THE SENIC PROJECT

STUDY ON THE EFFICACY OF NOSOCOMIAL INFECTION CONTROL (SENIC PROJECT)

SUMMARY OF STUDY DESIGN

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With the emergence of nosocomial infections as a serious problem among US hospitals, the Center for Disease Control undertook in 1974 a nationwide study to evaluate approaches to infection control. The three-phased project, now known as the Study on the Efficacy of Nosocomial Infection Control, or SENIC Project, was designed with three primary objectives: 1) to determine whether (and, if so, to what degree) the implementation of infection surveillance and control programs (ISCPs) has lowered the rate of nosocomial infection, 2) to describe the current status of ISCPs and infection rates, and 3) to demonstrate the relationships among characteristics of hospitals and patients, components of ISCPs, and changes in the infection rate. With data collection completed in a nationally representative sample of hospitals, analysis is underway to identify approaches to infection control that are most effective for the least cost to hospitals and to point out additional specific questions to be answered by future research.
Since the 1950s, when staphylococcal epidemics began to plague hospitals, the problem of nosocomial infections has emerged as a major public health issue. It is estimated that around 5 per cent (1) of the 35 million patients admitted to US hospitals (2) each year acquire such infections. In addition to the resulting morbidity and mortality, nosocomial infections have contributed substantially to the increasing cost of hospital care (3).

Various approaches to controlling the problem have evolved, but their effectiveness has not been definitively determined. Some of their prominent components have included: 1) designation of an infection control committee of key hospital officials to formulate and implement policies, 2) establishment of part- or full-time positions for an infection control nurse (ICN) and a hospital epidemiologist (HE), 3) periodic or continuous surveillance to detect outbreaks or trends and potentially preventable risk factors, 4) microbiologic monitoring of the inanimate environment, and 5) establishment of written policies prescribing correct technique for various patient-care practices and environmental hygiene. Because of the difficulty in carrying out scientifically valid evaluations of these approaches, hospitals currently find few published data with which to decide what combination of components is the most effective in reducing infection risks for the least cost.

Early in 1974, The Center for Disease Control (CDC) undertook the planning of a nationwide study to fill this void. The planning committee was aided by a multidisciplinary task force of experts from hospital epidemiology, infectious diseases, hospital administration, healthcare economics and biostatistics. This report is intended to summarize the design of the Project, designated the Study on the Efficacy of Nosocomial Infection Control, or SENIC Project. More detailed explanations of important elements of the design appear elsewhere in this issue.

**Formulation of hypotheses**

One of the first difficulties encountered in developing an effective evaluation strategy was the lack of a consistent nomenclature with which to express hypotheses. The term "infection control practices," for instance, was widely used to refer to certain patient-care practices performed by nurses at the bedside as well as the statistical or teaching activities of an ICN; a "surveillance program" was considered by some to be merely the collection and tabulation of statistical data, while to others it meant a comprehensive program of monitoring and active intervention. We therefore formulated a conceptual model of an infection control program, providing each term with a precise definition.

A simplified version of the resulting model (figure 1) outlines the basic elements of the central hypothesis being examined. (The detailed model and its description appear in Appendix A.) For this model, a nosocomial infection is defined as one that develops during hospitalization and is not present or incubating at the time of the patient's admission. (A nosocomial infection that develops after a...
patient is discharged was not studied in the Project, unless the patient had to be readmitted.) Recently, investigators (3–5) have estimated that as many as half of all nosocomial infections are potentially preventable given the current state of the art of hospital care, although difficulties in defining and measuring preventability preclude precise estimates.

The predisposing factors common to most preventable nosocomial infections are the diagnostic and therapeutic interventions, or patient-care practices, to which patients are subjected while hospitalized (figure 1). Unfortunately, preventive patient-care practices (PPCPs), such as aspirating urine specimens aseptically through the wall of closed urinary drainage systems, are generally more time-consuming and difficult to engender than their counterparts; consequently, through the general inertia of ward routine—and a lack of knowledge or resources—the undesirable practices are perpetuated. Given this state of “social equilibrium,” nosocomial infections are likely to be controlled only if personnel make deliberate efforts to identify the misdirected practices and change them through active infection control programs. These efforts may be designed to modify the risks directly, by changing the environment (e.g., providing closed system urinary catheter equipment), or indirectly, by changing the behavior of patient-care personnel (e.g., obtaining general compliance with handwashing or isolation policies).

Such active control programs are likely to be instituted effectively only if certain qualified personnel, the infection control staff (i.e., the ICN and the HE), are committed part- or fulltime to designing and managing them. To direct them effectively, the staff must know the general principles of prevention, either from studies published in the literature or from training courses in hospital epidemiology.

Such general knowledge alone, however, is not enough to ensure optimal infection control in any individual hospital. Ongoing control measures should be monitored regularly to assure that they have been successfully implemented and are appropriately targeted toward the most important infection problems. Furthermore, pathogenetic mechanisms for some infectious processes have not yet been completely defined, and the unique circumstances that underlie some common-source epidemics cannot be anticipated. Thus, maintaining sufficiently specific and up-to-date knowledge of infections and potential risk factors requires organized, ongoing infection surveillance (data collection, analysis and dissemination) together with ongoing review by appropriately qualified professional staff members. In addition to the guidance that surveillance gives to the overall program, the activity itself may influence patient care.
through the Hawthorne effect (6); that is, personnel may alter their practice when they see that someone is watching and is interested in how they are caring for patients.

Thus emerges a general statement of the sequential causal model, or central hypothesis, which allows us to test the efficacy of the complete infection surveillance and control program (ISCP): In hospitals conducting ongoing surveillance of infections and using the resulting information along with studies in the literature and guidelines from other sources to direct active infection control programs to overcome the inertia of ward routine and change high-risk patient-care practices to preventive ones, the incidence rate of nosocomial infections will drop and thereafter will remain at or near some irreducible minimum rate. Personnel specifically qualified in hospital epidemiology will be more likely to conduct surveillance meaningfully and to institute control measures effectively.

**DEVELOPMENT AND SUMMARY OF STUDY DESIGN**

At the beginning of the planning phase, we envisioned testing this central hypothesis with a prospective* experimental study. Hospitals without organized ISCPs would be randomly allocated to experimental and "control" groups. Those in the experimental group would implement active ISCPs, while those in the "control" group would implement no programs. The infection rates would then be monitored prospectively for a number of years to measure their change.

For several reasons, this design could not be carried out validly. First, the experiment could not be done blindly since hospitals would know whether or not they were conducting surveillance and thus which group (experimental or "control") they fell into. The consulting task force believed strongly that lack of blinding would create a serious bias in the result. Second, to measure the outcome of the experiment, the change in infection rates, we would have to perform prospective surveillance of infection in both groups of hospitals. Paradoxically, to measure the outcome of the experiment, we would be forced to use the very process whose result we were examining—we would be performing surveillance of infections in the non-surveillance hospitals. In addition, the withholding of information derived from surveillance in the "control" hospitals for more than the usual two- to three-month startup period of a new ISCP was considered unethical by the human rights review committee. Although the overall efficacy and cost-effectiveness of ISCPs have not been established quantitatively, the benefit of surveillance to individual patients has long been evident. When an outbreak is discovered in a hospital (occasionally by observing only a few patients), intervention to control it undoubtedly prevents infection in some patients, may shorten its course in others, and may even lead to appropriate life-saving therapy. For these conceptual reasons, then, and other pragmatic ones, the prospective experimental approach was abandoned.

After considering a number of alternative study designs, we chose to carry out an observational or quasi-experimental project in three phases, taking advantage of a natural experiment thought to be occurring among US hospitals at the time. Based on our contacts with hospitals, we believed that some proportion, perhaps close to half, had implemented organized ISCPs in the early 1970s, whereas very few had done so by the late 1960s. Thus,
we proposed a nationwide study with the following objectives:

I. To determine whether (and, if so, to what degree) the implementation of ISCPs has lowered nosocomial infection rates (NIRs) in major categories of US hospitals.

II. To describe the current status of ISCPs and NIRs in these hospitals.

III. To study in detail the relationships among a) the characteristics of hospitals and patients, b) the components of ISCPs, and c) changes in the components of NIRs (e.g., at specific sites and services).

Given these objectives, we designed Phase I, the Preliminary Screening Questionnaire (PSQ), to measure the extent of organized ISCP activity in each US hospital at a defined point midway through the decade and to pinpoint the beginning of each ISCP. According to these descriptions, we stratified the universe of hospitals and selected a random sample representing all levels of activity for study in Phases II and III.

We designed Phase II, the Hospital Interview Survey (HIS), to measure in greater detail, and under more controlled circumstances, all facets of the ISCPs that had been implemented in the selected hospitals. These observations, derived from structured on-site interviews with specified key personnel in each hospital, could be organized into appropriate indexes, along with information from the PSQ, for use as independent variables in an evaluative analysis.

We planned Phase III, the Medical Records Survey (MRS), to assess the efficacy of the various ISCP approaches identified in Phases I and II. To do so, we chose to compare the incidence rate of nosocomial infections among patients hospitalized in a year before any of the study hospitals had implemented organized ISCPs (Time 1 or T1) with that of the most current year corresponding roughly to the time that the measurements of Phases I and II were made (Time 2 or T2) (figure 2). On the basis of responses to the PSQ, 1970 was selected as the T1 year and the 12-month period April, 1975–March, 1976 as the T2 year. To measure the NIRs in each, we developed a new standardized method of diagnostic retrospective chart review (RCR) and validated its accuracy through a series of pilot studies (11). We designed the data collection efforts in Phases II and III to be performed by separate groups of CDC personnel so that either group would be unaware of the information gathered by the other.

**Phase I. Preliminary screening questionnaire (PSQ)**

We mailed the PSQ to all US hospitals in March, 1976. Designing the questionnaire, a two-and-one-half-year undertaking, included: 1) formulating detailed models of surveillance techniques, control programs, characteristics of the infection control staff, and PPCPs; 2) enumerating...
parameters for measuring the facets of these models; 3) constructing questions to measure these parameters; and 4) pretesting the questions to minimize ambiguity. In determining the content of the questionnaire, we attempted to balance quantitatively the extent of its “coverage” of surveillance and control components with its length, presumably a prime determinant of response rate (Appendix B).

To encourage the most candid and accurate replies, the following features were incorporated into the questionnaire (Appendix C):

1. The responding hospitals were guaranteed absolute confidentiality under statute.
2. The cover letter and introduction notified the respondents that a random sample would be visited later for a more detailed study of the ISCP activities.
3. The questionnaire was mailed to the hospital administrator, who was asked to refer it to the ISCP staff (and, indeed, almost all responses involved the ISCP staff, when present (12)).
4. A statement disclaiming endorsement of any particular practices or procedures was included at the beginning and end of the questionnaire.
5. A personal signature of the official responsible for the questionnaire was required at the end.

Recognizing that a high response rate was necessary to allow valid extrapolation of SENIC results nationwide, we also included in the questionnaire a clearly stated purpose pointing out the potential benefit to hospitals, provided a proper sequencing of the questions, with the least technical presented first, and made the request that the questionnaire be returned within two weeks. After the questionnaire was mailed to the 6586 US hospitals (defined by a mailing list from the American Hospital Association (AHA)), the survey was publicized in the AHA’s weekly newsletter, Hospital Week. Thereafter, we monitored responses daily and contacted nonrespondents by telephone and mail. Immediately upon receipt, the questionnaires were edited, and respondents were contacted to obtain, where possible, information that had been incorrectly omitted. At the close of the survey some three months later, 86 per cent of hospitals in the target population to be studied in Phases II and III had responded (figure 3).

**Selecting the sample of hospitals**

In selecting the sample from this target population, we sought to focus on the “mainstream” of hospital care in the country, thereby reducing the enormous additional expense of sampling the potentially large number of special, though relatively sparse, classes of hospitals (e.g., children’s specialty hospitals or tuberculosis sanitaria). Thus, the target population consisted of general medical and surgical hospitals that are short-term, not Federal- or State-owned, have at least 50 beds, and are located in the contiguous 48 states (2). The smallest hospitals were excluded because each of those hospitals admits too few patients and has too few nosocomial infections in a single year to allow meaningful comparisons; hospitals in Alaska and Hawaii were excluded to minimize data collection costs.

Using PSQ responses, we calculated surveillance and control indexes for each hospital in the target population (Appendix B), formulated from the models used to design the questionnaire, and constructed a sampling frame stratifying hospitals by surveillance level, control level, number of beds, and affiliation with a medical school (figure 4). We stratified by the two indexes to assure the selection of an adequate sample of hospitals with a variety of types and levels of ISCP activities; for instance, since hospitals with the most active ISCPs might be relatively uncommon, a simple random sample
would not select enough to allow meaningful assessment of their impact. We stratified by number of beds and affiliation with a medical school because these two variables were found to be the best predictors of NIRs in a multiple regression analysis using data collected in the National Nosocomial Infections Study in 1973 (Center for Disease Control: National Nosocomial Infections Study, 1973. Unpublished data). The information on these two variables, as well as that on the structure and facilities of the hospitals, was obtained from the AHA’s Annual Survey of Hospitals, conducted in collaboration with the National Center for Health Statistics (2); the 1973 survey was the latest available at the time.

According to a detailed sampling plan based on the Project’s three objectives, hospitals were selected randomly from each stratum, yielding a final sample of 433 hospitals for study in Phase II and 338 in Phase III. Besides the approximately 14 per cent that declined participation, we had to exclude from Phase III those hospitals that had started organized ISCPs before the \( T_1 \) period (4 per cent) and those found to have deleted nursing notes (and occasionally other key sections) from their \( T_1 \) medical records, most often during microfilming (14 per cent). In designing the sampling procedure, we considered several recommended plans for maintaining an adequate sample size despite the inevitable exclusions. We rejected as being too expensive the commonly used plan of initially inflating the sample size in each stratum by the estimated average exclusion rate, and instead we adopted the method of randomly selecting the number of additional hospitals required in each stratum after exclusions.

After all the hospitals had been selected, we compared the hospitals that had been excluded with the supplementary ones. We found no significant differences in their general characteristics (from the AHA data) or in those of their ISCPs (from PSQ data) (13). We therefore concluded that the exclusion process is
unlikely to have biased our sample of hospitals in a way that would jeopardize the validity of the three main objectives of the study. Details of the sampling plan and analyses examining potential selection biases are discussed in the following paper (13).

PHASE II. HOSPITAL INTERVIEW SURVEY (HIS)

The HIS was designed to measure, at approximately the $T_1$ period, those personnel, activities, and other resources that are expended, at least nominally, to control nosocomial infections and which satisfy one or more of the following criteria: 1) are thought to be effective in controlling infections, 2) are practiced by many hospitals, 3) are expensive, or 4) are recommended by CDC, AHA or the Joint Commission on Accreditation of Hospitals (JCAH). Among the major areas covered were: the characteristics and activities of ICNs, HEs and infection control com-
mittees; the techniques of infection surveillance and outbreak investigation; environmental monitoring; isolation practices; the relationships of the ISCP with the hospital administration and other departments; nurses' reports of their patient-care practices; methods used to train staff members in correct PPCPs; techniques of influencing behavior of patient-care personnel (14); housekeeping and disinfection techniques; and the role of the microbiology laboratory. Estimates of the costs of various ISCP approaches will be calculated from quantitative data, such as hours worked, salary levels, and numbers of cultures, together with regional salary norms (15) and cost data from other sources (16).

We obtained the data on ISCPs through standardized personal interviews with key hospital personnel (table 1), conducted on site by 58 CDC staff members. The interviewers had had no previous experience in hospital infection control but had been trained in structured interviewing techniques. Traveling generally in teams of two, and supervised by regional field managers, they conducted the interviews according to preprinted interview booklets that had been pretested in three sequential field tests. The field managers routinely called back a 20 per cent random sample of all persons interviewed to verify their responses by repeating selected questions. The interviews were arranged so that the information could be collected uniformly in all hospitals with the least time commitment by hospital staff (table 1).

In addition to these personal interviews, a representative sample of nurses who administered direct patient care in each hospital were also queried. These interviews were designed to measure the nurses' reports of their patient-care practices, their knowledge of infection control practices, and their views on various ISCP approaches. They were conducted on site by the interviewers in a single interview, lasting less than an hour.

### Table 1

<table>
<thead>
<tr>
<th>Hospital personnel</th>
<th>No. of persons interviewed</th>
<th>Average (±SD) interview time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Chairperson of the infection control committee and/or HE*</td>
<td>488</td>
<td>86 (±26)</td>
</tr>
<tr>
<td>2. ICN† (if none, the nursing representative on the infection control committee or other most knowledgeable infection control person)</td>
<td>465</td>
<td>176 (±49)†</td>
</tr>
<tr>
<td>3. Hospital Administrator (or Assistant Administrator more directly in charge of infection control)</td>
<td>437</td>
<td>20 (±7)</td>
</tr>
<tr>
<td>4. Director of the Microbiology Laboratory</td>
<td>435</td>
<td>24 (±9)</td>
</tr>
<tr>
<td>5. Technicians in the Microbiology Laboratory</td>
<td>432</td>
<td>17 (±6)</td>
</tr>
<tr>
<td>6. Director of the Nursing Service</td>
<td>447</td>
<td>15 (±5)</td>
</tr>
<tr>
<td>7. Operating Room Supervisor</td>
<td>437</td>
<td>25 (±8)</td>
</tr>
<tr>
<td>8. Head of Pharmacy</td>
<td>435</td>
<td>7 (±4)</td>
</tr>
<tr>
<td>9. Head of Inhalation Therapy</td>
<td>430</td>
<td>15 (±5)</td>
</tr>
<tr>
<td>10. Head of Intravenous Team (if IV team present)</td>
<td>121</td>
<td>15 (±5)</td>
</tr>
<tr>
<td>11. Head of Housekeeping</td>
<td>439</td>
<td>13 (±5)</td>
</tr>
<tr>
<td>12. Person in charge of cleaning anesthesia equipment</td>
<td>434</td>
<td>10 (±5)</td>
</tr>
<tr>
<td>13. Sample of the nursing staff</td>
<td>7188</td>
<td>50‡</td>
</tr>
<tr>
<td>TOTAL</td>
<td>12,969</td>
<td></td>
</tr>
</tbody>
</table>

* HE = hospital epidemiologist.
† ICN = infection control nurse.
‡ This interview had a scheduled break at approximately the midpoint to reduce the adverse effects of fatigue.
¶ Estimated.
SUMMARY OF STUDY DESIGN

policies, the visibility of the infection control staff, certain effects of training, and other parameters reflecting the influence of the ISCP on patient care. In each hospital, a current nursing schedule was stratified by service and shift, and a sample averaging 17 (±9 SD; range, 3–63) registered and licensed practical nurses (approximately a 25 per cent stratified random sample) was chosen by a CDC representative using a systematic random selection process. All nurses selected were queried in proctored group sessions via a self-administered written interview over a 24-hour period to minimize any bias that could have been interjected by their discussing the interviews with others. In all, some 13,000 hospital personnel were interviewed, including about 7200 staff nurses (table 1).

PHASE III. MEDICAL RECORDS SURVEY (MRS)

The objective of the MRS was to obtain in each hospital accurate estimates of the NIR in $T_1$ and $T_2$ with which to evaluate the effectiveness of the various elements of ISCPs measured in Phases I and II, in terms of their ability to prevent infections. In each hospital, we randomly selected some 500 patients' admissions from their patient listings (e.g., admission log, discharge/death list) for $T_1$ and $T_2$—a total of 1000 admissions per hospital or approximately 338,000 for all study hospitals combined (figure 2). Because some patients are known to be at extremely low risk of acquiring nosocomial infection (NIR <1 per cent) and would have required a prohibitively large sample size for valid study, several groups of patients were excluded from the lists before the random selection was made (table 2). In addition, patients admitted to burn units, though at high risk of infection, were excluded because of their relatively small numbers and the difficulty of diagnosing burn wound sepsis; similarly, patients admitted primarily for chronic renal dialysis were excluded because of the difficulty of defining an “admission” or other unit of exposure to the hospital. Essentially, we confined our selection to adults (18 years and over) on the general medical and surgical services.

The medical records from all admissions selected for the sample were reviewed by CDC medical record analysts trained to perform a standardized retrospective chart review (RCR). By recording on preprinted data collection forms (Appendix D) the demographic and clinical data relevant to nosocomial infections and applying algorithmic criteria (Appendix E), they rendered diagnoses of infection. The MRS field staff, composed of approximately 180 medical records professionals from CDC, were deployed to the sample hospitals in traveling teams of 12. The campaign used a tiered management structure directed by a central command and support staff at Project Headquarters in Atlanta.

DESIGN AND VALIDATION OF THE RETROSPECTIVE CHART REVIEW (RCR) TECHNIQUE

The RCR technique was developed to measure the NIRs in this large sample of hospitals accurately without influencing the events under study. The consulting
task force had warned of the traditional inaccuracies inherent in abstracting information from medical records. They had pointed out, however, that most chart review surveys in the past, such as those on health status and quality assessment, had involved *simple transcription* of diagnoses from the face sheets of charts, a process seriously limited by the incompleteness of recording on most face sheets and often by the inadequate training of data abstractors.

In contrast to this procedure, CDC and other organizations had routinely used a technique of reviewing the *complete* clinical data contained *within* medical records to investigate epidemic problems. Unlike the simple transcription technique, this *inferential chart review* approximated the method commonly used by physician-consultants to review records in hospital practice. We developed the RCR technique by analyzing this method and recording the individual steps in a procedure manual.

We restricted our review to the four major sites of infection believed to account for more than 80 per cent of all nosocomial infections (17): the urinary tract (with infections subdivided into symptomatic UTI and asymptomatic bacteriuria), the bloodstream (bacteremia), the lower respiratory tract (with infections subdivided into pneumonia and tracheobronchitis), and the surgical field (with infections subdivided into incisional surgical wound infection and deep surgical wound infection). For each of these sites, we stated the sets of rules that physicians generally apply in making the diagnosis and in distinguishing nosocomial from community-acquired infections. We then refined these rules so that the most accurate diagnoses could be made given the varied types and amounts of clinical data that might be found in the charts (Appendix E). Working backward from the diagnostic algorithms, we listed the specific clinical data bits needed to make each diagnosis (e.g., peak daily temperature, antibiotics received, bacteriologic cultures, chest x-rays, and clinical signs and symptoms, such as dysuria, purulent sputum, and pus from a wound), and, to teach medical record professionals to spot these data bits, we specified all synonyms that could be expected for each. The remaining 20 per cent of nosocomial infections were considered to be so diverse and to occur with such relative infrequency (e.g., hepatitis, gastroenteritis and cutaneous infection) that the degree of statistical power to be gained by including them did not justify the large additional expense in algorithm design and training.

Following the development and pretesting of the new RCR technique, we established two important adjuncts to the process: 1) a standardized system of training and certifying chart reviewers and 2) in-line quality control of the chart review and diagnostic process. Through a relatively new training technique, "criterion-referenced instruction" (18), the complex activities required of the chart reviewers were divided into simple, digestible components for which a specific training booklet, or module, was constructed. The training sessions were conducted by a group of carefully selected and trained course managers, who monitored the progress of all trainees and gave them final certification. This three-step process consisted of 1) testing the trainees' mastery of the material after they had completed each module, 2) prescribing limited restudy and retesting until they performed satisfactorily, and 3) measuring their overall competence in a quasi-field situation by having them review a sample of actual medical records. The training course was self-paced and lasted an average of four weeks.

The quality control system instituted included 1) on-site monitoring in each hospital of all data abstraction and diagnostic results, 2) a "multiple-read system"
consisting of blinded rereading of all charts found to indicate a nosocomial or community-acquired infection and a random sample of charts (between 1 and 5 percent) found to indicate no infection, 3) computerized editing in the data-processing phase, 4) continuous feedback of statistics on errors to all data collectors and their supervisors, and 5) remedial action when required.

Before beginning the actual surveys, we conducted a series of pilot studies 1) to refine the data collection, diagnosis and quality control procedures through successive field trials and, simultaneously, 2) to measure the sensitivity, specificity and reliability of RCR by comparing the diagnoses made by this method with the diagnoses made independently by an intensive prospective surveillance method (11). The pilots were conducted in four selected hospitals: a large city-county, university-affiliated hospital; a medium-sized university hospital; a medium-sized private suburban hospital; and a small surgical hospital. In each, prospective data collection (PDC) was performed by a team of trained surveillance nurses who studied daily every patient admitted during a two-to-three month period (except those admitted to the psychiatry, burn, renal dialysis and normal newborn services and those who remained in the hospital less than 12 hours) and who reported all possible cases of infection to a supervising physician-epidemiologist. The physician-epidemiologist then followed all potentially infected patients until discharge and confirmed all diagnoses. The PDC was conducted so as not to influence the staff's patient care or their recording of information in the medical records. Later, a team of chart reviewers, trained in the RCR technique, reviewed the medical records of all patients admitted during the pilot studies without knowing the results of the PDC diagnoses. From these data, we compared for each patient the diagnoses obtained by each method and calculated the sensitivity, specificity and reliability.

The planning of the pilot studies raised some perplexing questions about the interpretation of the results. Specifically, we asked, "How accurate must a method such as RCR be to be used in a nationwide study?" Finding no adequate guidelines in the literature, we developed specific criteria to answer this question by incorporating estimates of sensitivity and specificity into calculations of statistical power (19). The pilot studies demonstrated that the RCR method was accurate and consistent enough between hospitals to provide sufficient power for the analyses planned to achieve the three major objectives of the study (19), unless the data are biased by the potential effect of a hospital's ISCP on the accuracy of RCR (20).

Despite the levels of accuracy found, at the end of the pilot studies we compared the PDC and RCR data collection forms and the patients' charts, when necessary, to determine the source of disagreements in the diagnoses. From these case-by-case reviews, we modified the definitions, data abstracting techniques, diagnostic algorithms, training methods and quality control procedures of the RCR system before beginning the MRS. The improvements in RCR accuracy brought about by these changes were demonstrated in a restudy of the method performed at one of the pilot hospitals at about the midpoint of the MRS (11).

"Blinding" the observers

We assured that the HIS and MRS observers were "blinded" to both the ISCP and infection rate status of the hospitals to prevent the potential bias that such knowledge might introduce into their observations. Specifically, only a few of the principal investigators knew the hospitals' scores on the surveillance and control indexes and their positions in the sampling matrix. Since the MRS had not
yet been undertaken, the HIS interviewers had no information about the hospitals' infection rates. Likewise, the MRS chart reviewers were withheld all information on the hospitals' responses to the HIS. Moreover, during the MRS training course, a standard lecture was given to each chart reviewer on the importance of blinding in scientific studies, and each was instructed not to discuss anything about the type of ISCP in operation with hospital personnel. Therefore, all SENIC "observers" were blinded to the distribution of the "treatment" (viz., the ISCP status) among the hospitals.

**Analytic Strategy**

The analysis outlined to achieve Objective I will involve two approaches: 1) comparing the average change in NIR among the strata defined in the sampling matrix (figure 4), and 2) performing a covariance analysis of the relationships of the surveillance and control indexes with the change in NIR from $T_1$ to $T_2$, or with differences in NIR at $T_2$, while controlling for $T_1$ NIR and diverse other characteristics of the hospitals and patients found, in the SENIC data base, to be potentially important confounding variables (21). Probably of central importance in these analyses will be quantifying an individual's intrinsic risk of acquiring nosocomial infection, using information collected for each patient in the MRS (22). (Information on hospital characteristics was obtained from the 1970 and 1976 Annual Survey of Hospitals (2).)

In accordance with Objective II, we plan to estimate, on the basis of our 1976 statistical sample of US hospitals and patients: 1) the frequency of ISCP characteristics, 2) the related laboratory resources and techniques available, 3) the patient-care practices as reported by hospital nurses, 4) the NIRs stratified by appropriate hospital and patient characteristics, 5) host factors predisposing to infection, 6) antibiotic usage, and 7) antimicrobial resistance patterns. In addition, we plan to assess, on the basis of techniques developed in the pilot studies, the costs of conducting various ISCP approaches and the prolongation of stay and charges attributable to nosocomial infections. The initial descriptions of ISCPs (12) and of the ICN position (23) constitute the last two papers in this issue, while a description of the HE has appeared previously (5).

The analyses for Objective III will focus in greater detail on the relationships among the factors described for Objective II. The measurements of NIRs at $T_1$ and $T_2$ provide the longitudinal study design that should enable us to test hypotheses. The accuracy and consistency of the RCR method, the large sample sizes of patients and hospitals now available, and the use of statistical modeling and multivariate analysis techniques should provide substantial power for these more detailed analyses. The most important of these will be 1) identifying specific ISCP characteristics or activities that seem to influence patient-care practices, NIRs and costs, 2) quantifying the infection risks associated with various host factors and patient-care practices, and 3) exploring the relationships among antibiotic usage, antimicrobial resistance, and morbidity.

In summary, the aims of the SENIC Project are 1) to answer existing questions on the efficacy and cost-effectiveness of fundamental ISCP approaches, 2) to describe NIRs and ISCPs and identify specific risk factors, 3) to demonstrate whether certain ISCP components are important enough to be implemented widely, and 4) to point out discrete areas that need to be addressed by basic and applied research in the future.

**References**

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