is not practical, especially if there is no evident outbreak. Thus, there is a need for statistical procedures capable of simplifying acute variation detection and of continually evaluating event occurrence trends.[14]

Graphic statistic methodology consists in building and statistically analyzing control diagrams in order to study variations in collected data.[1,2,14] Control diagrams are graphs based on the Theory of Probabilities, which allow for comparisons between the observed incidence of a given event and the maximum and minimum incidence expected. The underlying principle of control diagrams as applied

to nosocomial infections is that NI rates present natural variations around the mean value, and that more distant values have smaller probability of representing random events.

The observation of NI occurrence and the evaluation of its variability show that NI incidence in a given time period tends to follow a statistical probability of occurrence frequently resembling normal distribution. These observations also reveal that significance tests have the ability to determine whether or not chance is a likely explanation for the difference in the values obtained.[1,2,14]

There are many different types of variables with different probabilities of distribution, such as measured values, counts, fractions, and rates. For each of these situations there is an appropriate graph model, usually referred to using letters np, p, c, u, X, and S. Graph type selection depends on the statistical distribution of the probabilities described by the studied variable: X and S for data with normal distribution, c and u for Poisson distribution, and np and p for binomial distribution.

Poisson distribution consists in the probability of distribution of the number of occurrences of a random event in a given interval of time or space. It frequently offers good statistical models when the number of occurrences is small, such as bacteremia/central vascular catheter day, or NI/patient day. Graphs c or u are the choice for monitoring total number or rate of occurrences per time period, respectively.[1,2,14]

The present study describes the construction and interpretation of a control diagram for the endemic level of NI/patient day rates, in an pediatric intensive care unit of a university hospital.

METHODS

A prospective cohort study was conducted in a pediatric intensive care unit (PICU) of a public general university hospital, between January 1998 and December 2000.

This hospital has 461 beds, of which 105 are reserved for children. The PICU is a general four-bed unit designed to care for children ages 29 days to 13 years, with a yearly admission rate of roughly 200 children.

Epidemiological surveillance of nosocomial infections was carried out systematically. Diagnostic concepts and criteria used for case identification were those proposed by the National Nosocomial Infection Surveillance System (NNIS) of the Centers for Disease Control and Prevention (CDC), in Atlanta in the United States,[7,10] and by the Brazilian Ministry of Health.[13]

Data collection was carried out between January 1998 and December 2000. General NI rates per 1,000 patients and site-specific infections per 1,000 procedures day were determined on a monthly basis.

Graph u, based on a Poisson probabilistic distribution, was selected for the monitoring of the rates of NI per thousand patient days. Diagram construction stages included: [14]

Stage 1

Mean NI incidence rate in the studied period (X) calculation, X= total n. Of infections/ total n. Of patient days.

Stage 2

Monthly mean patient days calculation.

Mean patient days = n. of patient days/ total n. of months.

Stage 3

Standard deviation of NI rates (σ)

$\sigma = \sqrt{X / n}$ where: X = mean incidence rate, n = number of patient days for each month of the study

Since the number of patient days for each month varied more than 20% in relation to mean patient days, σ was calculated for each month of the study.

Stage 4

Parallel line calculation

Central line – representing the mean NI incidence rate (CL).

Upper warning limit (UWL) – representing $X + 2\sigma$

Upper control limit (UCL) – representing $+ 3\sigma$

Lower control limit (LCL) – representing a $X - 3\sigma$. When the values obtained for LCL were negative (<0), they were limited by the x-axis (abscissa zero).

Stage 5

Monthly incidence calculation and plotting in graph.

Stage 6

Diagram interpretation. Statistical stability of NI rates was verified through the absence of the following criteria:

one of the rates was above UCL or below LCL;

two or three consecutive rates between 2σ and 3σ , on the same side of CL:

nine consecutive rates on either side of CL;

six consecutive rates with decrease or increase;

fourteen consecutive rates alternating between above and below CL;

fifteen consecutive rates below CL;

The presence of any of these parameters indicated the need for investigating and reevaluating epidemiological surveillance, since the NI rate distributions described in each of the criteria above have little probability of occurring by chance alone. [1,2,14]

Epidemic periods were defined when the NI rate rose above UCL. The presence of outbreaks lead to the construction of new diagrams, excluding such periods from the NI incidence means, standard deviations, and control limits.[1,2,14]

RESULTS

Between January 1998 and December 2000, 50 of the 460 patients admitted to the PICU had 60 episodes of nosocomial infection.

Monthly average was 83 patients. Mean NI incidence was 20.0 per thousand patient days, as seen in Table 1. Incidences of ventilator-associated pneumonia, central vascular catheter-associated bloodstream infection, and urinary catheter-associated urinary tract infection was 9.1 per thousand ventilator days, 7.0 per thousand central vascular catheter days, and 7.3 per thousand urinary catheter days, respectively. Invasive device utilization density was 0.66 for ventilator, 0.77 for central vascular catheter, and 0.51 for urinary catheter.

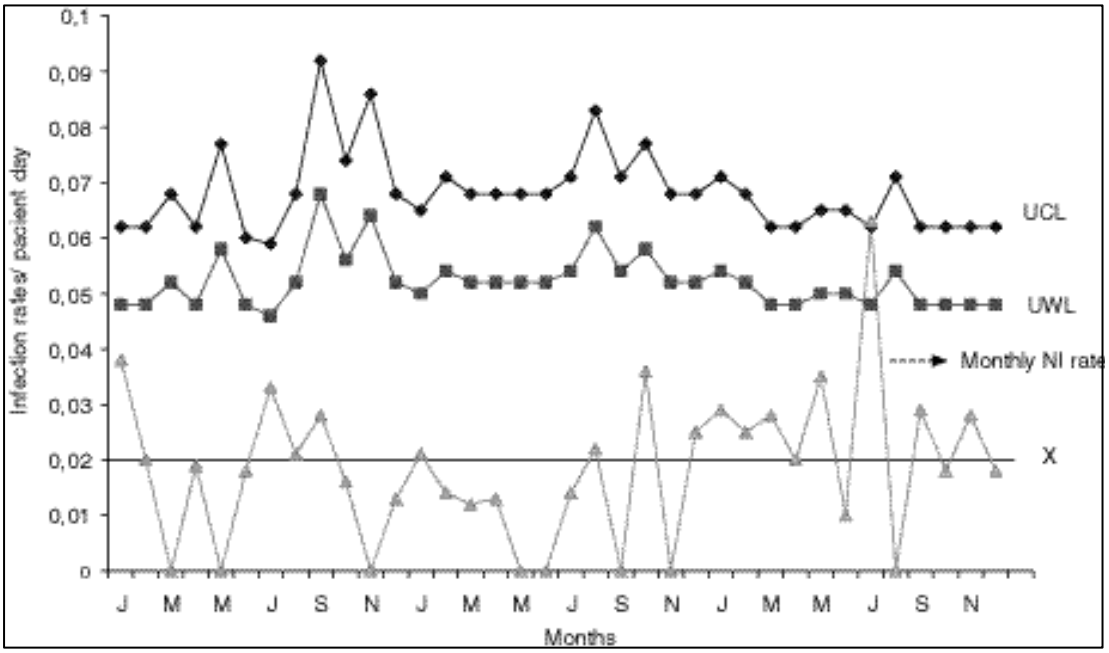
Table 1 – Nosocomial infection distribution, according to month/year and monthly number of patient days.

Month/ Year	NI	Patient day	Month/ Year	NI	Patient days
January / 1998	4	103	July / 1999	1	69
February / 1998	2	100	August / 1999	1	44
March / 1998	0	79	September/ 1999	0	74
April / 1998	2	101	October / 1999	2	55
May / 1998	0	63	November/ 1999	0	75
June / 1998	2	106	December/ 1999	2	78
July / 1998	4	119	January / 2000	2	69
August / 1998	2	94	February / 2000	2	80
September/ 1998	1	35	March / 2000	3	106
October / 1998	1	60	April / 2000	2	100
November / 1998	0	40	May / 2000	3	85
December/ 1998	1	77	June / 2000	1	92
January / 1999	2	92	July / 2000	7	110
February / 1999	1	69	August / 2000	0	73
March / 1999	1	79	September/ 2000	3	101
April / 1999	1	76	October / 2000	2	111
May / 1999	0	84	November/ 2000	3	105
June / 1999	0	83	December/ 2000	2	108

Sixty nosocomial infection episodes / 2,995 patient days

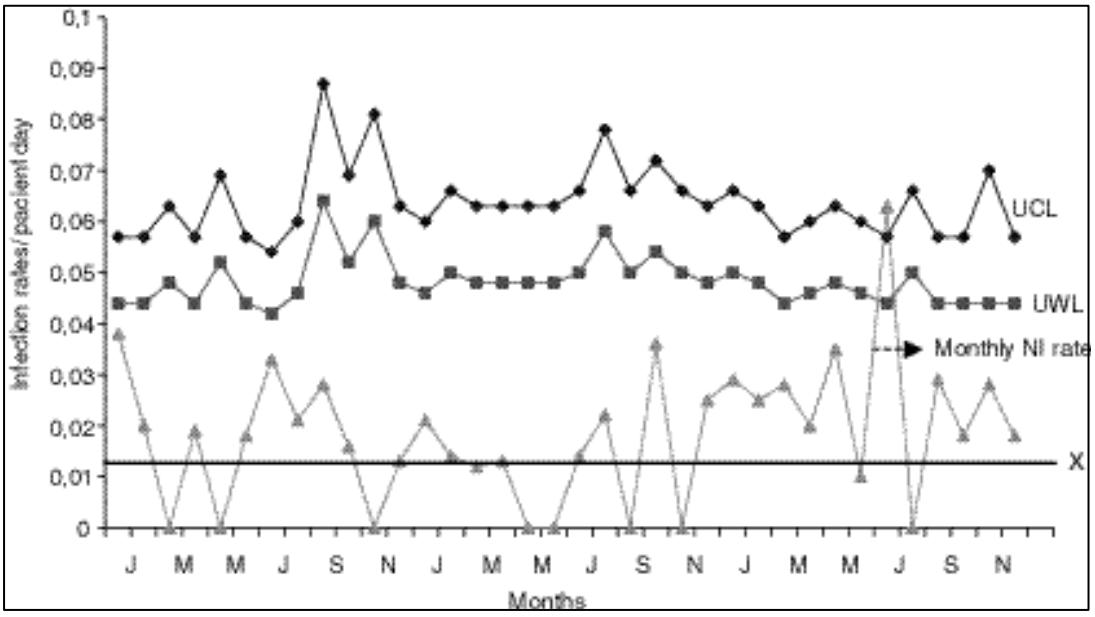
NI – nosocomial infection

Figure 1 presents the control diagram demonstrating the endemic limits of NI incidence per thousand patient days.



UCL – upper control limit (3σ + X), UWL – upper warning limit (2σ + X), X – central line (mean NI rate = 0.020).
Figure 1 – Endemic nosocomial infection level / patient-days in the January 1998 – December 2000 period.

The NI rate in July 2000 was 63.0 per thousand patient days, exceeding UCL, and characterizing a period of epidemic. This lead to the construction of a second control diagram, in which the month of the outbreak was excluded from mean NI incidence calculation, as shown by Figure 2. Mean NI rate in this evaluation was 18.0/1,000 patient days. No new outbreaks or other deviations from the expected NI rate distribution around the mean value were identified.



UCL – upper control limit (3σ + X), UWL – upper warning limit (2σ + X), X – central line (mean NI rate = 0.018).
Figure 2 - Endemic nosocomial infection level / patient-days in the January 1998 – December 2000 period, excluding the epidemic period from mean NI occurrence rate calculation.

During the period of epidemic, seven cases of NI were identified; three of catheter-associated urinary tract infection, one of ventilator-associated pneumonia, one of suppurated middle-ear otitis, also ventilator-associated, one of tracheitis in patients under mechanical ventilation, and one of central vascular catheter-associated phlebitis. Graphical evaluation of endemic level site-specific occurrence identified urinary tract infection (UTI) as the source for the July 2000 NI outbreak.

Table 2 presents an evaluation of UTI incidence in the 36 months of the study. Roughly one-half of the patients required urinary catheters – utilization density and mean catheterization period for this device were 0.51 and 6.8 days, respectively. Eleven cases of UTI were identified, all of which were associated to urinary catheterization. Candida spp was the microorganism most commonly isolated, through urine culture, occurring in nine patients, followed by E. faecalis identified in one patient, and K. pneumoniae associated with E. coli in another.

Table 2 – Urinary tract infection distribution, by month/year and monthly urinary catheter days.

Month/Year	UTI	Vesical cath.-days	Month/Year	UTI	Vesical cath. days
January / 1998	0	54	July / 1999	0	35
February / 1998	0	38	August / 1999	0	22
March / 1998	0	37	September/ 1999	0	41
April / 1998	0	55	October / 1999	0	37
May / 1998	0	19	November/ 1999	0	53
June / 1998	0	78	December/ 1999	1	45
July / 1998	1	67	January / 2000	1	34
August / 1998	0	66	February / 2000	1	50
September/ 1998	0	28	March / 2000	1	56
October / 1998	0	15	April / 2000	0	20
November / 1998	0	16	May / 2000	0	45
December/ 1998	0	30	June / 2000	0	69
January / 1999	1	84	July / 2000	3	59
February / 1999	0	16	August / 2000	0	24
March / 1999	0	25	September/ 2000	0	63
April / 1999	0	47	October / 2000	0	55
May / 1999	0	31	November/ 2000	1	54
June / 1999	0	24	December/ 2000	1	25

Eleven urinary infection episodes / 1,517 urinary catheter days

UTI – urinary tract infection

Mean UTI incidence for the 36-month period was 7.3 episodes per thousand urinary catheter days. Between February and November 1999, UTI rates remained constantly below mean incidence. There was an increase in occurrences during the December 1999-March 2000 period, albeit not statistically significant. An UTI outbreak occurred in July 2000, when urinary catheter-associated UTI rate rose to 50.9 per thousand catheter days. Mean UTI incidence excluding the month of the epidemic was 5.5 episodes/1,000 urinary catheter days; no further outbreak periods were identified.

DISCUSSION

Variations in nosocomial infection incidence are common during epidemiological surveillance. There is a constant concern with outbreaks and deviations above and below the rates considered as normal, and the observation of incidence rates alone does not provide enough evidence for deciding whether or not they are within the normal values expected.

In order to statistically assess NI indicators, the methodology proposed by NNIS constructs models based on the distribution of events in medians and percentiles.[4] However, the absence of indicators for sets of Brazilian pediatric intensive care units prevents the construction of a national distribution model according to these parameters. Thus, NI rate monitoring is carried out through external comparisons, using data from the annual NNIS System reports.

During the three years of the present study, there was a high utilization density for invasive devices, above Percentile (P) 90.0% when compared to those published by the NNIS System, probably reflecting the gravity of the cases admitted to the PICUs.[4] The analysis of incidences of bloodstream infection per thousand central vascular catheter days, pneumonias per thousand ventilator days, and urinary tract infection per thousand urinary catheter days showed values constantly above P 50% and below P 90%, therefore not indicating significant deviations in the occurrence of these infections. Nevertheless, annual evaluation demonstrated that the urinary infection rate for the year 2000 was above P 90%, suggesting the existence of control problems for this infection.

A comparison of results obtained in different studies must be approached cautiously, even when dealing with similar methodologies. Differences in laboratory testing availability and utilization for NI diagnosis purposes and in the intensity of infection surveillance and accuracy of reports, as well as the lack of an index by which to adjust infections to the severity of patients' diseases, ought to be considered.[5,6]

Among the parameters used for evaluating alterations in NI occurrence trends, endemic level determination is a fairly simple resource. According to some authors,[1,2,14] the detection of an uncommon statistical pattern for NI rate distribution around the mean value suggests the need for a more in-depth epidemiological investigation.

In the present study, the NI occurrence rate for July 2000 exceeded the control limit, established at 3σ above mean incidence, and, influenced by other factors in addition to those responsible for the endemic variations in these infection rates, probably constituted an outbreak.

The use of the 3σ above mean as an upper control limit has been questioned when SPC charts are applied to healthcare. For this reason, more sensitive and less specific criteria, such as 2σ control limits, have been used. According to Sellick[14] (1993), the adoption of such a pattern results in a diminution of specificity and, consequently, in a large number of outbreak investigations, based on false-positive warning signs. Supplementary-test application (Stage 6 of "Methods") increases control chart sensitivity and slightly reduces specificity in the identification of NI occurrence rate patterns, when compared to the application of a single criterion, such as graph points above the control limits.

The construction of graphs that exclude outbreak periods was based on the fact that such periods increase baseline NI occurrence rates, consequently widening endemic control limits, and thus obscuring other probable outbreaks and uncommon trends, as described by Sellick[14] (1993) and Benneyan[1,2] (1993). In the present study, the exclusion of July 2000 from NI rate calculation reduced mean incidence from 20.0 to 18.0 per thousand patient days. However, the determination of new control limits did not identify any further periods of epidemic. NI rates were considered as statistically stable, submitted only to variations explainable by chance. Nevertheless, one must note that stable rates, and occurrence predictability, signify only statistical stability, and do not imply the acceptance

of the NI levels found, nor the absence of a need for the implementation of measures aimed at reducing the incidence of such infections.

The study of the epidemic period identified an increase in urinary tract infection rates. The analysis of the endemic levels of this infection revealed a statistically significant uncommon occurrence pattern between February and November 1999, when no UTIs were detected. No justification was found for such an occurrence. In the seven months prior to the outbreak, there was an increase in the number of UTI occurrences; however, none of them were statistically significant, even after UCL was set at 2σ above mean incidence. Epidemic period evaluation failed to identify any cause-effect relationships responsible for the increase in UTIs, and the outbreak was controlled spontaneously. According to CDC[3] data, the probability of identifying such relationships is small, even when an excessive number of cases are confirmed.

Despite its simplicity, very few NI control studies have used the graphical methodology employed in the present study, probably due to the relative disadvantage inherent to SPC-chart use when the number of occurrences is relatively small. In this case, assuring control method and NI incidence rate stability requires monitoring for at least 25 consecutive months.[1,2,14]

In conclusion, the use of SPC charts for controlling endemic levels of NI, through both global and site-specific evaluation, allowed for the identification of uncommon variations in NI rates, such as outbreaks and epidemics, and for their distinction from the natural variations observed in NI occurrence rates, without the need for calculations or hypothesis testing.

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