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FINAL
MISSION REPORT

QUALITY IMPROVEMENT/
INFECTION CONTROL
DEMONSTRATION PROGRAM FOR HUNGARY

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EXECUTIVE SUMMARY

The QI/IC Team conducted comprehensive surveys of existing quality improvement and infection control programs at Flór Ferenc Hospital, Kistarcsa, Hungary from Nov. 28 - Dec. 2 and at Kátai Gábor Hospital, Karcag, Hungary from Dec. 5 - 9. This work was supported by the United States Agency for International Development Health Markets Project through its principal contractor Health Enterprises International, Inc. These surveys were completed successfully in large measure due to the dedication and assistance of hospital leaders and personnel in both institutions.

It was evident that there is a pressing need for reliable data regarding nosocomial infections, antibiotic use, and hospital and resource utilization. The HELICS (Hospitals in Europe Link for Infection Control through Surveillance) Project, in which both hospitals will be participating, will provide an excellent opportunity to begin rigorous collection of a portion of the required data, but plans must be made to continue this surveillance indefinitely beyond the formal HELICS Project period. (The HELICS Project is a multicenter study of surgical site infection (SSI) in European Community nations. More than twenty hospitals will be participating in Hungary). In addition, emphasis should be placed on using the resulting data in specific improvement projects and for feeding back data to hospital staff, including administrators and clinicians.

Both hospitals have quality assurance and infection control (called hospital hygiene in Hungary) committees and programs; however, the time is right to increase the scope of activity in these areas. This will involve training of specific personnel, especially infection control nurses, as well as general familiarization of the hospital staff concerning quality improvement and infection control principles and methods. It will be important to decide on strategic priorities for quality improvement and infection control, to disseminate these goals to hospital staff, and to support the multidisciplinary project teams that will be asked to meet the goals. All goals should include measurable indicators that can be used to assess progress, and there should be rapid adjustment in plans as necessitated by analysis of the resulting data. Additional specific observations and recommendations based on the hospital surveys are detailed in the final reports for each hospital in Appendix 1.

Based on the results of these surveys and the overall objectives of this project, it was decided to concentrate on improving antimicrobial use and reducing surgical site infections (SSI) in high volume surgical procedures. Therefore, the five day workshop held at Flór Ferenc Hospital from Dec. 12 - 16 had the dual purpose of educating participants concerning relevant infection control and quality improvement principles and methods and of providing a hands-on quality improvement practicum in which working groups would set their own strategic priorities, analyze the hospital systems involved in meeting these goals, determine accurate measures to evaluate success, an develop a specific preliminary plan for improvement. There were ten participants from Flór Ferenc Hospital and eight participants from Kátai Gábor Hospital. The group was appropriately multidisciplinary and included necessary representatives of the hospital leadership. A detailed summary of the workshop in Appendix 2.

The working groups were highly successful in using quality improvement techniques, including brainstorming, flow charting, consensus building, and priority setting. Although additional quality improvement training would be highly desirable, these individuals clearly have grasped fundamental aspects of the quality improvement approach, and could serve as a nidus for quality improvement activities in their institutions. Their work was comparable to (and perhaps exceeded) what could be expected from project teams at a similar stage of development in our own hospital.

The strategic goals and the implementation plans developed during the workshop can be summarized briefly as follows:

General Aim: Cost-effective reduction in surgical site infection rates

Specific Goals:

1. Introduce a surgical site infection (SSI) surveillance system
   - Begin data collection using the HELICS Project methodology (January, 1995)

2. Provide confidential feedback to surgeons regarding procedure-specific, risk adjusted SSI rates and procedure-specific duration of surgery for 5 or more high volume procedures
   - Discuss surveillance and reporting methodology with surgeons and develop appropriate safeguard to insure confidentiality of these data (January, 1995)
   - Confidentially report data to individual surgeons on a quarterly basis
   - Monitor impact of surveillance/feedback on SSI rates

3. Reduce the length of preoperative stay for 5 or more high volume procedures
   - Collect LOS data in surgical patients as a part of the HELICS Project
   - Report LOS for 5 or more of the most common surgical procedures to the surgical services, the quality improvement program, and the hospital administration/finance group on a quarterly basis
   - Review components of preoperative evaluation, determine truly necessary components, and determine components that can be performed on an outpatient basis (January - February, 1995)
   - Develop systems to complete preoperative evaluations in outpatient clinics (March - June, 1995)
   - Monitor impact of systems for outpatient evaluation on LOS and SSI rates

4. Optimize cost-effectiveness of perioperative antimicrobial prophylaxis (PAP) for 5 or more high volume procedures
   - Collect data regarding use of PAP as a part of the HELICS Project
   - Establish a system for monitoring costs of PAP (January - February, 1995)

Review existing guidelines for PAP and select preferred regimens based on effectiveness and cost (January - February, 1995)
Evaluate the use of PAP including agent(s) used, dosage, duration, timing, and cost;
Report data to the surgical and anesthesiology services, the pharmacy, the quality improvement program, and the hospital administration/finance group on a quarterly basis
Design and implement improvements in systems based on data
Monitor impact of improvements on cost and SSI rates

5. Optimize preoperative preparation of surgical patients
   Review preoperative preparation procedures and practices related to preoperative bathing, hair removal, and skin antisepsis (January, 1995)
   Design and implement system improvements based on data
   Monitor impact of improvements on SSI rates

It should be noted that this work plan incorporates the principal elements of standard total quality management models. There is a clear statement of what the hospitals teams want to improve. Data required to evaluate success are specified clearly and methods to collect these data are articulated. Data feedback plans are noted and preliminary improvement measures are described. Participants understand the concept of PDCA (Plan-Do-Check-Act), in which interventions are initiated, their impact monitored, and revisions in the improvement plan monitored accordingly. Importantly, surveillance is not being performed only to accumulate data, which is a major limitation of infection control and quality improvement programs in many institutions. Rather, data are being used to drive and evaluate change and improvement.

If the interventions outlined by the workshop participants can be applied successfully in their hospitals, the chances of reducing LOS, improving use of PAP, reducing SSI rates, and reducing hospital costs are very high. The participation of members of the leadership of both hospitals in the workshop working groups should enhance acceptance and implementation. However, the obstacles to hospital-wide application of the plans of the project teams are well known, especially when there is little or no preexisting understanding of quality improvement principles and methods (QI culture) among the general hospital staff. Opposition by key opinion leaders probably would be fatal. Therefore, we strongly recommend continued oversight, tracking, and support of this project by the hospitals' quality improvement committees and designated sponsors (preferably hospital leaders) selected from the membership of the quality improvement committee, as well as ongoing consultation by our project team.

The stakes are very high because we believe that successful completion of this project will provide a powerful model for further application of quality improvement techniques in these hospitals. Experience demonstrates that individuals who have been involved in successful quality improvement projects can replicate their experience and training in new projects, resulting in rapid scale-up of quality improvement programs. Scale-up will require training and support beyond the period of the present project, but a self-sustaining hospital quality improvement program is feasible within approximately three years. We further believe that the experience of the two

hospitals can serve as a model for other institutions in Hungary, and we anticipate that the HSQA can play a major role in facilitating dissemination and replication of this model.

The relationship between the HELICS (Hospitals in Europe Link for Infection Control through Surveillance) Project and the present USAID-sponsored Project deserves special comment because of concerns that these two initiatives may overlap, with USAID essentially supporting a project that is already funded and is capable of fulfilling the Action Plan. Such concerns are unfounded.

When the QI/IC Team arrived in Hungary senior hospital administrators at Flór Ferenc Hospital and Kátai Gábor Hospital had already made a commitment to participate in the HELICS Project. Surveillance nurses from both hospitals were in the midst of a training course regarding the HELICS Project methodology and had planned to begin data collection in January, 1995. The QI/IC Team recognized that data collected during the HELICS Project would provide information regarding process and outcome indicators included in the Action Plan for the USAID-sponsored Project. Since the HELICS Project was already underway, there was no reason to require that the hospitals undertake a duplicate, independent data collection effort. The QI/IC Team emphasized both verbally and in this written report that both hospitals should make a commitment to continue data collection after the self-limited 3-month period of data collection for the HELICS Project was finished. We also emphasized that additional data elements not included in the HELICS Project would need to be collected for the USAID-sponsored Project. It should be noted that, with our guidance, the workgroups from both hospitals specified the data elements that they would need to collect to implement and evaluate their specific quality improvement aims. They articulated the absolute requirement to collect not only baseline data, but also ongoing follow-up data, as well as to feed back data to their clinical staff. Their own action document drafted at the conclusion of the 5-day workshop clearly expresses their commitment to this plan.

Consequently, while data collected during the HELICS Project will be useful in completing the Action Plan, progress in this regard should not depend on the hospital's participation in the HELICS Project. Conversely, participation in the HELICS Project would fulfill only a small portion of the Action Plan. It is critical to understand that the HELICS Project does not include provision for facilitating improvements in individual hospitals such as those outlined in the Action Plan and, thus, does not compete in any way with the USAID-sponsored Project. The HELICS project currently is designed as a quality assurance benchmarking project, not a quality improvement project of the type outlined in the Action Plan, which emphasizes improved performance and reduced costs in individual hospitals.

BACKGROUND

The HEI/USAID 1994 country plan for Hungary proposes to (a) assist two hospitals in adjusting to the new Diagnostic Related Group (DRG) payment system and improve internal management, in order to allocate hospital resources more efficiently and improve quality of care, and (b) assist the Hungarian Society for Quality Assurance (HSQA) in developing model quality assurance programs within community hospitals as candidates for replication in other parts of the country. With approvals by USAID/Washington and USAID/Budapest, these two activities were combined within the same two hospitals. Consequently, the Health Markets Project's financial management and quality improvement consultant teams are organized to work collaboratively in demonstrating improvements in efficiency and effectiveness at both institutions.

In June 1994 a team comprised of Raymond Kaden; Eugene Arnone; Walter Ballinger, M.D.; James O. Hepner, Ph.D. FACHE; Edward James O'Rourke, M.D., and Walter Unger visited Hungary to develop action plans and initiate programs at Flor Ferenc County Hospital, Kerepestarcsa (Pest County) and Korcag City Hospital (Szolnok County). The purpose of the combined programs is to develop educational models to demonstrate to other hospitals in Hungary:

a. Improved efficiency within the parameters of the DRG reimbursement system through the development of internal management systems, which make possible the reallocation of hospital resources, and

b. Improved effectiveness through the institution of quality improvement programs.

For a complete presentation of the findings of this team and the action plan, see the Draft Report titled "Initiation of Combined DRG/QA Demonstration Programs in Hungary", September 1, 1994 and a related document titled "Responsibilities of Participating Organizations", September 1, 1994.

DESCRIPTION OF ACTIVITIES

Project Indicators and Phase I and II Tasks

Indicator 1: Reduce case mix adjusted length of stay by 10%.

Phase I

Task A. Work with finance team to develop appropriate DRG coding.

The need for improved DRG coding was reviewed with the Finance Team.

Task B. Establish baseline LOS for past year if possible, otherwise collect adjusted LOS for Oct. 94 - Dec. 94 as baseline.

LOS data for the prior year were not available. We reviewed LOS in two specific patient populations (surgical and obstetric patients) with the Finance Team and hospital personnel.

LOS for surgical patients will be prospectively collected at both hospitals by hospital personnel participating in the HELICS (Hospitals in Europe Link for Infection Control through Surveillance) Project beginning Jan. 1995. (The HELICS Project is a multicenter study of surgical site infection (SSI) in European Community nations. More than 20 hospitals will be participating in Hungary).

Recognizing that the length of preoperative stay is a documented risk factor for SSI, a plan to reduce the length of preoperative hospitalization for high volume surgical procedures was developed during the workshop as a part of the overall quality improvement project to reduce SSI rates (see Indicators 3 and 4). The plan is to:

1. Collect LOS data in surgical patients as a part of the HELICS Project;
2. Report LOS for five or more of the most common surgical procedures to the surgical services, the quality improvement program, and the hospital administration/finance group on a quarterly basis;
3. Review components of preoperative evaluation, determine truly necessary components, and determine components that can be performed on an outpatient basis;
4. Develop systems to complete preoperative evaluations in outpatient clinics;
5. Monitor impact of systems for outpatient preoperative evaluation on LOS and SSI rates (see Recommendations).

From discussions with hospital personnel, it is apparent that LOS is long for uncomplicated vaginal delivery (typically five days) and uncomplicated cesarean section delivery (typically 6-7 days). A number of explanations for the long LOS were cited;

most important was the lack of a primary care system to effectively care for mothers and infants in the perinatal period. Consequently, it seems doubtful that significant reductions in LOS for obstetric patients can be achieved in the immediate future. We view this as an important intermediate-term goal that will likely be dependent on improvements in outpatient primary care. Nonetheless, evaluation of the obstetric population may identify a subpopulation of patients who could be discharged early because of their greater access to established perinatal care systems. Establishing baseline LOS for uncomplicated vaginal and cesarean section deliveries will be an important outcome measure for this effort (see Recommendations).

Phase II

Task A. Quarterly summary of adjusted LOS to be reported from finance group. Feedback and discussion with hospitals via internet or fax.

LOS for five or more of the most common surgical procedures should be reported to the surgical services, the quality improvement program, and the hospital administration/ finance group on a quarterly basis (see Recommendations). LOS for uncomplicated vaginal delivery and uncomplicated cesarean section should be collected and reported quarterly to the obstetric service, the quality improvement program, and the hospital administration/finance group (see Recommendations). These data should be communicated by fax to the QI/IC and Finance Teams, who will comment via fax (see Recommendations).

Indicator 2: Reduce inappropriate use of high cost antibiotics in surgical departments by 25%.

Phase I

Task A. Work with finance team to account for antibiotic dispensing from central pharmacy to target medical and surgical services.

i. Determine baseline use over past 12 months
ii. Establish tracking/accounting system for the next year

Data regarding the use of antimicrobial agents over the past 12 months were not available.

As a part of the prevalence survey, we collected data regarding the use of intravenous antimicrobial agents. It is important to note that only agents prescribed for the patient at the time of the survey were recorded since it was beyond the scope of the survey to record agents administered at any point in the hospital course, including agents used for perioperative antimicrobial prophylaxis (PAP). Data for each hospital ward are reported in the individual final hospital reports (see Appendix 1). We found

that the use of expensive, broad spectrum agents, such as second and third generation cephalosporins, ciprofloxacin, and ampicillin/sulbactam, was modest (3.0% of patients were receiving these agents in one hospital and 7.4% in the other hospital). The use of antimicrobial agents in general was greatest in the surgical wards and the intensive care units; however, even in these areas the use of expensive, broad spectrum agents was modest. These data are limited and may be biased due to short-term fluctuations in prescription patterns. Additional data must be collected and analyzed (see below) before firm conclusions can be reached. Nonetheless, while improvements in the use of antimicrobial agents may improve patient outcome (see discussion of PAP below), our prevalence survey data suggest that major cost savings from reductions in the use of antimicrobial agents may not be forthcoming.

Data regarding the use of all antibiotic use (prophylactic and treatment) in surgical patients (including PAP) will be prospectively collected in both hospitals by hospital personnel participating in the HELICS (Hospitals in Europe Link for Infection Control through Surveillance) Project. We strongly support this effort (see Recommendations).

During the prevalence survey, it was apparent that the time when PAP is administered is not recorded in the patient's chart. Workshop participants had widely divergent opinions regarding the frequency with which PAP is administered at the appropriate time. Since the PAP must be administered at the appropriate time (e.g., within the 2 hours before the incision) in order to be effective, it is critical that improved documentation of the time of PAP administration is needed in order to assess performance regarding this process measure. A major theme of the workshop was the development of systems to ensure proper timing and documentation of PAP. Follow-through on this work is a very high priority (see Recommendations).

Task B. Review use of antibiotics with Chiefs of Services and agree on optimal use strategy of empiric antibiotic therapy and also establish protocols for surgical wound prophylaxis.

Since the prevalence survey showed that use of expensive, broad spectrum antimicrobial agents was modest, we focused all of our effort at this stage of the project on the use of PAP. This approach is supported by published literature which shows that PAP typically accounts to 1/3 or more of hospital antimicrobial use. Guidelines for PAP (including the cost of various regimens) have been published by the Hungarian National Institute of Health and were available in both hospitals (see Appendix 3). We reviewed these guidelines and have several comments (see Recommendations):

1. A first generation cephalosporin (cefazolin) is not included in Hungarian guidelines. Cefazolin is used for PAP for many types of surgery in U.S. hospitals and is considerably cheaper than second and third generation cephalosporins (which are recommended in Hungarian guidelines).

2. If cefazolin is not available, second generation cephalosporins (cefuroxime) are preferred over third generation cephalosporins in most circumstances because they are cheaper and have better gram positive activity (especially against *Staphylococcus aureus*).

3. Regimens using combinations of cheaper agents, such as the combinations of gentamicin and clindamycin or gentamicin and metronidazole for surgery involving the large intestine, are likely to be as effective and cheaper than the use of broad spectrum agents, such as third generation cephalosporins.

4. The duration of PAP should be brief as recommended in the guidelines.

It was our qualitative impression during the prevalence survey that PAP may be underutilized, especially in surgeries with clean wounds. If utilization of PAP increases, this may increase overall cost for PAP. This increased cost should be more than offset by reduced expenditures for treatment of SSI, in addition to reducing unnecessary patient morbidity. Except for the limited data generated by the prevalence survey, no reliable data regarding SSI in clean surgeries were available. However, workshop participants were polled using consensus methods and estimated the rate to be 7-10%, which clearly would make PAP highly cost effective based on published data.

A plan to optimize the cost-effectiveness of PAP for five or more high volume surgical procedures (e.g., hernia repair, elective cholecystectomy, colorectal surgery) was developed during the workshop as a part of an overall quality improvement project to reduce SSI (see Indicators 3 and 4). The plan is to:

1. Collect data regarding use of PAP as a part of the HELICS Project;
2. Establish a system for monitoring costs of PAP;
3. Review existing guidelines for PAP and select preferred regimens based on effectiveness and cost (U.S. guidelines are provided for reference in Appendix 4);
4. Evaluate the use of PAP including agent(s) used, dosage, duration, timing, and cost;
5. Report data to the surgical and anesthesiology services, the pharmacy, the quality improvement program, and the hospital administration/finance group on a quarterly basis;
6. Design and implement improvements in systems based on data;
7. Monitor impact of improvements on cost and SSI rates (see Recommendations).

An order form for antimicrobial agents is not in use. The merits of an order form for antimicrobial agents (especially for PAP) were discussed at the workshop. Such a form has been shown to improve the choice of agents for PAP and to virtually eliminate excessive duration of prophylaxis. A sample order form is provided in Appendix 5.

Task C. Begin educational campaign with "counter detailing" literature to promote strategy (b) above.

Optimization of PAP was discussed in one of the lectures at the workshop. Relevant literature regarding PAP are provided in Appendix 4. Improved drug delivery systems, educational programs, especially by opinion leaders, and "engineering" solutions (e.g., PAP order form with restriction of drugs available for prophylaxis and automatic "stop" orders) should take priority over formal counter detailing at this point.

Phase II

Task A. Quarterly summary of antibiotic use to be reported from finance/pharmacy dept. and reviewed. Feedback to hospitals via internet or fax.

Data regarding the use of PAP in five or more high volume surgical procedures should be reported to the surgical and anesthesiology services, the pharmacy, the quality improvement program, and the hospital administration/ finance group on a quarterly basis (see Recommendations). These data should include agents, dosage, duration, and timing of the first dose in relation to the time of the incision. Overall expenditures related to the use of antimicrobial agents and specifically PAP, if possible, should also be provided. These data should be communicated by fax to the QI/IC and Finance Teams, who will comment via fax (see Recommendations).

Indicator 3: Determine baseline SSI at each facility and demonstrate a 25% decline over one year.

Phase I

Task A. A point prevalence survey of nosocomial infections, utilization of high risk invasive devices, and utilization of antibiotics. These data will also serve as a baseline to gauge improvement efforts.

A point prevalence survey was conducted in Flór Ferenc Hospital from Nov. 28 - Dec. 2 and in Kátai Gábor Hospital from Dec. 5 - 9. [A point prevalence survey measures factors present at a particular point in time (i.e., when a ward is visited)]. In each hospital, the survey was performed on all surgical wards, obstetrics/gynecology wards, and in the intensive care unit (see the individual final hospital reports in Appendix 1 for a detailed description of survey methodology). Bed occupancy, nosocomial infection rates (including SSI), utilization of invasive devices, and utilization of intravenous antimicrobial agents by ward are provided and discussed in the individual hospital reports (Appendix 1).

Prevalence survey data are useful in quickly assessing rates of nosocomial infection (including SSI). Repeat prevalence surveys can also be performed to monitor progress

over time. However, prospective surveillance of SSI collected in both hospitals as a part of the HELICS Project will be a much more useful outcome measurement because it is less likely to be affected by short term variability in bed occupancy, the frequency of specific surgical procedures, and infection rates. We discussed the methodology used in the HELICS Project in detail with Dr. László Gulácsi, the Secretary General of the HSQA and the coordinator of the HELICS Project in Hungary.

We supported the commitment of each hospital to participate in the HELICS Project and strongly encouraged them to continue prospective surveillance for surgical site infections after the HELICS Project has been concluded (see Recommendations). We suggested that consideration should also be given to performing active surveillance for other important nosocomial infections (such as post-operative pneumonia, pneumonia in mechanically ventilated patients, urinary tract infections in catheterized patients, and postpartum endometritis) as a part of other quality improvement efforts (see Recommendations).

During the workshop, we assisted the participants in developing a quality improvement project with the aim of reducing endemic rates of SSI. This project is an overarching initiative that incorporates efforts related to Indicators 1, 2, and 3 (see discussion of Indicators 1, 2 and 3 and Recommendations). The specific goals of the project are to:

1. Introduce a surgical site infection (SSI) surveillance system (see above);
2. Provide confidential feedback to surgeons regarding procedure-specific, risk adjusted SSI rates and procedure-specific duration of surgery for five or more high volume procedures (see below);
3. Reduce the length of preoperative stay for five or more high volume procedures (see Indicator 1);
4. Optimize cost-effectiveness of perioperative antimicrobial prophylaxis (PAP) for five or more high volume procedures (see Indicator 2);
5. Optimize preoperative preparation of surgical patients.

Phase II

Task A. Quarterly incidence data for SSI will be reported by the local infection control teams and reviewed. Feedback and discussion with hospitals via internet or fax.

Strategies for reporting data regarding SSI were discussed in detail with hospital personnel participating in the workshop (see Indicator 4). We recommended that rates of surgical site infection be adjusted using a risk index similar to that used by the U.S. Centers for Disease Control and Prevention's National Nosocomial Infection Surveillance System (NNIS) (see Appendix 6). We recommended that procedure-specific, risk-adjusted rates of SSI and procedure-specific duration of surgery be

confidentially reported on a quarterly basis (or semi-annually if necessary due to small numbers of surgeries) to individual surgeons. The surveillance and reporting methodology should be discussed with the surgeons at the outset to assure their agreement and cooperation. Appropriate safeguards should be taken to assure the confidentiality of the data (see Recommendations). Workshop participants were enthusiastic about this approach and suggested novel methods for assure confidentiality. These data should be communicated by fax to the QI/IC and Finance Teams, who will comment via fax (see Recommendations).

Indicator 8: Facilitate the creation of an Infection Control Team at the demonstration sites.

Phase I

Task A. Hospital officials will be educated on how infection prevention can serve as a model for designing and implementing a more global quality improvement program.

Both hospitals have infection control (called hospital hygiene in Hungary) and quality assurance programs already in existence. We emphasized greater integration and coordination of the overall infection prevention and quality improvement efforts in the workshop (see below). We also recommended review of committee membership to insure inclusion of clinical opinion leaders as well as appropriate multidisciplinary representation. A member of the quality improvement committee should serve as the sponsor for the project outlined in this report. This individual should track progress and help the project team identify and remove barriers to success.

There is a plan at both hospitals to support the infection control training of one or more experienced nurses once a training course is developed by the Central Training Institute for Qualified Health Workers, the national agency responsible for post-graduate medical education. This nurse(s) would then join the infection control (hospital hygiene) program as a full-time member(s).

Phase II

Tasks A and B. A five-day seminar/workshop in fundamental aspects of infection prevention and its relationship to quality improvement will be offered in Hungary.

The seminar/workshop will focus on:

i. hospital infection prevention within a quality improvement model
ii. strategies for conducing nosocomial infection surveillance
iii. monitoring improvement efforts

iv. establishing quality improvement programs

The workshop was conducted at the Flór Ferenc Hospital during Dec. 12 - 16. A summary of the workshop and a list of the participants are included in Appendix 2. There were 10 participants from Flór Ferenc Hospital and eight participants from Kátai Gábor Hospital. The QI/IC Team and senior hospital administrators collaborated in the selection of participants to insure multidisciplinary representation (general surgeons, obstetrician/gynecologists, ward nurses, operating room nurses, quality improvement personnel, infection control personnel, pharmacists, and senior administrators).

A series of lectures was provided by the workshop faculty covering the following topics (see Appendix 7 for course materials):

Concepts underlying quality improvement;

Rationale for using infection control as a model for quality improvement;
Practical aspects of designing and conducting quality improvement projects (multidisciplinary teams, group process techniques, quality improvement tools, Plan-Do-Check-Act model for QI);

Clinical practice guidelines;

Transmission of microorganisms in the hospital environment;

Surgical wound infections (epidemiology, diagnosis, treatment, prevention);

Reducing endemic rates of surgical wound infections using quality improvement techniques;

Surveillance of nosocomial infections;

Infection control programs (organization, personnel, activity);

Nosocomial urinary tract infection (epidemiology, diagnosis, treatment, prevention);

Nosocomial lower respiratory tract infection (epidemiology, diagnosis, treatment, prevention);

Nosocomial bloodstream infection (epidemiology, diagnosis, treatment, prevention);

Epidemiology/study design and basic biostatistics.

The bulk of the workshop was devoted to assisting participants in developing a quality improvement project. We modeled the use of quality improvement techniques discussed in the lectures as a part of this process. At the conclusion of the workshop the participants had designed a broad quality improvement initiative with the goal of reducing endemic rates of surgical site infection (see Indicator 3). It is our opinion that the workshop participants were highly successful in using the quality improvement approach to set strategic goals, analyze the systems involved in delivering these goals, and developing an action plan.

Evaluations of the workshop from the participants were elicited at the end of the second and third days. Adjustments were made in the workshop to respond to their needs and critique (see the summary of the workshop in Appendix 2).

Indicator 9: Perform comprehensive assessments of infection prevention in the demonstration hospitals.

Phase I

Tasks A and B. Structured interviews with key personnel, including administrators, physician and nurse leaders, a representative sample of staff nurses, and directors of relevant departments. Direct observations of facilities and infection prevention practices on major hospital wards to verify information from the interviews and to collect quantitative and qualitative data that will be used as a baseline when assessing the success of improvement efforts.

A hospital survey was conducted in Flór Ferenc Hospital from Nov. 28 - Dec. 2 and in Kátai Gábor Hospital from Dec. 5 - 9. In each hospital, interviews with key hospital personnel and direct observations were conducted. Detailed descriptions of the survey methodology in each hospital are included in the final hospital reports (see Appendix 1).

Phase II

Task A. A written report will summarize the specific recommendations for each hospital based on information collected during the comprehensive survey, the measures of structure, process, and outcome that will be monitored to assess improvement, and recommendations for design and development of an overall quality assessment and quality improvement program.

Preliminary written recommendations were provided to senior hospital administrators and quality improvement/infection control personnel before the QI/IC Team left Hungary. These recommendations were discussed at length during meetings

at the conclusion of the hospital survey and again at the conclusion of the workshop. Final written summaries of the survey findings and recommendations for improvement are provided in the final hospital reports (see Appendix 1).

Additional Activities

Currently, Hungary does not have infection control nurses (ICNs). We were informed that a one year infection control training course for nurses is planned to start in the fall of 1995. Dr. Dr. Szabadfalvi András, Medical Director at Flór Ferenc Hospital, requested that Carol O'Boyle Williams provide advice regarding the curriculum for this course. Ms. O'Boyle Williams was Vice Chairperson of the Association of Practitioners in Infection Control and Epidemiology's Curriculum Committee which developed the *APIC Curriculum for Infection Control Practice*, (first edition). This two volume book is used as the primary training resource for infection control practitioners in the U.S.

Ms. O'Boyle Williams met with Dr. Maria Hok, Director of the Central Training Institute for Qualified Health Workers, the national agency that would be responsible for developing the curriculum for this training course. Content areas and possible resources for the one year training program planned for 1995-96 were also discussed. Dr. Hok asked Ms. O'Boyle Williams for assistance in curriculum development and training activities.

RECOMMENDATIONS

Indicator 1: Reduce case mix adjusted length of stay by 10%.

1. Collect LOS data at least for surgical patients and obstetric patients.

2. Report LOS for five or more of the most common surgical procedures (preferably those specified by the workshop participants) to the surgical services the quality improvement program, and the hospital administration/finance group on a quarterly basis.

3. Report LOS for uncomplicated vaginal delivery and uncomplicated cesarean section to the obstetric service, the quality improvement program, and the hospital administration/finance group on a quarterly basis.

4. Communicate LOS data by fax to the QI/IC and Finance Teams on a quarterly basis. The QI/IC and Finance Teams will comment promptly via fax.

5. Review components of preoperative evaluation, determine truly necessary components, and determine components that can be performed on an outpatient basis.

6. Develop systems to complete preoperative evaluations in outpatient clinics.

7. Monitor impact of systems for outpatient preoperative evaluation on LOS and SSI rates.

8. Develop a plan for a project to reduce LOS after uncomplicated vaginal delivery and uncomplicated cesarean section delivery. Evaluate the obstetric population to determine if there is a subpopulation of patients who could be discharged early because of their greater access to established perinatal care systems.

9. Dr. Goldmann and Dr. Huskins will visit each hospital from March 20 - 28, 1995 and assess progress regarding this indicator.

Indicator 2: Reduce inappropriate use of high cost antibiotics in surgical departments by 25%.

1. Collect data regarding use of antimicrobial agents (agent, dosage, duration, timing, and cost) in surgical patients. Use should be categorized as "prophylaxis" or "treatment" to facilitate analysis of PAP regimens. A reliable system will need to be developed to assure recording of the time that PAP is administered.

2. Establish a system for monitoring costs of PAP.

3. Determine if a first generation cephalosporin (cefazolin) is available in Hungary. If cefazolin is available, use this agent in PAP regimens. If cefazolin is not available, determine what steps are necessary to obtain this agent for use. In the interim, use a second generation cephalosporin (cefuroxime) instead of a third generation cephalosporin since there are few, if any, indications for using expensive, third generation cephalosporins for PAP.

4. Review National Institute of Health guidelines for PAP and select preferred regimens for each type of surgery based on effectiveness and cost. U.S. guidelines are provided for reference in Appendix 4). Include surgeons, anesthesiologists, pharmacists, and infectious diseases specialists as available in this review process. The QI/IC Team will answer questions regarding PAP or comment on guidelines developed specifically for use in either hospital via fax.

5. Evaluate the use of PAP including agent(s) used, dosage, duration, timing, and cost.

6. Report data to the surgical and anesthesiology services, the pharmacy, the quality improvement program, and the hospital administration/finance group on a quarterly basis.

7. Communicate data regarding use of antimicrobial agents for PAP by fax to the QI/IC and Finance Teams on a quarterly basis. The QI/IC and Finance Teams will comment promptly via fax.

8. An order form for PAP may be useful for facilitating selection of preferred PAP regimens and dosages (see Appendix 5 for sample order form).

9. Dr. Goldmann and Dr. Huskins will visit each hospital from March 20 - 28, 1995 and assess progress regarding this indicator.

Indicator 3: Determine baseline surgical site infection rate (SSI) at each facility and demonstrate a 25% decline over one year.

1. We strongly support the commitment of each hospital to participate in the HELICS Project and encourage them to continue prospective surveillance for surgical site infections after the HELICS Project has been concluded.

2. Consider performing active surveillance for other important nosocomial infections (such as post-operative pneumonia, pneumonia in mechanically ventilated patients, urinary tract infections in catheterized patients, and postpartum endometritis) as a part of other quality improvement efforts.

3. Discuss the surveillance and reporting methodology with the surgeons. Assure appropriate safeguards for the confidentiality of the data.

4. Confidentially report procedure-specific, risk-adjusted rates of SSI and procedure-specific duration of surgery to individual surgeons on a quarterly basis.

5. Communicate progress regarding this indicator by fax to the QI/IC Team, who will comment via fax (see Recommendations).

6. Dr. Goldmann and Dr. Huskins will visit each hospital during March 20 - 28, 1995 and assess progress regarding this indicator.

Indicator 8: Facilitate the creation of an Infection Control Team at the demonstration sites.

1. We strongly support the plan in each hospital to have one or more experienced nurses complete training in infection control (once such a training course is developed by the national agency for post-graduate medical education) and join the infection control (hospital hygiene) program.

2. We recommend review of quality improvement and infection control committee membership to assure inclusion of clinical opinion leaders as well as appropriate multidisciplinary representation. A member of the quality improvement committee should serve as the sponsor for the project outlined in this report. This individual should track progress and help the project team identify and remove barriers to success.

3. Dr. Goldmann and Dr. Huskins will visit to each hospital during March 20 - 28, 1995 and assess progress regarding this indicator.

Indicator 9: Perform comprehensive assessments of infection prevention in the demonstration hospitals.

1. Detailed recommendations for quality improvement and infection prevention are provided in the individual final hospital reports (see Appendix 1).

2. Dr. Goldmann and Dr. Huskins will visit to each hospital during March 20 - 28, 1995 and assess progress regarding this indicator.

Additional Activities

Although Hungary has experts in many of the content areas of infection control, such as microbiology and epidemiology, there are no infection control nurses (ICNs) to provide guidance in the integration of these content areas into the practice of infection control.

Because of this lack of experienced Hungarian ICNs, there is a need for assistance in planning and content development of an ICN training course. In addition, there is a need for experienced ICNs to provide information on the application of various infection control theories and principles to real-life, clinical situations.

The one year ICN training program to be offered through the Central Training Institute for Qualified Health Workers is an opportunity to develop a core of knowledgeable ICNs, who will serve as resources on infection control and establish the role of the ICN in Hungary. The development of a cadre of knowledgeable ICNs is important in establishing clinically-focused, outcome-based infection surveillance and control programs. The course participants will benefit from having the opportunity to have individual consultation and mentoring from experienced ICNs regarding infection control problems and issues from their respective hospitals.

Specific recommendations are:

1. Two senior ICNs from the U. S. who are skilled curriculum development should meet with Dr. Maria Hok and other faculty responsible for the ICN training course for a one week period in March, 1995. The purpose of this visit is to assist in course planning and development and to identify training resources. A meeting in March will allow sufficient time for translation of materials. (This trip could coincide with the trip by Dr. Huskins and Dr. Goldmann March 20 - 28 described above to allow for greater interchange of ideas in relation to this curriculum development effort and the other Phase III-IV tasks described above.) The development of the curriculum and identification of resources for a one year program requires a substantial amount of planning with knowledgeable sources. In addition to general planning meetings, we anticipate that work sessions will be needed with individual faculty members. One week is a extremely short period of time for planning and writing the curriculum for an entire year. We believe the presence of two senior ICNs at this planning meeting will offer an opportunity for many of the faculty members to meet individually with at least one of the senior ICNs and obtain in-depth consultation regarding specific content areas.

   We recommend Carol O'Boyle Williams, RN, MS, CIC and Barbara Soule, RN, MPA, CIC as the two senior ICNs. Ms. O'Boyle Williams and Ms. Soule are experienced in infection control, have served in leadership roles in many national infection control projects, and are recognized as expert ICNs by the U. S. infection control community. Ms. Soule served as the Chairperson, and Ms. O'Boyle Williams as Vice Chairperson, of the Association of Practitioners in Infection Control and Epidemiology's (APIC) Curriculum Committee which developed the *APIC Curriculum for Infection Control Practice*, (first edition). Ms. Soule was the Editor of this curriculum and Ms. O'Boyle Williams was a contributor. Ms. Soule is the senior editor of a nursing infection control textbook, *Infection in Nursing Practice: Prevention and Control*, published in the U.S. in 1995. Both Ms. Soule and

Ms. O'Boyle Williams contributed chapters for this text. They have both participated in international infection control projects, including projects in Brazil (Ms. Soule) and Costa Rica, Thailand, and Hungary (Ms. O'Boyle Williams).

2. Two senior U.S. ICNs skilled in operating, managing, planning, and performing the activities of the infection control program participate in the training course for a two week period in the fall of 1995 or early 1996. This two week period will focus intensively on surveillance methods, prevention activities, and the role of the infection control nurse. In addition to providing lectures, Ms. O'Boyle Williams and Ms. Soule will provide individual consultations to course participants regarding specific infection control problems. The timing of the second visit would depend upon the sequence of classes in the training program. To provide the optimum benefit to the course participants, we believe this visit should occur after the course participants have had some clinical experience in infection control.

TIMELINE FOR PHASE III AND IV
(January - June, 1995)

Tasks	January	February	March	April	May	June
			1995			
Indicator 1:						
Collect LOS data for surgical patients	X	X	X	X	X	X
Collect LOS data for obstetric patients	X	X	X	X	X	X
Report LOS to hospital personnel and QI/IC and Finance Teams			X			X
QI/IC and Finance Teams comment			X			X
Review components of preoperative evaluation	X	X				
Develop systems to complete preoperative evaluations in outpatient clinics			X	X	X	X
Plan project to reduce LOS in obstetrics				X	X	X
Dr. Huskins and Dr. Goldmann visit each hospital and assess progress			X (Mar 20-28)			
Indicator 2:						
Develop a reliable system for recording administration of PAP	X					
Collect data on use and cost of PAP	X	X	X	X	X	X

Determine if cefazolin is available in Hungary	X					
Review NIH and U.S. guidelines for PAP and select preferred regimens	X	X				
Report data regarding use of PAP to hospital personnel and QI/IC and Finance Teams			X			X
QI/IC and Finance Teams comment			X			X
Dr. Huskins and Dr. Goldmann visit each hospital and assess progress			X (Mar 20-28)			
Indicator 3:						
Discuss surveillance and reporting methodology with surgeons. Insure safeguards for confidentiality of data.	X					
Prospective surveillance for SSI as a part of the HELICS Project	X	X	X	X	X	X
Confidentially report procedure-specific, risk-adjusted rates of SSI and procedure-specific duration of surgery to individual surgeons			X			X

Report progress to QI/IC Team via fax			X			X
QI/IC Team comment			X			X
Dr. Huskins and Dr. Goldmann visit each hospital and assess progress			X (Mar 20-28)			
Indicator 8:						
Review QI committee membership. Assign a sponsor for the project.	X					
Dr. Huskins and Dr. Goldmann visit each hospital and assess progress			X (Mar 20-28)			
Indicator 9:						
Implement detailed recommendations regarding QI & IC in final hospital report	X	X	X	X	X	X
Dr. Huskins and Dr. Goldmann visit each hospital and assess progress			X (Mar 20-28)			

Appendix 1 Hospital Reports

HOSPITAL QUALITY IMPROVEMENT AND INFECTION CONTROL SURVEY REPORT

FLÓR FERENC HOSPITAL

January 4, 1994

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I. INTRODUCTION

The International Hospital Infection Prevention and Quality Assessment Program (INQUAL) from the Children's Hospital and Harvard University (Boston, Massachusetts) conducted an evaluation of quality improvement and infection control at Flór Ferenc Hospital. This work was supported by the United States Agency for International Development (USAID) Health Markets Project through its principal contractor Health Enterprises International, Inc. (HEI).

The survey was conducted by a physician, W. Charles Huskins, MD, and a nurse, Carol O'Boyle Williams, MS, RN, CIC, from November 28 to December 2, 1994. These surveys were completed successfully in large measure due to the dedication and assistance of hospital leaders and personnel. We are grateful for this assistance.

We were very impressed with the overall commitment of the hospital management, physicians, nurses, other professional staff, and other hospital workers to providing high quality medical care. Of course, there is always a possibility that we misinterpreted information provided to us or that an observation we made was in error. If so, we apologize for the error.

II. SUMMARY OF RECOMMENDATIONS

Quality Improvement Program

1.The hospital's quality improvement effort needs more overall focus and coordination. While quality improvement efforts can and should be conducted within individual departments these efforts should be consistent with the hospital's overall strategic quality improvement goals determined by the highest level of hospital management. These goals should reflect input from hospital staff and the expressed needs and perceptions of the hospital's patients (internal and external consumer, respectively). There should also be greater coordination and cooperation between different departments in quality improvement efforts.

To achieve these goals we recommend the following:

a) Establishment of a quality improvement "steering" committee to oversee and coordinate quality improvement efforts.
b) Elaboration of the hospital's overall quality improvement goals. These goals should be in written form and publicized to hospital workers through their departmental leaders. Individual departments should be encouraged to develop their own quality improvement goals, but these goals should be reviewed and approved by the steering committee.
c) Subcommittees or task forces (such as the Medicine QAC and the Nursing QAC) should design and conduct specific projects and should provide regular reports of their progress to the steering committee. Each project or task force should have a designated sponsor on the steering committee who can track progress and assist in coordinating inter-departmental work and remove barriers.
d) At least in the early stages, all quality improvement projects should be reviewed and approved by the steering committee. This should be a simple, not burdensome, process designed to ensure coordination of the overall effort and adequate cooperation between departments.

2. In addition to clinical and administrative personnel, personnel involved with fiscal management and information services should be included on the steering committee. Other departments, such as pharmacy, microbiology, etc., should be included as ad hoc members.

3. The steering committee should ensure that appropriate training and resources are provided in support of approved quality improvement initiatives.

4. Current and future quality improvement projects should emphasize inclusion of measurable indicators of key processes and outcomes that can be used to monitor performance.

5. A procedure for submission and critique of specific quality improvement proposals is needed to facilitate discussion of the merits of various projects. This should include a written format for quality improvement proposals and a well-defined process for review and critique of these proposals.

6. The quality improvement project developed at the workshop Dec. 12 - 16 is well conceived and has a high likelihood of success if adequately supported and implemented. Details of the development of this project, as well as recommendations for implementation and a timeline for tasks associated with this project from January - June, 1995, are included in the overall project report, titled "Quality Improvement/Infection Control Demonstration Project for Hungary: Report for Phases I and II."

Infection Control (Hospital Hygiene) Program

1. We support the plan to train one or more nurses in infection control and include these individuals into the Hospital Hygiene Program as full time personnel.

2. A program of active, prospective surveillance for nosocomial infections is needed. The hospital's participation in the HELICS Project is an important first step in this regard since it will provide valuable information regarding the occurrence of surgical wound infections and will train personnel in the collection, analysis, interpretation, and reporting of surveillance data. Surveillance of other important nosocomial infections should be considered in the future. Written definitions of nosocomial infections are needed. A written surveillance plan should be developed, reviewed each year, revised as necessary by the Hospital Hygiene Service, and approved by the Hospital Hygiene Committee.

3. Improved surveillance data will probably identify more potential clusters than have been detected in the past. Clusters of nosocomial infections should be completely investigated since important problems with infection prevention efforts are often identified during the course of these investigations, even if they are not the direct cause of the observed infections.

4. Except in unusual circumstances (such as point source outbreaks of nosocomial infections), microorganisms recovered from cultures of the environment are not the direct cause of nosocomial infections. Except for the educational purpose of illustrating the role of the hands of health care workers in the indirect transmission of hospital microorganisms, results of hand cultures are rarely, if ever, useful in infection prevention efforts. We recommend discontinuing these cultures since they are unlikely to have any impact of the incidence of nosocomial infections.

5. A plan for optimizing the use of perioperative antimicrobial prophylaxis was developed as a part of the quality improvement project developed at the workshop Dec. 12 - 16. Details of the development of this project, as well as recommendations for implementation and a timeline for tasks associated with this project from January - June, 1995, are included in the overall project report, titled "Quality Improvement/Infection Control Demonstration Project for Hungary: Report for Phases I and II."

6. The frequency of antimicrobial resistant microorganisms should be monitored and specific strategies developed to limit spread of these organisms. Of specific concern are: methicillin resistant *Staphylococcus aureus*, vancomycin and high-level gentamicin resistant *Enterococcus* sp., penicillin resistant *Streptococcus pneumoniae*, and third generation cephalosporin and aminoglycoside resistant gram negative bacteria (especially *Pseudomonas aeruginosa*, *Enterobacter* sp., *Klebsiella* sp., *Serratia* sp., and *Acinetobacter* sp.). There are insufficient data to determine if any of these organisms are responsible for a significant number of nosocomial infections in the hospital at the present time (see below, "Microbiology Laboratory"). We suggest that the infection control (hospital hygiene) service develop a plan in collaboration with the microbiology laboratory for tracking these organisms, identifying infected and colonized individuals, and a strategy for minimizing spread of these organisms.

7. It is likely that there is considerable underreporting of needlestick injuries and other significant occupational exposures to blood or potentially infectious body fluids by hospital personnel. Hospital personnel should be encouraged to report exposures and a mechanism should be established for monitoring the frequency, location, and circumstances of the exposure. Processes of care should be

examined to identify situations and practices that increase the risk of an occupational exposure. Interventions to reduce the risk of exposure should be implemented and included in written procedures. If an exposure occurs, prompt investigation of the source of the exposure (the person whose blood was involved in the exposure) should be performed to determine if prophylaxis, counseling, and follow-up serologic testing is necessary.

Patient Care Practices

1. Alcohol-based waterless handwashing agents should be available in greater supply, particularly for use by doctors and nurses when they move from bed to bed examining patients or performing procedures. A simple, inexpensive waterless handwashing agent, such as alcohol (70% by weight)/glycerin (1% by weight), can be formulated by the Pharmacy and provided in closed, pour top bottles.

2. Only patients with infections which are spread via the airborne route (i.e., active pulmonary tuberculosis, varicella, measles) need to be transported to another hospital for appropriate isolation. All other patients may be cared for in the hospital using appropriate isolation precautions.

3. There should be greater awareness of the presence of potential pathogens, particularly antimicrobial resistant microorganisms, in secretions and excretions of all patients. These microorganism can be spread to other patients via direct and indirect transmission (especially on the hands of health care workers). Hospital personnel should be educated on strategies to prevent this transmission through improved compliance with handwashing (see above), use of barriers (gloves, gowns), and appropriate patient placement.

4. The use of shoe covers in the Operating Theater as well as elsewhere in the hospital does not contribute infection prevention.

5. An antiseptic which contains chlorhexidine or povidone-iodine should be used since these agents provide residual antibacterial activity on the skin during the surgery. It was not clear whether Dodosept contains either of these agents in addition to alcohol.

6. The use of feeding tubes as central venous catheters should be discontinued. These catheters are stiff and made of a material that increases the risk of thrombosis, thrombophlebitis, and bloodstream infection. In addition, these catheters are not designed for percutaneous insertion and, therefore, must be inserted by cut-down (venous dissection), which also increases the risk of thrombophlebitis and bloodstream infection. Only the Subclavia-Jugular Catheter sets should be used for central venous catheterization since these catheters are made of a more compliant, less thromobogenic material and since they can be inserted percutaneously.

7. IV infusion tubing does not need to be changed every day. In the absence of evidence that nosocomial bloodstream infections are a significant problem, it is reasonable to change IV infusion tubing every 3 days.

8. Urine drainage bags can be drained (instead of changing and discarding the entire drainage system) when the bag is full. This will reduce the risk of urinary tract infection since it will significantly reduce the frequency of disruption of the catheter-drainage system junction. To facilitate easier emptying of urine drainage bags, consider purchase of a different type of urine drainage systems with drainage ports on the bottom of the drainage bag.

9. Ventilator circuits do not need to be changed as frequently as every 2 days. There is currently no well-established guideline addressing this issue, but it is reasonable not to change ventilator circuits at all during short term ventilation. During long-term ventilation, it is still not clear that ventilator circuits need to be changed; however, if they are changed it is reasonable to change them no more frequently than once a week.

Sterilization, Disinfection, and Cleaning

1. Personnel cleaning instruments should wear better protective equipment, including, heavy duty gloves and goggles and a mask or a face shield to prevent splashes of contaminated substances to their eyes or mouth. Sharp instruments should not be handled by hand to avoid percutaneous injuries.

2. We are not familiar with the particular chemical indicators presently in use and are not aware of the efficacy of these tests in ensuring adequate functioning of steam sterilizers. The standard in the U.S. is to monitor the functioning of steam sterilizers and ethylene oxide sterilizers using biologic indicators (microbiologic tests using bacterial spores). Steam sterilizers are monitored using a biologic indicator once a day and ethylene oxide sterilizers are monitored using a biologic indicator in every load. When implantable items are sterilized, a biologic indicator is used in each load and these materials are not released for use until the biologic indicator test is known to be negative (i.e., that sterilization was adequate). It is not clear that it is absolutely necessary to adhere to this exact standard if sterilization parameters are being monitored routinely. However, we recommend use of biologic indicators much more frequently than is done presently.

3. We are not aware of any data that demonstrates that formaldehyde liquid as it is used in the hospital is an adequate method of sterilization. We recommend that critical items (items that will contact sterile tissues or fluids) that cannot be steam sterilized should be sterilized by ethylene oxide. If this is not possible due to time constraints, we recommend that chemical sterilization with glutaraldehyde be used.

4. Endoscopes should be meticulously cleaned after use and should have a longer contact time (20-30 minutes) with glutaraldehyde to ensure high-level disinfection. Preferably, endoscopes should be rinsed with sterile water although distilled water is an acceptable alternative if rinsing with sterile water is not possible. The endoscope should be completely dried before reuse. Biopsy forceps used with endoscopes should be sterilized since they may contact sterile tissues. If this is not possible, they should be at least be processed in a manner consistent with high-level disinfection.

5. Depending on the manufacturer's recommendations, glutaraldehyde preparations may be used for periods of 14 to 28 days if kept in a covered basin or tub.

6. There are a large number of "ready-made" disinfectants and antiseptics in use. Cost savings may be achieved by reviewing the use of each of these solutions and reducing unnecessary use and by eliminating unnecessary or redundant solutions.

7. A standard procedure for cleaning antiseptic containers before they are refilled should be developed, if such a procedure is not already in existence. Autoclaving the bottles is desirable, if it can be accomplished easily. If not, cleaning with soap and water followed by thorough drying before refilling is necessary.

8. The use of formaldehyde for disinfection in the operating room should be discontinued. The use of this potentially toxic agent is not necessary if another disinfectant is used. Cleaning procedures should be the same after all procedures regardless of whether the patient had an infection. Closing the operating room after a surgery involving an infection is not necessary since microorganisms causing these infections are not likely to be spread via the air.

Microbiology Laboratory

1. A yearly summary of antimicrobial susceptibility results should be compiled and distributed to the infection control program and physicians and nurses caring for patients.

2. Use of selective media (media with antibiotics such as oxacillin or gentamicin) can be relatively easily and inexpensively prepared. This media can be used to screen selected patient populations antimicrobial resistant bacteria.

III. SURVEY METHODS

The survey at was performed by conducting:

1) Interviews of key hospital personnel;
2) Observations of facilities, supplies, equipment, and practices;
3) A point prevalence survey of active nosocomial infections in patients hospitalized at the time of the survey.

The following hospital personnel were interviewed:

Dr. Szabadfalvi András, Medical Director
Vértes Tamásné, Nursing Director
Dr. Vass László, Chairman, Medical Quality Assurance Committee
Dr. Vámai László, Chief Hygienist
Dr. Rákay, Assistant Hygienist
Elek Marta, Sanitary Inspector
Dr. Végh Titus, Surgeon
Zenoné Vertetits, Head Nurse of the Operating Theater
Head Nurse of the Surgery Ward (name not recorded)
Imrené Koreny Zeuzsa, Head Nurse of the Urology Ward
Head Nurse of the Obstetrics/Gynecology Ward (name not recorded)
Dr. Zaray István, Chief of Anesthesia/Intensive Care
Sári Katalin, Head Nurse of the Intensive Care Unit
Nyáry Mihály, Chief of Central Sterilization
Dr. Fülöpné Nagy Judit, Pharmacist
Dr. Pogácsásné Kis Katalin, Pharmacist
Gabriella Barta, Microbiology Technician

The following wards, ICUs, and support departments were toured and observations of facilities, equipment, supplies, and practices were recorded:

Intensive Care Unit
Surgery Ward
Urology Ward
Obstetrics/Gynecology Ward
Operating Room
Central Sterilization unit
Endoscopy Room
Pharmacy

The Microbiology Laboratory was not visited as it was under construction at the time of our visit.

Information regarding patient care practices was obtained from a single source on each ward (i.e., a head nurse or a physician), since time constraints prohibited interviews with a large number of individual nurses or physicians. Observation of a large number of patient care practices was also not possible. Consequently, variations in the conduct of specific patient care practices may exist which are not reflected in this report.

A prevalence survey of active nosocomial infections was conducted following a standardized methodology ("Outline for Surveillance and Control of Nosocomial Infections", U.S. Centers for Diseases Control, 1972). Standard definitions for nosocomial infections were used ("CDC Definitions of Nosocomial Infections, 1988" U.S. Centers for Diseases Control, Am J Infect Control 1988;16:128-140). On each ward included in the survey, a bed-to-bed survey was first conducted to determine the number of occupied beds, the patient's primary diagnosis, and whether the patient had been hospitalized for > 2 days. During this survey, observations of the following factors were recorded: the type and use of invasive catheters and

devices (intravascular catheters, urinary catheters, mechanical ventilation, peritoneal dialysis catheters), evidence of phlebitis at catheter insertion sites, a history of a surgical procedure(s) performed in the previous 4 weeks, and the use of intravenous antibiotics. For patients hospitalized for > 2 days, the presence of cough, diarrhea (5 or more loose stools/day), or fever (T >38.0^{0}C on each of the previous two days) was also assessed. If any of these factors were present the patient's entire hospital chart was reviewed (including vital signs, nurse's and physician's notes, medication records, and laboratory studies) to determine the presence or absence of a nosocomial infection. If necessary, the patient was examined.

Due to time constraints, it was not possible to conduct a prevalence survey on all wards. The following wards were surveyed:

Intensive Care Unit
Surgery Ward
Urology Ward
Obstetrics/Gynecology Ward

IV. SURVEY RESULTS AND RECOMMENDATIONS

A. General Hospital Information

FINDINGS:

Location: Kistarcsa, Hungary (just outside of Budapest)

Catchment Area: Pest County (a county in close proximity to Budapest but not including Budapest)

Patient population: Patients referred from primary care clinics and nearby municipal hospitals. The Psychiatry and Ophthalmology programs also care for patients from other parts of Hungary.

Number of beds: 1010

Operating Rooms: 4 operating theaters (General Surgery/Urology/Gynecology, Ophthalmology, Otorhinolaryngology, Obstetrics) with a total of approximately 8 operating rooms

Intensive Care Units:

Adult ICU (8 beds)

Services:

Adult Medicine and subspecialties
Pediatrics
Obstetrics/Gynecology
General Surgery, including Vascular Surgery
Urology
Otorhinolaryngology
Ophthalmology
Rheumatology
Neurology
Dermatology
Psychiatry
Urgent Care (Emergency)

Medical School Affiliation: Medical students and physicians-in-training receive clinical training at the hospital

Nursing School Affiliation: Nursing students from nearby diploma programs receive clinical training at the hospital

B. Organization of the Quality Improvement Program

FINDINGS:

The responsibilities and authority of the quality assessment program are described in the regulations governing the hospital approved by the hospital governance and the Pest County Government in 1994. There is no formal quality assessment department. There are two Quality Assurance Committees (QAC), one for the Medicine Department and one for the Nursing Department. The Medicine QAC has been in existence since late 1993 and reports directly to the Medical Director. The Nursing QAC has been in existence since 1990 and reports to the Nursing Director and the hospital's Council of Nurses. The Medicine QAC and the Nursing QAC work independently with little interaction or coordination of effort.

RECOMMENDATIONS:

The hospital's quality improvement effort needs more overall focus and coordination. While quality improvement efforts can and should be conducted within individual departments these efforts should be consistent with the hospital's overall quality improvement goals determined by the highest level of hospital management. These strategic goals should reflect input from hospital staff and the expressed needs and perceptions of the hospital's patients (internal and external consumer's, respectively). Since quality improvement efforts often involve several different hospital departments, there should be greater coordination and cooperation between different departments in these efforts.

To achieve these goals we recommend the following:

1. Establishment of a quality improvement "steering" committee to oversee and coordinate quality improvement efforts. This committee should be an oversight committee, not a committee that takes on specific quality improvement projects. Consequently, the committee should include senior hospital managers.
2. Elaboration of the hospital's overall quality improvement goals. These goals should be in written form and publicized to hospital workers through their departmental leaders. Individual departments should be encouraged to develop their own quality improvement goals, but these goals should be reviewed and approved by the "steering committee." These goals should be consistent with concepts embodied in what is termed "continuous quality improvement" or "total quality management." It is extremely important to develop appropriate outcome and process measures and to trend these measures over time so that progress towards meeting hospital and departmental goals can be monitored concurrently.
3. Subcommittees or task forces (such as the Medicine QAC and the Nursing QAC) should design and conduct specific projects and should provide regular reports of their progress to the "steering committee."
4. At least in the early stages, all quality improvement projects should be reviewed and approved by the steering committee. This should be a simple, not burdensome, process designed to ensure coordination of the overall effort and adequate cooperation between departments. With time, formal approval of individual projects may not be necessary.

C. Quality Improvement Program Personnel

FINDINGS:

The Medical QAC is composed of 6 physicians (2 internists, 2 surgeons, 1 anesthesiologist/intensivist, and 1 pathologist and the Deputy Medical Director, Dr. Marczell Mihaly. Other ad hoc members are recruited as necessary. Dr. Vass, the Chief of Pathology, is the Chairman of the Medical QAC. He is a member of the Board of Directors of the Hungarian Quality Assurance Society (HSQA). The other physicians are described as junior physicians.

The Nursing QAC is composed of the Nursing Director, Vértes Tamásné, the Deputy Nursing Director, Lórincz Marta, head nurses representing each of the wards, and the Sanitary Inspectors. Vértes Tamásné is the Chairperson of the Nursing QAC.

RECOMMENDATIONS:

The involvement of persons involved in clinical care (physicians and nurses) and management (senior hospital managers) in present quality improvement efforts is a strength. However, additional personnel should be involved, including personnel involved with fiscal management, information services, and support departments (Pharmacy, Microbiology Laboratory, Environmental Services, Nutrition Services, etc.).

Appropriate training and resources should be provided to hospital personnel participating in approved quality improvement initiatives.

D. Quality Improvement Program Activity

FINDINGS:

The Medical QAC meets every 3-4 weeks. Activity has centered around "brainstorming" sessions to discuss new ideas for improving the quality of care and the development of several specific initiatives to improve performance.

Meetings of the Nursing QAC are included as a part of the monthly Council of Nurses meeting. Activity of the committee includes routine inspections of wards to review staffing, documentation of nursing notes, patient care practices, procedures for disinfection of equipment on the wards, and the status of equipment and supplies. If any problems are identified, additional inspections are performed as necessary.

Several initiatives are in various stages of development:

1. Determining the appropriateness and cost-effectiveness of consultations from subspecialists

A new consultation form is being developed to facilitate the evaluation of consultations. The content of this form has reportedly been a topic of considerable discussion; consequently final version of this form has not yet been determined. Once such a form is developed, a descriptive study of consultations performed by the Neurology Department is planned. Criteria for determining the appropriateness of consultations will be developed based on the results of this descriptive study.

2. Reducing the incidence of surgical site infections

The hospital will participate in the "Hospitals in Europe Link for Infection Control through Surveillance" (HELICS) Project with the support of Johnson & Johnson. The HELICS Project is a multi-center study which will be conducted in a number of European Community countries (and Hungary) with the goal of reducing surgical site infections through standardized surveillance, feedback of surveillance results to surgeons, and improvements in practices related to the care of surgical patients. Twenty-two hospitals in Hungary will participate in the HELICS Project. The details of the study are being finalized and a training course for nurses who will perform the surveillance is presently being conducted. Two persons who will perform surveillance in the hospital are attending this training course. Data collection will reportedly begin in January, 1995. Pertinent to this effort, the hospital has also committed to select one or more nurses (likely candidates are the nurses participating in the HELICS Project) to attend an infection control training course which is being developed in cooperation with the Central Training Institute for Training of Qualified Health Workers.

3. Improved DRG coding

We did not assess the current status of the DRG coding system initiative.

4. Development of a unit dose system for pharmaceuticals to reduce pharmaceutical costs

The unit dose system for pharmaceuticals is presently being pilot tested on one of the adult internal medicine wards. The lack of a sufficient number of computers to enable computerized physician ordering

and billing, a computer network to communicate physician orders to the pharmacy, and additional pharmacy assistants were cited as impediments to wider application of this program.

RECOMMENDATIONS:

Many ideas for improvements in quality of care have apparently been discussed and several projects have been developed and are in various stages of implementation. These efforts are laudable. However, none of these projects were sufficiently developed for us to clearly determine the extent to which measurable indicators of process and outcome had been incorporated into their design or to determine how these indicators would be used to improve overall performance. Consequently, we have the following general recommendations to improve current and future projects.

The quality improvement project developed at the workshop Dec. 12 - 16 is well conceived and has a high likelihood of success if adequately supported and implemented. Details of the development of this project, as well as recommendations for implementation and a timeline for tasks associated with this project from January - June, 1995, are included in the overall project report, titled "Quality Improvement/Infection Control Demonstration Project for Hungary: Report for Phases I and II."

Quality improvement projects should focus on improving overall performance, not merely identifying and correcting bad or "low quality" performance. Minimizing "low quality" performance is, of course, an important first step in quality management. However, this effort alone will not result in substantial improvement in overall performance. Real gains in performance are achieved by reducing variability in performance and by improving the level of overall performance. The use of process and outcome indicators to measure and monitor improvements in performance is critical to this effort. In the future, there should be an explicit description of the indicators that will be used to monitor performance and how performance measurements will guide improvement.

There does not appear to be a formal process for the development of specific quality improvement initiatives. Our recommendations for the hospital-wide coordination of quality improvement initiatives are discussed above (see above, "Organization of the Quality Improvement Program"). However, even within an improved organizational framework, a better process for designing and implementing quality improvement projects is needed. Each project should have a "sponsor" from the "steering committee" and a team leader who is accountable for the performance and reporting of the project. A procedure for submission and critique of specific quality improvement proposals is needed to facilitate discussion of the merits of various projects. This procedure should include:

1. Establishing a written format for submission of proposals including:

    a) The overall aim of the proposal;
    b) The specific goals of the proposal;
    c) Relevant, published background information and the potential significance of the project;
    d) Preliminary data, if available;
    e) Personnel participating in the project, including representation of all relevant hospital departments;
    f) Target population (including inclusion and exclusion criteria);
    g) Methods by which key process and outcome indicators will be chosen, measured, interpreted, and reported to other hospital personnel;
    h) Means by which indicator data will be used to analyze and improve performance using the Plan-Do-Study-Act model;
    i) Means by which improvements will be established as a new or improved system;
    j) Timeline;
    k) Budget, if indicated, and/or an estimate of personnel time required to complete the project.

2. Establishing a process by which written proposals are evaluated, prioritized, and approved

E. Organization of Infection Control

FINDINGS:

The Hospital Hygiene Service is a separate hospital department which reports to the Medical Director and the Hospital Hygiene Committee. The Chief Hygienist is the director of this department. He also oversees technical aspects of work conducted in the Central Sterilization Unit. The Hospital Hygiene Committee is composed of the Chief Hygienist (Chairman), the Director of Microbiology (Secretary), and several Chiefs of Services (i.e., Surgery, Pediatrics, Anesthesiology, Laboratory). The committee is responsible for discussing and approving hospital wide policies and procedures related to hospital hygiene. Policies and procedures approved by the committee are submitted to the Medical Director for his approval. The Committee meets at least every 6 months and on ad hoc basis as necessary.

The responsibilities and authority of the Hospital Hygiene Service are described in the regulations governing and by another document developed by the Service and approved by the hospital governance and the Pest County Government in 1994.

RECOMMENDATIONS:

It is likely that more frequent meetings of the Hospital Hygiene Committee (at least quarterly) will be needed to plan, direct, and monitor the activities of the program. In addition, consideration should be given to broadening the membership of the committee to include other departments, such as Nursing and support departments.

F. Infection Control Program Personnel

FINDINGS:

The Chief Hygienist, Dr. Vámai, is a certified hospital hygienist and has additional training in toxicology. Another physician, Dr. Rákay, is a part of the department and is awaiting the opportunity to sit for her board test in hospital hygiene. There are two Sanitary Inspectors, one of whom is presently on maternity leave. Sanitary Inspectors complete 4 years of post-secondary training in public health hygiene, which includes training in hospital hygiene. There is a plan that one or more of the nurses participating in the HELICS Project will attend an infection control training course when this course is established (see above, "Activity of the Quality Improvement Program").

Personnel are provided the opportunity to increase their knowledge and skills by attending post-graduate courses and a variety of meetings and conferences.

RECOMMENDATIONS:

We strongly support the plan to train one or more experienced nurses in infection control and include these individuals into the Hospital Hygiene Program as full time personnel.

G. Infection Control Program Activity

1. Surveillance Activity

FINDINGS:

Surveillance of nosocomial infections, as well as communicable community infections, is accomplished by passive reporting of infections by physicians and nurses to the Hospital Hygiene Service. Infections are recorded and reported on an annual basis to the Medical Director, the Hospital Hygiene Committee, and the Pest County Dept. of Health. Only the absolute number of infections are reported; rates of infection are not calculated.

The Hygiene Service receives and reviews weekly reports of any positive microbiology results.

There are no written definitions of nosocomial infections used for surveillance.

RECOMMENDATIONS:

Since passive surveillance systems likely result in significant under-reporting of nosocomial infections, a program of active, prospective surveillance for nosocomial infections is needed. The hospital's participation in the HELICS Project (see above, "Activity of the Quality Improvement Program) is an important first step in this regard since it will provide valuable information regarding the occurrence of surgical wound infections (likely to be among the most common nosocomial infections in this hospital) and will train personnel in the collection, analysis, interpretation, and reporting of surveillance data. Post-discharge surveillance of surgical wounds is critical to this effort, especially if the length of post-operative stay is shortened, since most studies of surgical site infections indicate that 50-60% of infections are detected only after discharge. The mechanism by which post-discharge surveillance can be accomplished is not clear at the present time and needs further consideration.

Surveillance of other important nosocomial infections should be considered in the future, possibly including: urinary tract infections in patients with urinary catheters, pneumonia in mechanically ventilated patients and post-operative patients, postpartum endometritis, mastitis, and post-cesarean section wound infections in obstetric patients, and infections in newborn infants in the "Pathologic Nursery."

Written definitions of nosocomial infections are needed. The CDC (Centers for Disease Control and Prevention) Definitions of Nosocomial Infections could be used, although the use of laboratory tests to document infections will need to be improved. If this cannot be achieved, alternative definitions that do not rely as heavily on laboratory tests should be developed.

A written surveillance plan should be developed, reviewed each year, revised as necessary by the Hospital Hygiene Service, and approved by the Hospital Hygiene Committee. The plan should include statements regarding the goal of each surveillance component, methods for case finding, definitions of infections, calculation of rates of infection, and reporting of infection rates. Regular, timely feedback of infection rates to the physicians and nurses involved in patient care, the chiefs of services, the Hospital Hygiene Committee, and the hospital administration is critical.

Except in unusual circumstances (such as point source outbreaks of nosocomial infections), microorganisms recovered from cultures of the environment are not the direct cause of nosocomial infections. Except for the educational purpose of illustrating the role of the hands of health care workers in the indirect transmission of hospital microorganisms, results of hand cultures are rarely, if ever, useful in infection prevention efforts. We recommend discontinuing these cultures since they are unlikely to have any impact of the incidence of nosocomial infections.

2. Outbreaks

FINDINGS:

The Hospital Hygiene Service investigates potential outbreaks of nosocomial infections reported by physicians and nurses and potential exposures among patients and hospital workers to communicable infections. A investigation of a possible outbreak of post-cesarean section wound infections was conducted earlier in 1994. Six potential cases occurring over a 3 month period were reported by the Chief of Obstetrics/Gynecology. After review of the medical records, the results of clinical microbiology cultures obtained from the potential cases, the results of clinical cultures obtained from non-infected patients, and the results of various environmental cultures, it was concluded that only one case represented a true infection. A report of the investigation was written. No other significant outbreaks have been reported.

RECOMMENDATIONS:

Most hospitals experience at least one cluster of nosocomial infections every 12-18 months. The improved surveillance data will probably identify more potential clusters than have been detected in the past. Clusters of nosocomial infections should be completely investigated since important problems with infection prevention efforts are often identified during the course of these investigations, even if they are not the direct cause of the observed infections.

3. Policies and Procedures

FINDINGS:

There are written policies and procedures covering many topics relevant to infection control including isolation precautions, specific patient care practices, and sterilization and disinfection. These policies and practices are governed by some degree by national hospital hygiene regulations/guidelines, although there is reportedly some latitude allowed for implementation in individual hospitals. We did not review written hospital policies and practices or national hospital hygiene regulations/guidelines.

The Sanitary Inspectors conduct regular inspections of hospital wards and treatment areas. The frequency of these inspections varies according to the intensity/invasiveness of care provided; Operating Theaters, the Intensive Care Unit, and the Maternity/Delivery ward are inspected every 3 months. During inspections, relevant written hospital policies and procedures are reviewed with the head nurse, facilities are inspected, nursing practices are observed, and a number of microbiologic investigations are conducted. Microbiology investigations vary according to the area inspected. As an example, during an inspection of the Operating Room microbiology tests include: sterility tests of instruments and supplies prepared in the hospital, cultures of hands of surgeons and nurses participating in surgery, swab cultures of various surfaces, and settle plates. By report, there have been no positive sterility tests in the past year. Tests of surgical instruments are also conducted after cleaning to determine if there is any residual blood.

RECOMMENDATIONS:

Periodic reviews such as those conducted by the Sanitary Inspectors are extremely useful. However, we have serious doubts about the value of the microbiologic investigations of the environment and personnel described above. Except in unusual circumstances (such as point source outbreaks of nosocomial infections), microorganisms recovered from cultures of the environmental or hospital personnel are difficult to interpret and are not the direct cause of nosocomial infections. We recommend discontinuing these cultures since they are unlikely to have impact of the incidence of nosocomial infections. Sterility tests of items manufactured in the hospital are necessary and should be continued.

4. Personnel Education and Training

FINDINGS:

We did not perform an detailed assessment of existing education and training programs for hospital personnel.

RECOMMENDATIONS:

None

5. Antimicrobial Utilization and Control

FINDINGS:

The utilization of antimicrobial agents is monitored by a pharmacy committee. The Hospital Hygiene Service is not involved in this activity. There are presently no restrictions on the prescription of antimicrobial agents.

RECOMMENDATIONS:

A plan for optimizing the use of perioperative antimicrobial prophylaxis was developed as a part of the quality improvement project developed at the workshop Dec. 12 - 16. Details of the development of this project, as well as recommendations for implementation and a timeline for tasks associated with this project from January - June, 1995, are included in the overall project report, titled "Quality Improvement/Infection Control Demonstration Project for Hungary: Report for Phases I and II."

The utilization of antimicrobial agents should be monitored and, in the future, it may be necessary to restrict prescription of expensive broad spectrum antimicrobial agents.

6. Antimicrobial Resistant Organisms

FINDINGS:

There is presently no program for monitoring of antimicrobial resistant organisms.

RECOMMENDATIONS:

The frequency of antimicrobial resistant microorganisms should be monitored and specific strategies developed to limit spread of these organisms. Of specific concern are: methicillin resistant *Staphylococcus aureus*, vancomycin and high-level gentamicin resistant *Enterococcus* sp., penicillin resistant *Streptococcus pneumoniae*, and third generation cephalosporin and aminoglycoside resistant gram negative bacteria (especially *Pseudomonas aeruginosa*, *Enterobacter* sp., *Klebsiella* sp., *Serratia* sp., and *Acinetobacter* sp.). There are insufficient data to determine if any of these organisms are responsible for a significant number of nosocomial infections in the hospital at the present time (see below, "Microbiology Laboratory"). We suggest that the infection control (hospital hygiene) service develop a plan in collaboration with the microbiology laboratory for tracking these organisms, identifying infected and colonized individuals, and a strategy for minimizing spread of these organisms.

7. Occupational Health

FINDINGS:

Hepatitis B Vaccine: Hepatitis B vaccine is available to susceptible, at-risk hospital workers free-of-charge through the national public health service. Periodic vaccination campaigns are conducted in the hospital in specific departments. A standard dosing regimen (administered intramuscularly at months 0, 1, and 6) is used. Post-vaccination antibody titers are not checked.

Occupational Exposure to Blood and Potentially Infectious Body Fluids: Percutaneous injuries involving exposure to blood or other potentially infectious body fluids are reportedly uncommon. Hospital personnel are instructed to report occupational exposures to blood and potentially infectious body fluids to the Occupational Safety Officer in their department. These officers investigate the case and inform the Hospital Hygiene Service if the clinical history of the source of the exposure suggests a communicable infection. If there is clinical evidence of a communicable infection, additional investigation of the source is conducted on a case-by-case basis and prophylaxis or treatment provided, if indicated. There is no protocol for evaluating the source of the exposure for evidence of blood-borne pathogens if the clinical history is not suggestive.

Influenza Vaccine: Influenza vaccine is offered free-of-charge to hospital workers every autumn. Acceptance of the vaccine is variable.

Tuberculosis: There is no specific evaluation for occupational exposure to TB or active tuberculosis among hospital workers within the hospital. Hospital workers are supposed to undergo yearly radiographic examinations for pulmonary tuberculosis as a part of the general screening procedure conducted by the national public health service on the entire Hungarian population.

Other: There are no other vaccines or examinations offered to hospital workers.

RECOMMENDATIONS:

We suspect that there is considerable underreporting of needlestick injuries and other significant occupational exposures blood or potentially infectious body fluids by hospital personnel. Hospital personnel should be encouraged to report exposures and a mechanism should be established for monitoring frequency, location, and circumstances of the exposure.

Processes of care should be examined to identify situations and practices that increase the risk of an occupational exposure (such as recapping of needles contaminated with blood). Interventions to reduce the risk of exposure should be implemented and included in written procedures.

If an exposure occurs, prompt investigation of the source of the exposure (the person whose blood was involved in the exposure) should be performed to determine if prophylaxis against hepatitis B is necessary (HBsAg testing on the patient and HBsAb testing on the employee). The expense of testing should be borne by the hospital. There is no known effective prophylaxis for infection against HIV so no specific recommendations in this regard are made, except to provide counseling and follow-up serologic testing as is presently performed.

There is good reason for increased concern about the potential for occupational exposure to TB. Even though patients with TB are likely to be referred to other hospitals, the potential for exposure still exists. The most useful approach is to promptly identify patients with TB and initiate effective therapy as soon as possible. If patients with TB are cared for in the hospital, they should be placed in a single room and hospital personnel should wear masks when caring for these patients. Although these precautions will be helpful in reducing the risk of transmission of TB and other airborne infections, some risk will remain given the lack of isolation rooms with special ventilation systems capable of generating negative pressure relative to adjacent hallways. As a long term goal, improved isolation rooms for patients with infections spread by the airborne route are needed (see below, "Facilities").

H. Facilities

FINDINGS:

General Organization: On the Surgery, Urology, and Obstetrics/Gynecology wards, most rooms are 6 bed rooms. The Intensive Care Unit is in a temporary location while a new unit is being constructed.

Isolation Rooms: There are no specific isolation rooms on the general wards, although two-bed rooms, which are located at the end of the halls, can be used for this purpose if needed. These rooms do not have any special ventilation or anterooms. The new Intensive Care Unit will have two isolation rooms with independent ventilation systems, although it is not clear whether these ventilation systems will be capable of generating negative pressure relative to adjacent hallways

Preparation Area for Intravenous Fluids and Medications: Designated rooms or areas are used.

Clean and Dirty Utility Areas: Separate areas are used for clean and dirty equipment.

General Organization of the Operating Theaters: There are 4 operating theaters: General Surgery/Urology/Gynecology, Ophthalmology, Otorhinolaryngology, Obstetrics). In the General Surgery/Urology/Gynecology Operating Theater, patients enter and leave through the same doorway. There is a room for pre-op and post-op patients. There is a central corridor for movement of sterile instruments and supplies.

Ventilation in the Operating Rooms: Ventilation is provided by a central air conditioning system. The number of air exchanges per hour provided by this ventilation system is not known.

Hospital Water Supply: We did not assess the source or quality of the hospital water supply.

RECOMMENDATIONS:

As a long term goal, isolation rooms with special ventilation systems capable of generating negative air pressure relative to adjacent hallways are needed.

I. Patient Care

1. Handwashing Facilities, Supplies, and Practices

FINDINGS:

Sinks: Functional sinks for handwashing were available at nursing stations and patient care areas. However, the number of sinks for handwashing in patient rooms was not always adequate.

Aerators/Filters on Faucets: Aerators or filters are not used on the faucets.

Soap: Liquid soap in closed, pour top containers or pump dispensers was generally available.

Towels (type and availability): Paper towels were generally available.

Waterless Handwash Agents: An alcohol-based waterless handwashing agent was available in closed, pour top bottles.

Handwashing Practices: It was not possible to perform a systematic assessment of handwashing practices.

RECOMMENDATIONS:

Alcohol-based waterless handwashing agents are very effective antiseptics for reducing the microbial load, especially transient colonizers, on the hands of caregivers. However, these agents should be available in greater supply, particularly for use by doctors and nurses when they move from bed to bed examining patients or performing procedures (i.e., changing dressings). A simple, inexpensive waterless handwashing agent, such as alcohol (70% by weight)/glycerin (1% by weight), can be formulated by the Pharmacy and provided in closed, pour top bottles.

2. Isolation Precautions, Universal Precautions, and General Use of Barriers

FINDINGS:

Written guidelines are available (see above, "Policies and Procedures"). Patients with communicable diseases are usually transferred to an infectious diseases hospital (Saint László Hospital) in Budapest. The Hospital Hygiene Service assists in determining whether a patient is likely to have a communicable disease. Specific isolation rooms are not available, although rooms can be used for this purpose, if necessary (see above, "Facilities"). These rooms do not have any special ventilation. Gloves, cloth gowns, and synthetic, disposable masks are available. Shoe covers are used on a number of areas, including the Operating Theater and the Intensive Care Unit. We did not assess the use of appropriate barriers in a comprehensive manner; however, by casual observation it was evident that staff often did not use appropriate barriers (gloves) when handling supplies contaminated with blood or potentially infectious body fluids. In addition, patients with draining wounds are often cared for in the same room as other surgical patients.

RECOMMENDATIONS:

There should be greater awareness of the presence of potential pathogens, particularly antimicrobial resistant microorganisms, in secretions and excretions of all patients. These microorganism can be spread to other patients via direct and indirect transmission (especially on the hands of health care workers). Hospital personnel should be educated on strategies to prevent this transmission through improved compliance with handwashing (see above), use of barriers (gloves, gowns), and appropriate patient placement.

Since there are no data demonstrating the efficacy of shoe covers in preventing nosocomial infections, their use can be discontinued from an infection control perspective.

3. Surgery and Wound Care

FINDINGS:

Pre-op Bath: Performed with standard soap the night before surgery for elective surgeries.

Pre-op Hair Removal: Removed with a disposable razor immediately before surgery.

OR Staff Scrub: Wash with soap and water, then wash with an alcohol-based agent (either Sterilium or Dodosept)

OR Staff Attire: Cloth scrubs and disposable, synthetic hats, masks, and shoe covers.

Gloves: Sterile gloves. We did not assess whether these gloves are reused.

OR Staff Mucus Membrane Protection: we did not assess whether OR staff use mucus membrane protection (goggles or face shields).

Patient Skin Antisepsis: Wash with soap and water, then apply an alcohol-based agent (Dodosept) for surgery involving the chest or abdomen or povidone iodine preparation for surgery on the groin.

Perioperative Antimicrobial Prophylaxis: There are no written guidelines for perioperative antimicrobial prophylaxis. It was not clear how often intravenous antimicrobial prophylaxis is used for surgeries with clean wounds or, if prophylaxis is used, which agent is ordered. A variety of methods of preparing patients for colon or rectal surgery, including oral metronidazole, enemas, and osmotic cathartics. The first dose of intravenous perioperative antimicrobial prophylaxis is usually administered when the patient is on the ward.

Wound Care Instruments and Supplies: A dressing cart is used for wound care supplies and instruments. Instruments used for dressings are supplied in individual sterile packs on some wards and in bulk in large sterile containers on other wards (Surgery). Supplies used for dressings (sterile cotton balls, cotton tipped applicators, and gauze) are supplied in bulk in large sterile containers. Antiseptics used in dressing changes are changed weekly on some wards and daily on other wards (Surgery).

Burn Wound Care: Patients with burns are rarely cared for in the hospital. A systematic assessment of the care of burn wounds was not performed.

RECOMMENDATIONS:

An antiseptic which contains chlorhexidine or povidone-iodine should be used since these agents provide residual antibacterial activity on the skin during the surgery. It was not clear whether Dodosept contains either of these agents in addition to alcohol.

A plan for optimizing preoperative preparation of the patient's skin at the site of the incision and for optimizing the use of perioperative antimicrobial prophylaxis was developed as a part of the quality improvement project developed at the workshop Dec. 12 - 16. Details of the development of this project, as well as recommendations for implementation and a timeline for tasks associated with this project from January - June, 1995, are included in the overall project report, titled "Quality Improvement/Infection Control Demonstration Project for Hungary: Report for Phases I and II."

4. Intravascular Catheters, Intravenous Fluids, and Medications

FINDINGS:

Indications for Use:

Peripheral intravenous catheters (PIV) are used for infusion of most intravenous fluids and mediations.

Percutaneous central venous catheters (PCVC) are occasionally used in some patients for hemodynamic monitoring and central venous access.

Peripheral arterial catheters are not used.

The use of umbilical arterial or venous catheters was not assessed.

Duration of Use: Catheters are used for as long as they are needed. There is no routine schedule

for removal of catheters.

Personnel Inserting: PIVs are inserted by nurses; PCVCs are inserted by physicians.

Types of Intravascular Catheters (catheter material):

PIV

--Vasofix (Teflon)--short, over-the-needle catheters

PCVC

--Subclavia-Jugular Catheter set (material not stated, ? polyetherethylene)--long, over-the-needle catheters

--Feeding tube (material not stated, ? polyvinylchlorine)

All catheters are discarded after use.

Skin Antisepsis: Povidone-iodine or an alcohol-based antiseptic.

Insertion Technique: Inserted percutaneously except for PCVC feeding tubes which require insertion by cut-down, usually on the external jugular vein.

Barriers Used During Insertion: Non-sterile gloves are used during insertion of PIVs. Sterile gloves, gowns, masks, and drapes are used for insertion of PCVCs.

Dressing: Gauze and tape is used.

Monitoring of Site Inspection: Insertion sites are monitored regularly by nurses.

Syringes: Only disposable syringes are used; they are discarded after one use.

Needles: Only disposable needles are used; they are discarded after one use.

Types of IV Fluid Containers and Administration Sets: Both commercially manufactured and "in-house" manufactured IV fluids are used. Both types of fluid are available in glass bottles with rubber tops which are spiked by the IV infusion tubing. The rubber tops are covered by metal covers; there are no screw tops caps. Connections between the components of the infusion system are compatible and tight connections can be maintained.

IV Fluid Manufacture Within the Hospital: Simple intravenous fluids are prepared in a laminar flow hood and autoclaved in the Pharmacy. Cultures of these fluids are performed in the Pharmacy to ensure sterility. Tests to ensure that these fluids are pyrogen-free are performed at a laboratory outside the hospital.

IV Fluid and Medication Preparation: Admixture of IV fluid and medications is performed on the wards by nurses on an "as needed" basis. Single-dose ampoules of electrolyte solutions and medications are used and discarded after opening.

Parenteral Nutrition Preparation: Commercially manufactured parenteral nutrition solutions (dextrose/amino acid/electrolytes/vitamins) and lipid emulsions are used in the Intensive Care Unit, but rarely elsewhere in the hospital. Bottles are used for an individual patients.

Frequency of IV Fluid Container and Administration Set Change: IV fluid bottles and parenteral fluid bottles are changed when they are finished, which is usually within several hours and always within 24 hours. "Keep open" infusions are generally not used. IV infusion tubing is changed every day. Infusion tubing is changed after a blood product infusion.. IV and parenteral nutrition containers and administration sets are disposed after use.

Hemodynamic Monitoring: Hemodynamic monitoring is performed using disposable manometers which are discarded after use.

RECOMMENDATIONS:

The use of feeding tubes as central venous catheters should be discontinued. These catheters are stiff and made of a material that increases the risk of thrombosis, thrombophlebitis, and bloodstream infection. In addition, these catheters are not designed for percutaneous insertion and, therefore, must be inserted by cut-down (venous dissection), which also increases the risk of thrombophlebitis and bloodstream infection. Only the Subclavia-Jugular Catheter sets should be used for central venous catheterization since these catheters are made of a more compliant, less thromobogenic material and since they can be inserted percutaneously.

IV infusion tubing does not need to be changed every day. In the absence of evidence that nosocomial bloodstream infections are a significant problem, it is reasonable to change IV infusion tubing every 3 days.

5. Indwelling Urinary Catheters and Urine Drainage Systems

FINDINGS:

Indications for Use: Monitoring urine output in severely ill patients, post-operative patients in whom voiding difficulties are expected, irrigation of the bladder after urologic procedures, bladder outlet obstruction, and incontinence.

Duration of Use: Used as long as needed. There is no routine schedule for removal.

Personnel Inserting: Nurse or physician

Types of Catheters: Foley catheters are used. Urinary catheters designed for continuous irrigation of the bladder are used in patients after urologic surgeries, such as transurethral resection of the prostate.

Antiseptic Used to Cleanse the Meatus Prior to Insertion of a Urinary Catheter: Povidone-iodine

Type of Drainage System: Closed drainage systems are used exclusively.

Integrity of Foley Catheter/Drainage System Junction: Foley catheters are not routinely irrigated. Drainage systems are discarded when the drainage bag is full, although it is possible to drain these catheters. This procedure requires disruption of the catheter-drainage system junction. Sometimes, urinary catheters are clamped and disconnected from the drainage system to allow the patient to ambulate without carrying the drainage bag.

Measuring Containers: Measuring containers are not used at the bedside since drainage systems are usually disconnected and discarded (instead of drained) when the drainage bag is full.

RECOMMENDATIONS:

Urine drainage bags can be drained (instead of changing and discarding the entire drainage system) when the bag is full. This will reduce the risk of urinary tract infection since it will significantly reduce the frequency of disruption of the catheter-drainage system junction. To facilitate easier emptying of urine drainage bags, consider purchase of a different type of urine drainage systems with drainage ports on the bottom of the drainage bag.

6. Mechanical Ventilation and Respiratory Equipment

FINDINGS:

Indications for Use: Predominantly for respiratory failure, but also after head trauma with cerebral edema and major surgery.

Duration of Use: As long as necessary. Long term ventilation is not frequently needed.

Monitoring of Oxygenation and Ventilation: Analysis of blood gases is available. Capillary blood samples are used. Pulse oximetry is available.

Ventilator Humidifiers: Bubble-through heated humidifiers are used on all ventilators. Humidifiers are filled with sterile distilled water. Humidifiers are used for the duration of ventilation for an individual patient.

Frequency of Ventilator Tubing Change: Disposable ventilator tubing is generally changed every 2-3 days and discarded after use.

Suctioning: Suction catheters are used once and discarded. Ampoules (10cc) of sterile saline are used to loosen secretions during suctioning.

Nebulizers: Reusable small volume nebulizers are used to administer inhaled medications and are reprocessed between uses.

RECOMMENDATIONS:

Ventilator circuits do not need to be changed as frequently as every 2 days. There is currently no well-established guideline addressing this issue, but it is reasonable not to change ventilator circuits at all during short term ventilation. During long-term ventilation, it is still not clear that ventilator circuits need to be changed; however, if they are changed it is reasonable to change them no more frequently than once a week.

J. Reprocessing of Supplies and Equipment

FINDINGS:

Location: The Central Sterilization unit performs all steam sterilization and ethylene oxide sterilization for the hospital. Anesthesia equipment used in the Operating Room is reprocessed in Central Sterilization, except for laryngoscope blades which are disinfected in the Operating Room by the anesthesiologists. Respiratory equipment used in the ICUs is reprocessed in the ICUs. Endoscopes are reprocessed in the room where endoscopy is performed.

Separation of Contaminated, Clean, and Sterile Items: The Central Sterilization has adequate separation of contaminated, clean, and sterile items.

Cleaning: Instruments and equipment used on the wards and the Intensive Care Unit receive superficial cleaning before transport to Central Sterilization where they receive additional manual cleaning. Surgical instruments are soaked in Haemosol (a detergent plus a disinfectant) in the Operating Theater, manually cleaned, dried, packaged, and transported to Central Sterilization. Workers wear vinyl gloves and an apron during cleaning. Goggles to protect against splashes to the eyes or mouth are not used.

Packaging: Materials for steam sterilization are wrapped in muslin. Materials for ethylene oxide sterilization are sealed in plastic wrapping.

Steam Sterilization: Four large autoclaves are used for steam sterilization in the Central Sterilization unit. Two autoclaves are automatically operated and one is semi automatically operated.

Quality Control of Steam Sterilization: Monitoring gauges are functional and are visually monitored. Chart recorders are functional and record sterilization cycle parameters. Chemical indicator tape is used on the outside of each item. Additional chemical indicators are used inside and outside of individual items once a day. Biologic indicators used every 6 months during the inspection performed by governmental inspectors. Written logs are maintained of cycle parameters and the results of chemical and biologic indicator test results.

Ethylene Oxide Sterilization: There are a number of small ethylene oxide sterilizers contained in a separate room with venting to outside air.

Quality Control of Ethylene Oxide Sterilization: Chemical indicator tape is used on the outside of each item. Additional chemical indicators are used inside and outside of individual items once a day. Biologic indicators used every 6 months during the inspection performed by governmental inspectors. Written logs are maintained of cycle parameters and the results of chemical and biologic indicator test results.

Shelf life: Items are dated and a defined shelf life has been established which varies according to the item and the method of sterilization.

Storage: Sterilized items are stored in the Operating Theater and on the wards and ICUs.

Surgical Instruments: Surgical instruments that can tolerate heat are sterilized using steam sterilization.

Heat/Moisture Sensitive and Delicate Surgical Instruments: Most heat sensitive items are sterilized using ethylene oxide. We did not assess the methods used to sterilize delicate ophthalmologic instruments.

Laparoscopes: Laparoscopes are washed and then soaked in a disinfectant. Heat-resistant components are steam sterilized. Heat-sensitive components are placed in a sealed box with a container of formaldehyde until needed again (at least 24 hours). Reportedly, ethylene oxide

sterilization of heat-sensitive components is not possible because laparoscopes are in short supply and ethylene oxide sterilization cannot be accomplished quickly enough.

Endoscopes: Endoscopes used for upper and lower GI endoscopy are washed after use with soap and water, submerged in 2% glutaraldehyde for 15 minutes, rinsed with tap water, and allowed to drip dry. Biopsy forceps are reprocessed in the same manner.

Ventilator and Respiratory Equipment: Reused ventilator and respiratory equipment (with the exception of small volume nebulizers) used in the Intensive Care Unit is cleaned, submerged in 2% glutaraldehyde for several hours, rinsed with distilled water, dried, and packaged in plastic. Small volume nebulizers are clean and sterilized using ethylene oxide between uses.

Anesthesia Equipment: Anesthesia equipment is cleaned and then steam sterilized (circuits) or sterilized using ethylene oxide (all other non-metal equipment). Laryngoscope blades are cleaned, disinfected for 20 minutes in 2% glutaraldehyde, rinsed with distilled water, and dried.

RECOMMENDATIONS:

Personnel cleaning instruments should wear heavy duty gloves. Goggles and a mask or a face shield should be used to prevent splashes of contaminated substances to their eyes or mouth. Sharp instruments should not be handled by hand to avoid percutaneous injuries.

We are not familiar with the particular chemical indicators presently in use and are not aware of the efficacy of these tests in ensuring adequate functioning of steam sterilizers. The standard in the U.S. is to monitor the functioning of steam sterilizers once a day using a biologic indicator (a test using bacterial spores). When implantable items are sterilized, the standard in the U.S. is to use a biologic indicator in each load in which these materials are sterilized and to determine that the biologic indicator test is negative (i.e., that sterilization was adequate) before these materials are released for use. Biologic indicators should be wrapped in muslin or, preferably, placed inside an instrument pack.

We are not aware of any data that clearly demonstrates that the use of formaldehyde as it is described above is an adequate method for sterilization. We recommend that critical items (items that will contact sterile tissues or fluids) that cannot be steam sterilized should be sterilized by ethylene oxide. If this is not possible due to time constraints, we recommend that chemical sterilization with glutaraldehyde be used for 10 hours, followed by sterile water rinsing, drying, and packaged in a sterile fashion.

Endoscopes should be meticulously cleaned after use and should have a longer contact time (20-30 minutes) with glutaraldehyde to ensure high-level disinfection. Preferably, endoscopes should be rinsed with sterile water although distilled water is an acceptable alternative if rinsing with sterile water is not possible. The endoscope should be completely dried before reuse. Biopsy forceps used with endoscopes should be sterilized since they may contact sterile tissues. If this is not possible, they should be at least be processed in a manner consistent with high-level disinfection described above.

Depending on the manufacturer's recommendations, glutaraldehyde preparations may be used for periods of 14 to 28 days if kept in a covered basin or tub.

K. Preparation, Distribution, and Monitoring of Antiseptics and Disinfectants Used in Patient Care

FINDINGS:

Preparation of Antiseptics and Disinfectants: Antiseptics and disinfectants are purchased "ready-made."

Distribution of Antiseptics and Disinfectants : Antiseptics and disinfectants are stored in the Pharmacy and dispensed to the wards, ICUs, and Operating Theaters. It is the responsibility of individuals in these areas to fill individual containers with these solutions. Small (<500ml) glass bottles with tops are used for antiseptics used in patient care.

Monitoring of Antiseptics and Disinfectants: Practices for emptying and cleaning of containers of antiseptics and disinfectants used in patient care vary by ward according to extent to which they

are used. Bottles of antiseptics are emptied and refilled least every week, but it was not clear whether there is a standard procedures for cleaning antiseptic bottles before they are refilled.

RECOMMENDATIONS:

There are a large number of "ready-made" disinfectants and antiseptics in use. Cost savings may be achieved by reviewing the use of each of these solutions and reducing unnecessary use and by eliminating unnecessary or redundant solutions.

A standard procedure for cleaning antiseptic containers before they are refilled should be developed, if such a procedure is not already in existence. Autoclaving the bottles is desirable, if it can be accomplished easily. If not, cleaning with soap and water followed by thorough drying before refilling is necessary.

L. Environmental Cleaning and Waste

FINDINGS:

General wards: General cleaning on the wards was not assessed.

Operating Room: The operating room table and other surfaces contacted by the patient are wiped with a disinfectant (Metasept, active ingredient not determined). After surgeries involving abscesses, surfaces are also wiped with liquid formaldehyde and the operating room is closed until the next day. Spills of blood are mechanically removed, the area is disinfected with Metasept, and then cleaned. These same procedures are followed regardless of the type of case. Cleaning of the walls, cabinets, and fixtures in the Operating Room is performed on a routine basis.

Disposal of Infectious Waste: Potentially infectious waste is discarded in special labeled containers and incinerated outside the hospital.

RECOMMENDATIONS:

The use of formaldehyde for disinfection in the operating room should be discontinued. The use of this potentially toxic agent is not necessary if another disinfectant is used. Cleaning procedures should be the same after all procedures regardless of whether the patient had an infection. Closing the operating room after a surgery involving an infection is not necessary since microorganisms causing these infections are not likely to be spread via the air.

M. Microbiology Laboratory

FINDINGS:

Services: Routine stains and bacterial cultures are performed. At the time of this survey, the Microbiology Laboratory was closed for renovations. Clinical specimens were being sent to an outside laboratory.

Culture Processing and Identification Procedures: Specimens are inoculated onto standard media. Blood cultures are processed manually and are monitored visually for turbidity every day and by subculture on days 1, 3, 6, 10. Blood cultures are kept for 10 days and then discarded. Identification of bacteria is performed using basic procedures. Identification of gram negative bacteria is performed using biochemical tests.

Susceptibility Testing: Disk diffusion (Kirby-Bauer) testing is performed. Reference strains with known antimicrobial susceptibilities are obtained from the National Institutes of Health and are used for quality control of antimicrobial susceptibility results.

Reporting: Results are reported via paper slips which are placed in the medical record. Log books are used to record specimens and results. Results are entered into a computer. There has been no summary of antimicrobial susceptibility results. A summary of antimicrobial susceptibility results was recently compiled and discussed with physicians at a conference. Copies of this summary are reportedly available on the wards.

Other Special Cultures: The laboratory has performs environmental and personnel cultures as described above (see above, "Infection Control Program Activity"). or other special cultures

in the past, but this may be done in the future. Screening media to identify patients colonized with antibiotic resistant bacteria are not used.

RECOMMENDATIONS:

A yearly summary of antimicrobial susceptibility results should be compiled and distributed to the infection control program and physicians and nurses caring for patients.

Use of selective media (media with antibiotics such as oxacillin or gentamicin) can be relatively easily and inexpensively prepared. This media can be used to screen selected patient populations antimicrobial resistant bacteria.

V. PREVALENCE SURVEY RESULTS

The results of the prevalence survey of nosocomial infections are displayed in Tables 1, 2, 3, and 4. Four wards with a total of 182 beds were surveyed; 135 (74.2%) of the beds were occupied at the time of the survey. Of these 135 patients, 104 (77.0%) had been in the hospital at least 48 hours at the time of the survey or were recently readmitted (nosocomial infections are, by definition, infections which are present after 48 hours of hospitalization and which were not present or incubating at the time of admission).

A total of 3 infections were identified in 3 of these 104 patients. Thus the prevalence of patients with nosocomial infections was 2.9%. The prevalence rate by ward is shown in Table 1. The total numbers of infected patients on each ward are small; consequently, the confidence intervals (which are not displayed) for these prevalence rates are large.

Table 2 displays the specific sites of nosocomial infection by ward.

Table 3 displays data regarding utilization of invasive devices and procedures and the prevalence of specific nosocomial infections in these "at-risk" patients. Again, the total numbers of infected patients in each of these categories is small; consequently, the confidence intervals (which are not displayed) for these prevalence rates are large. These data should not be over interpreted since they represent only the prevalence of active nosocomial infections in the hospital at a particular point in time.

The prevalence of surgical wound infections in post-operative patients was 3.3%. Wound classification or other measures of risk were not recorded so the risk-adjusted prevalence of surgical wound infection is not provided.

Indwelling urinary catheters were used on all wards surveyed. The prevalence of urinary tract infections in patients with indwelling urinary catheters was 0%. It is important to remember that the diagnosis of urinary tract infections in catheterized patients is very dependent on laboratory studies (evidence of pyuria determined by positive leukocyte esterase test on urine dipstick or by urinanalysis and urine cultures). If laboratory studies are not ordered for patients in whom infection is suspected or if laboratory data is not documented in the record, the prevalence survey would not detect these infections.

Mechanical ventilation was used only in the intensive care unit. The prevalence of lower respiratory tract infections in mechanically ventilated patients was 0%.

High-risk intravascular catheters (central venous catheters of any kind, hemodialysis catheters, arterial catheters, umbilical catheters, and intravascular catheters placed by cut-down) were used infrequently in surgical and urology patients. The prevalence of bloodstream infections in patients with these high-risk intravascular catheters was 0%.

Table 4 displays the prevalence of use of intravenous antimicrobial agents by ward. The overall prevalence of intravenous antimicrobial agent use was 20.7%. The prevalence of use of expensive, broad spectrum antimicrobial agents (second or third generation cephalosporins, ciprofloxacin, and ampicillin/sulbactam) was 7.4%. No patients were receiving vancomycin.

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TABLE 1
PREVALENCE OF NOSOCOMIAL INFECTIONS BY WARD

WARD	# OF BEDS	# OF PTS (% beds occupied)	# OF PTS IN HOSPITAL >48 HOURS* (% of total patients)	# OF NOSOCOMIAL INFECTIONS*	# OF PTS WITH NOSOCOMIAL INFECTIONS*	PREVALENCE OF PTS WITH NOSOCOMIAL INFECTIONS**
Intensive Care Unit	7	6 (85.7)	4 (66.7)	0	0	0%
Surgery	68	63 (92.6)	44 (69.8)	2	2	4.6%
Urology	35	25 (71.4)	24 (96.0)	1	1	4.2%
Obstetrics/Gynecology	72	41 (56.9)	32 (78.1)	0	0	0%
TOTAL	182	135 (74.2)	104 (77.0)	3	3	2.9%

* Only patients hospitalized for >48 hours were evaluated for nosocomial infections.
** The prevalence of patients with nosocomial infections was calculated by dividing the number of patients with nosocomial infections by the number of patients hospitalized for >48 hours and multiplying by 100.

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TABLE 2
NUMBER OF NOSOCOMIAL INFECTIONS BY SITE AND WARD

WARD	# OF NOSOCOMIAL INFECTIONS	SURGICAL SITE INFECTION	URINARY TRACT INFECTION	LOWER RESPIRATORY TRACT INFECTION	BLOOD-STREAM INFECTION	SKIN AND SOFT TISSUE INFECTION	GASTRO-INTESTINAL INFECTION	OTHER
Intensive Care Unit	0	0	0	0	0	0	0	0
Surgery	2	2	0	0	0	0	0	0
Urology	1	0	0	1	0	0	0	0
Obstetrics/ Gynecology	0	0	0	0	0	0	0	0
TOTAL	3	2 (66.7%)	0	1 (33.3%)	0	0	0	0

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TABLE 3
NUMBER OF NOSOCOMIAL INFECTIONS IN PATIENTS AFTER INVASIVE PROCEDURES BY WARD

WARD	# POST-OP PTS	# SURGICAL SITE INFECTIONS IN POST-OP PTS (%)	# PTS WITH URINARY CATHETERS	# URINARY TRACT INFECTIONS IN PTS WITH URINARY CATHETERS (%)	# VENTILATED PTS	# LOWER RESPIRATORY TRACT INFECTIONS IN VENTILATED PTS (%)	# PTS WITH HIGH-RISK INTRA-VASCULAR CATHETERS	# BLOOD-STREAM INFECTIONS IN PTS WITH HIGH-RISK INTRA-VASCULAR CATHETERS (%)
Intensive Care Unit	0	0	3	0	3	0	0	0
Surgery	38	2 (5.3)	4	0	0	0	1	0
Urology	16	0	7	0	0	0	1	0
Obstetrics/Gynecology	7	0	4	0	0	0	0	0
TOTAL	61	2 (3.3)	18	0	3	0	2	0

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TABLE 4
PREVALENCE OF INTRAVENOUS ANTIMICROBIAL AGENT USE BY WARD

WARD	# OF PTS	# OF PTS RECEIVING INTRAVENOUS ANTIMICROBIAL AGENT(S) (%)	# OF PTS RECEIVING AN EXPENSIVE, BROAD SPECTRUM ANTIMICROBIAL AGENT* (%)	# OF PTS RECEIVING VANCOMYCIN (%)
Intensive Care Unit	6	0	0	0
Surgery	63	14 (22.2)	5 (7.9)	0
Urology	25	9 (36.0)	2 (8.0)	0
Obstetrics/ Gynecology	41	5 (12.2)	3 (7.3)	0
TOTAL	135	28 (20.7)	10 (7.4)	0

*A broad spectrum antibiotic is defined as a single antibiotic (not a combination of two or more antibiotics) with a broad range of activity against gram-positive and gram-negative bacteria. For the purpose of this survey, second and third generation cephalosporins, ciprofloxacin, and ampicillin/sulbactam were included in this category.

HOSPITAL QUALITY IMPROVEMENT AND INFECTION CONTROL SURVEY REPORT

KÁTAI GÁBOR HOSPITAL

January 4, 1994

By

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I. INTRODUCTION

The International Hospital Infection Prevention and Quality Assessment Program (INQUAL) from the Children's Hospital and Harvard University (Boston, Massachusetts) conducted an evaluation of quality improvement and infection control at Kátai Gábor Hospital. This work was supported by the United States Agency for International Development Health Markets Project through its principal contractor Health Enterprises International, Inc.

The survey was conducted by a physician, W. Charles Huskins, MD, and a nurse, Carol O'Boyle Williams, MS, RN, CIC, from December 5 - 9, 1994. These surveys were completed successfully in large measure due to the dedication and assistance of hospital leaders and personnel. We are very grateful for this assistance.

We were very impressed with the overall commitment of the hospital management, physicians, nurses, other professional staff, and other hospital workers to providing high quality medical care. Of course, there is always a possibility that we misinterpreted information provided to us or that an observation we made was in error. If so, we apologize for the error.

II. SUMMARY OF RECOMMENDATIONS

Quality Improvement Program

1. The hospital's quality improvement effort needs more overall focus and coordination. While quality improvement efforts can and should be conducted within individual departments these efforts should be consistent with the hospital's overall strategic quality improvement goals determined by the highest level of hospital management. These goals should reflect input from hospital staff and the expressed needs and perceptions of the hospital's patients (internal and external consumer, respectively). There should also be greater coordination and cooperation between different departments in quality improvement efforts.

   To achieve these goals we recommend the following:

   a) Establishment of a quality improvement "steering" committee to oversee and coordinate quality improvement efforts.
   b) Elaboration of the hospital's overall quality improvement goals. These goals should be in written form and publicized to hospital workers through their departmental leaders. Individual departments should be encouraged to develop their own quality improvement goals, but these goals should be reviewed and approved by the steering committee.
   c) Subcommittees or task forces (such as the Medicine QAC and the Nursing QAC) should design and conduct specific projects and should provide regular reports of their progress to the steering committee. Each project or task force should have a designated sponsor on the steering committee who can track progress and assist in coordinating inter-departmental work and remove barriers.
   d) At least in the early stages, all quality improvement projects should be reviewed and approved by the steering committee. This should be a simple, not burdensome, process designed to ensure coordination of the overall effort and adequate cooperation between departments.

2. In addition to clinical and administrative personnel, personnel involved with fiscal management and information services should be included on the steering committee. Other departments, such as pharmacy, microbiology, etc., should be included as ad hoc members.

3. The steering committee should ensure that appropriate training and resources are provided in support of approved quality improvement initiatives.

4. Current and future quality improvement projects should emphasize inclusion of measurable indicators of key processes and outcomes that can be used to monitor performance.

5. A procedure for submission and critique of specific quality improvement proposals is needed to facilitate discussion of the merits of various projects. This should include a written format for quality improvement proposals and a well-defined process for review and critique of these proposals.

6. The quality improvement project developed at the workshop Dec. 12 - 16 is well conceived and has a high likelihood of success if adequately supported and implemented. Details of the development of this project, as well as recommendations for implementation and a timeline for tasks associated with this project from January - June, 1995, are included in the overall project report, titled "Quality Improvement/Infection Control Demonstration Project for Hungary: Report for Phases I and II."

Infection Control (Hospital Hygiene) Program

1. We support the plan to train one or more nurses in infection control and include these individuals into the Hospital Hygiene Program as full time personnel.

2. A program of active, prospective surveillance for nosocomial infections is needed. The hospital's participation in the HELICS Project is an important first step in this regard since it will provide valuable information regarding the occurrence of surgical wound infections and will train personnel in the collection, analysis, interpretation, and reporting of surveillance data. Surveillance of other important nosocomial infections should be considered in the future. Written definitions of nosocomial infections are needed. A written surveillance plan should be developed, reviewed each year, revised as necessary by the Hospital Hygiene Service, and approved by the Hospital Hygiene Committee.

3. Improved surveillance data will probably identify potential clusters of nosocomial infections that have not been detected in the past. Clusters of nosocomial infections should be completely investigated since important problems with infection prevention efforts are often identified during the course of these investigations, even if they are not the direct cause of the observed infections.

4. Except in unusual circumstances (such as point source outbreaks of nosocomial infections), microorganisms recovered from cultures of the environment are not the direct cause of nosocomial infections. Except for the educational purpose of illustrating the role of the hands of health care workers in the indirect transmission of hospital microorganisms, results of hand cultures are rarely, if ever, useful in infection prevention efforts.

5. A plan for optimizing the use of perioperative antimicrobial prophylaxis was developed as a part of the quality improvement project developed at the workshop Dec. 12 - 16. Details of the development of this project, as well as recommendations for implementation and a timeline for tasks associated with this project from January - June, 1995, are included in the overall project report, titled "Quality Improvement/Infection Control Demonstration Project for Hungary: Report for Phases I and II."

6. The frequency of antimicrobial resistant microorganisms should be monitored and specific strategies developed to limit spread of these organisms. Of specific concern are: methicillin resistant *Staphylococcus aureus*, vancomycin and high-level gentamicin resistant *Enterococcus* sp., penicillin resistant *Streptococcus pneumoniae*, and third generation cephalosporin and aminoglycoside resistant gram negative bacteria (especially *Pseudomonas aeruginosa*, *Enterobacter* sp., *Klebsiella* sp., *Serratia* sp., and *Acinetobacter* sp.). A recent summary of antimicrobial sensitivity indicates that more than 50% of *Staph. aureus* strains may be resistant to methicillin. Since susceptibility testing of this microorganism can be complicated, we agree that a collection of these *Staph. aureus* strains should be sent to a reference laboratory for confirmatory testing. We suggest that the infection control (hospital hygiene) service develop a plan in collaboration with the microbiology laboratory for tracking these organisms, identifying infected and colonized individuals, and a strategy for minimizing spread of these organisms.

7. It is likely that there is considerable under-reporting of needlestick injuries and other significant occupational exposures to blood or potentially infectious body fluids by hospital personnel. Hospital personnel should be encouraged to report exposures and a mechanism should be established for

monitoring the frequency, location, and circumstances of the exposure. Processes of care should be examined to identify situations and practices that increase the risk of an occupational exposure. Interventions to reduce the risk of exposure should be implemented and included in written procedures. If an exposure occurs, prompt investigation of the source of the exposure (the person whose blood was involved in the exposure) should be performed to determine if prophylaxis, counseling, and follow-up serologic testing is necessary.

Facilities

1. It is unlikely that ultraviolet lights contribute to infection control since the source for bacteria causing most nosocomial infections is not the air. Since there is an occupational risk associated with these lights, we recommend that their use be discontinued.

Patient Care Practices

1. Alcohol-based waterless handwashing agents should be available in greater supply, particularly for use by doctors and nurses when they move from bed to bed examining patients or performing procedures. A simple, inexpensive waterless handwashing agent, such as alcohol (70% by weight)/glycerin (1% by weight), can be formulated by the Pharmacy and provided in closed, pour top bottles.

2. There should be greater awareness of the presence of potential pathogens, particularly antimicrobial resistant microorganisms, in secretions and excretions of all patients. These microorganisms can be spread to other patients via direct and indirect transmission (especially on the hands of health care workers). Hospital personnel should be educated on strategies to prevent this transmission through improved compliance with handwashing (see above), use of barriers (gloves, gowns), and appropriate patient placement.

3. The use of shoe covers in the Operating Theater as well as elsewhere in the hospital does not contribute infection prevention.

4. An antiseptic which contains chlorhexidine or povidone-iodine should be used since these agents provide residual antibacterial activity on the skin during the surgery. It was not clear whether Dodosept contains either of these agents in addition to alcohol.

5. Hair should be removed from the patient's skin only if this is necessary. If hair removal is necessary it should be clipped instead of shaved. If shaving is necessary, it should be done immediately before surgery.

6. IV infusion tubing does not need to be changed every day. In the absence of evidence that nosocomial bloodstream infections are a significant problem, it is reasonable to change IV infusion tubing every 3 days.

7. Urine drainage bags can be drained (instead of changing and discarding the entire drainage system) when the bag is full. This will reduce the risk of urinary tract infection since it will significantly reduce the frequency of disruption of the catheter-drainage system junction. To facilitate easier emptying of urine drainage bags, consider purchase of a different type of urine drainage systems with drainage ports on the bottom of the drainage bag.

8. Ventilator circuits do not need to be changed as frequently as every day. There is currently no well-established guideline addressing this issue, but it is reasonable not to change ventilator circuits at all during short term ventilation. During long-term ventilation, it is still not clear that ventilator circuits need to be changed; however, if they are changed it is reasonable to change them no more frequently than once a week.

Sterilization, Disinfection, and Cleaning

1. Personnel cleaning instruments should wear better protective equipment, including, heavy duty gloves and goggles and a mask or a face shield to prevent splashes of contaminated substances to their eyes or mouth. Sharp instruments should not be handled by hand to avoid percutaneous injuries.

2. We are not familiar with the particular chemical indicators presently in use and are not aware of the efficacy of these tests in ensuring adequate functioning of steam sterilizers. The standard in the U.S. is to monitor the functioning of steam sterilizers and ethylene oxide sterilizers using biologic indicators (microbiologic tests using bacterial spores). Steam sterilizers are monitored using a biologic indicator once a day and ethylene oxide sterilizers are monitored using a biologic indicator in every load. When implantable items are sterilized, a biologic indicator is used in each load and these materials are not released for use until the biologic indicator test is known to be negative (i.e., that sterilization was adequate). It is not clear that it is absolutely necessary to adhere to this exact standard if sterilization parameters are being monitored routinely. However, we recommend use of biologic indicators much more frequently than is done presently.

3. Endoscopes should be meticulously cleaned after use and should have a longer contact time (20-30 minutes) with glutaraldehyde to ensure high-level disinfection. Preferably, endoscopes should be rinsed with sterile water although distilled water is an acceptable alternative if rinsing with sterile water is not possible. The endoscope should be completely dried before reuse. Biopsy forceps used with endoscopes should be sterilized since they may contact sterile tissues. If this is not possible, they should be at least be processed in a manner consistent with high-level disinfection (see above).

4. Respiratory and anesthesia equipment are, in effect, undergoing double disinfection/sterilization. Either high level disinfection with a glutaraldehyde containing solution or ethylene oxide sterilization are adequate.

5. Depending on the manufacturer's recommendations, glutaraldehyde preparations may be used for periods of 14 to 28 days if kept in a covered basin or tub.

6. There are a large number of "ready-made" disinfectants and antiseptics in use. Cost savings may be achieved by reviewing the use of each of these solutions and reducing unnecessary use and by eliminating unnecessary or redundant solutions.

7. A standard procedure for cleaning antiseptic containers before they are refilled should be developed, if such a procedure is not already in existence. Autoclaving the bottles is desirable, if it can be accomplished easily. If not, cleaning with soap and water followed by thorough drying before refilling is necessary.

8. Closing the operating room after a surgery involving an infection is not necessary since microorganisms causing these infections are not likely to be spread via the air.

Microbiology Laboratory

1. The recent preparation of a summary of antimicrobial susceptibility results should be commended. These summaries should be compiled and distributed to the infection control program and physicians and nurses caring for patients on a yearly basis.

2. Use of selective media (media with antibiotics such as oxacillin or gentamicin) can be relatively easily and inexpensively prepared. This media can be used to screen selected patient populations antimicrobial resistant bacteria.

III. SURVEY METHODS

The survey at was performed by conducting:

1) Interviews of key hospital personnel;
2) Observations of facilities, supplies, equipment, and practices;
3) A point prevalence survey of active nosocomial infections in patients hospitalized at the time of the survey.

The following hospital personnel were interviewed:

Dr. Karasay Karl, Acting Medical Director, Chief of Obstetrics/Gynecology
Mészárosné Hakucsák Erika, Nursing Director
Dr. Hersko Gyula, Obstetrician/Gynecologist and Chairman, Medical Quality Assurance Committee
Dr. Gyarmati Elizabeth, Hospital Hygienist
Igas Esther, Sanitary Inspector
Dr. Fábián Lajos, Chief of Surgery
Toth Julia, Head Nurse of the Operating Theater
Szabo Ilona, Head Nurse of the Surgery Ward
Chief of Traumatology (name not recorded)
Kovacs Irene, Head Nurse of the Traumatology Ward
Vigh Edina, Head Nurse of the Obstetrics/Gynecology Ward
Dr. Odór István, Chief of Anesthesia/Intensive Care
Külüs Edit, Head Nurse of the Intensive Care Unit
Dr. Szabolcs Tanko, Chief of Infectology
Kabainel Piraska, Chief of Central Sterilization
Dr. Szalay László, Pharmacist
Dr. Dögei László, Chief of the Laboratory

The following wards, ICUs, and support departments were toured and observations of facilities, equipment, supplies, and practices were recorded:

Intensive Care Unit
Surgery Ward
Traumatology Ward
Obstetrics/Gynecology Ward
Operating Room
Central Sterilization unit
Endoscopy Room
Pharmacy
Microbiology Laboratory
Blood Bank

Information regarding patient care practices was obtained from a single source on each ward (i.e., a head nurse or a physician), since time constraints prohibited interviews with a large number of individual nurses or physicians. Observation of a large number of patient care practices was also not possible. Consequently, variations in the conduct of specific patient care practices may exist which are not reflected in this report.

A prevalence survey of active nosocomial infections was conducted following a standardized methodology ("Outline for Surveillance and Control of Nosocomial Infections", U.S. Centers for Diseases Control, 1972). Standard definitions for nosocomial infections were used ("CDC Definitions of Nosocomial Infections, 1988" U.S. Centers for Diseases Control, Am J Infect Control 1988;16:128-140). On each ward included in the survey, a bed-to-bed survey was first conducted to determine the number of occupied beds, the patient's primary diagnosis, and whether the patient had been hospitalized for > 2 days. During this

survey, observations of the following factors were recorded: the type and use of invasive catheters and devices (intravascular catheters, urinary catheters, mechanical ventilation, peritoneal dialysis catheters), evidence of phlebitis at catheter insertion sites, a history of a surgical procedure(s) performed in the previous 4 weeks, and the use of intravenous antibiotics. For patients hospitalized for > 2 days, the presence of cough, diarrhea (5 or more loose stools/day), or fever (T >38.0^{0}C on each of the previous two days) was also assessed. If any of these factors were present the patient's entire hospital chart was reviewed (including vital signs, nurse's and physician's notes, medication records, and laboratory studies) to determine the presence or absence of a nosocomial infection. If necessary, the patient was examined.

Due to time constraints, it was not possible to conduct a prevalence survey on all wards. The following wards were surveyed:

Intensive Care Unit
Surgery Ward
Traumatology Ward
Obstetrics/Gynecology Ward
Infectious Diseases Ward

IV. SURVEY RESULTS AND RECOMMENDATIONS

A. General Hospital Information

FINDINGS:

Location: Karcag, Hungary (a town in a rural area of eastern Hungary)

Catchment Area: Surrounding communities

Patient population: The hospital is a municipal hospital (a hospital of first referral) receiving patients referred from primary care clinics in the catchment area.

Number of beds: ~800

Operating Rooms: 4 operating theaters (General Surgery/Traumatology/Gynecology, Ophthalmology, Otorhinolaryngology, Obstetrics) with a total of approximately 7 operating rooms

Intensive Care Units:

Adult ICU (9 beds)

Services:

Adult Medicine and subspecialties
Pediatrics
Obstetrics/Gynecology
Nursery
General Surgery
Traumatology
Otorhinolaryngology
Ophthalmology
Neurology
Dermatology
Infectious Diseases
Psychiatry
Urgent Care (Emergency)

Medical School Affiliation: none

Nursing School Affiliation: none

B. Organization of the Quality Improvement Program

FINDINGS:

There is no formal quality assessment department. There are two Quality Assurance Committees (QAC), one for the Medicine Department and one for the Nursing Department. The Medicine QAC has been in existence since 1994 and reports directly to the Medical Director. The Nursing QAC has been in existence since 1991 and reports to the Nursing Director. The Medicine QAC and the Nursing QAC work independently with little interaction or coordination of effort.

RECOMMENDATIONS:

The hospital's quality improvement effort needs more overall focus and coordination. While quality improvement efforts can and should be conducted within individual departments these efforts should be consistent with the hospital's overall quality improvement goals determined by the highest level of hospital management. These strategic goals should reflect input from hospital staff and the expressed needs and perceptions of the hospital's patients (internal and external consumer's, respectively). Since quality improvement efforts often involve several different hospital departments, there should be greater coordination and cooperation between different departments in these efforts.

To achieve these goals we recommend the following:

1. Establishment of a quality improvement "steering" committee to oversee and coordinate quality improvement efforts. This committee should be an oversight committee, not a committee that takes on specific quality improvement projects. Consequently, the committee should include senior hospital managers.
2. Elaboration of the hospital's overall quality improvement goals. These goals should be in written form and publicized to hospital workers through their departmental leaders. Individual departments should be encouraged to develop their own quality improvement goals, but these goals should be reviewed and approved by the "steering committee." These goals should be consistent with concepts embodied in what is termed "continuous quality improvement" or "total quality management." It is extremely important to develop appropriate outcome and process measures and to trend these measures over time so that progress towards meeting hospital and departmental goals can be monitored concurrently.
3. Subcommittees or task forces (such as the Medicine QAC and the Nursing QAC) should design and conduct specific projects and should provide regular reports of their progress to the "steering committee."
4. At least in the early stages, all quality improvement projects should be reviewed and approved by the steering committee. This should be a simple, not burdensome, process designed to ensure coordination of the overall effort and adequate cooperation between departments. With time, formal approval of individual projects may not be necessary.

C. Quality Improvement Program Personnel

FINDINGS:

The Medical QAC is composed the Medical Director, the Nursing Director, the Deputy Nursing Director, the Hospital Hygienist, the Sanitary Inspector, and obstetrician/gynecologist, and a general surgeon. Dr. Hersko Gyula, an obstetrician/gynecologist, is the Chairperson of the Medical QAC.

The Nursing QAC is composed of the Nursing Director, the Deputy Nursing Director, the Chief OR Nurse, the Sanitary Inspector, the Dietitian, a Radiology Technician, and the Clinical Instructor. The Nursing Director, Mészárosné Hakucsák Erika, is the Chairperson of the Nursing QAC.

It is important to note that the hospital's former Medical Director, Dr. Szabo Janos, and its current Nursing Director, Mészárosné Hakucsák Erika, are members of the Hungarian Society for Quality Assurance (HSQA).

RECOMMENDATIONS:

The involvement of persons involved in clinical care (physicians and nurses) and management (senior hospital managers) in present quality improvement efforts is a strength. However, additional personnel should be involved, including personnel involved with fiscal management, information services, and support departments (Pharmacy, Microbiology Laboratory, Environmental Services, Nutrition Services, etc.).

Appropriate training and resources should be provided to hospital personnel participating in approved quality improvement initiatives.

D. Quality Improvement Program Activity

FINDINGS:

The Medical QAC has been meeting on an ad hoc basis. One of the first goals for the Medical QAC was to develop links with the Dept. of Social Medicine at the University Medical School of Debrecen. The purpose of this link was to draw on the resources of the School to assist in training hospital personnel in quality assurance/quality improvement and enlist their advice and support in instituting quality improvement initiatives in the hospital. Another major goal was to expand the hospital's infection control (called hospital hygiene in Hungary) program. A Hospital Hygienist was hired in the summer of 1994.

The Chairman of the QAC (Dr. Hersko) has instituted a number of improvements in obstetrical care, although it was not clear to us if these were formally endorsed by the QAC. This work was described as moving toward more "family-centered" birthing practices. Included in the this project were: 1) improved prenatal education; 2) greater involvement of male partners in prenatal education and the birthing process; 3) an emphasis on facilitating bonding between mothers (and partners) and their newborn infants. Rooming-in was introduced earlier in 1994. Some data were cited regarding this effort (only 5% of partners were present during the birthing process in 1993), although follow-up data were not available yet.

Meetings of the Nursing QAC occur monthly. There is an overall written "mission" statement for the committee and each ward has specified goals. The Nursing QAC has undertaken a number of initiatives: 1) improving nursing documentation; 2) performing inspections of facilities, supplies, procedures and practices on wards on a regular basis; 3) performing needs assessments of nurses working on the wards; 4) performing a patient satisfaction survey. A number of changes have occurred as a result of these efforts including: 1) hiring a Sanitary Inspector to improve infection control; 2) providing resuscitation kits on every ward; 3) providing only new disposable gloves for the Operating Theaters and delivery rooms; 4) providing linen carts on the wards to improve efficiency; 5) providing needs-directed educational activities for nurses; 5) introduction of religious services for patients who desire them.

Another Nursing QAC initiative deserves mention. Patients are given a "smile cheque" at the time of admission and are given instructions to give the smile cheque to a nurse that provides good care to them. Nurses collecting a number of these cheques are given a bonus by the Nursing Director. This program has been developed in part to reward nurses providing high quality care and in part as an alternative to the system of "gray money" or "gratitude money" offered by patients to health care workers to insure good quality care.

RECOMMENDATIONS:

From the above discussion it is clear that there is real dedication to improving the quality of care provided in the hospital and that this dedication stems a commitment to quality made by senior hospital management. In addition, a number of important improvements have already been made or are in progress. These efforts are laudable and provide a solid foundation for further development of the quality improvement program. We have the following general recommendations regarding current and future projects.

The quality improvement project developed at the workshop Dec. 12 - 16 is well conceived and has a high likelihood of success if adequately supported and implemented. Details of the development of this project, as well as recommendations for implementation and a timeline for tasks associated with this project from January - June, 1995, are included in the overall project report, titled "Quality Improvement/Infection Control Demonstration Project for Hungary: Report for Phases I and II."

Quality improvement projects should focus on improving overall performance, not merely identifying and correcting bad or "low quality" performance. Minimizing "low quality" performance is, of course, an important first step in quality management. However, this effort alone will not result in substantial improvement in overall performance. Real gains in performance are achieved by reducing variability in performance and by improving the level of overall performance. The use of process and outcome indicators to measure and monitor improvements in performance is critical to this effort. In the future, there should be an explicit description of the indicators that will be used to monitor performance and how performance measurements will guide improvement.

There does not appear to be a formal process for the development of specific quality improvement initiatives. Our recommendations for the hospital-wide coordination of quality improvement initiatives are discussed above (see above, "Organization of the Quality Improvement Program"). However, even within an improved organizational framework, a better process for designing and implementing quality improvement projects is needed. Each project should have a "sponsor" from the "steering committee" and a team leader who is accountable for the performance and reporting of the project. A procedure for submission and critique of specific quality improvement proposals is needed to facilitate discussion of the merits of various projects. This procedure should include:

1. Establishing a written format for submission of proposals, including:

    a) The overall aim of the proposal;
    b) The specific goals of the proposal;
    c) Relevant, published background information and the potential significance of the project;
    d) Preliminary data, if available;
    e) Personnel participating in the project, including representation of all relevant hospital departments;
    f) Target population (including inclusion and exclusion criteria);
    g) Methods by which key process and outcome indicators will be chosen, measured, interpreted, and reported to other hospital personnel;
    h) Means by which indicator data will be used to analyze and improve performance using the Plan-Do-Study-Act model;
    i) Means by which improvements will be established as a new or improved system;
    j) Timeline;
    k) Budget, if indicated, and/or an estimate of personnel time required to complete the project.

2. Establishing a process by which written proposals are evaluated, prioritized, and approved.

E. Organization of Infection Control

FINDINGS:

The Hospital Hygiene Service reports to the Medical Director. The Hospital Hygienist (Dr. Gyarmati) is the director of this department. There is Hospital Hygiene Committee is composed of the Chief Hygienist (Chairperson), the Director of Microbiology, an infectologist, a surgeon, and an operating room nurse. We did not assess the frequency of meetings of this group.

The responsibilities and authority of the Hospital Hygiene Service are described in the regulations promulgated by the National Ministry of Health in 1980. These regulation have reportedly been rescinded recently, but have not been replace by new regulations.

RECOMMENDATIONS:

Consideration should be given to broadening the membership of the committee to include other departments, such as Nursing and support departments.

F. Infection Control Program Personnel

FINDINGS:

The Chief Hygienist, Dr. Gyarmati, is a certified hospital hygienist and worked for a number of years at the county Sanitary Inspection Station. There is one Sanitary Inspector, Igas Esther, who is a nurse with extensive clinical experience (including intensive care unit experience). There is a plan that the Sanitary Inspector and perhaps other nurses will attend an infection control training course when this course is established.

Personnel are provided the opportunity to increase their knowledge and skills by attending post-graduate courses and a variety of meetings and conferences.

RECOMMENDATIONS:

We strongly support the plan to train one or more experienced nurses in infection control and include these individuals into the Hospital Hygiene Program as full time personnel.

G. Infection Control Program Activity

As a general statement, the activities of the Hospital Hygiene Service have been undergoing review and revision recently as a result of the hiring of a new Hospital Hygienist. There was no Hospital Hygienist in the past (it is reportedly not common for municipal hospitals to have Hospital Hygiene Services). A work plan is being developed based on the regulations promulgated by the National Ministry of Health in 1980. These regulation have reportedly been rescinded recently, but have not been replace by new regulations. For these reasons activities in some the categories below may be in flux.

1. Surveillance Activity

FINDINGS:

Surveillance of nosocomial infections, as well as communicable community infections, is accomplished by passive reporting of infections by physicians and nurses to the Hospital Hygiene Service. This system was established this fall after the hiring of a Hospital Hygienist; however, few infections have been reported.

There are no written definitions of nosocomial infections used for surveillance.

There is no current review of microbiology results although there is a plan to do this in the future.

RECOMMENDATIONS:

Since passive surveillance systems likely result in significant under-reporting of nosocomial infections, a program of active, prospective surveillance for nosocomial infections is needed. The hospital's participation in the HELICS Project (see above, "Activity of the Quality Improvement Program) is an important first step in this regard since it will provide valuable information regarding the occurrence of surgical wound infections (likely to be among the most common nosocomial infections in this hospital) and will train personnel in the collection, analysis, interpretation, and reporting of surveillance data. Post-discharge surveillance of surgical wounds is critical to this effort, especially if the length of post-operative stay is shortened, since most studies of surgical site infections indicate that 50-60% of infections are detected only after discharge. The mechanism by which post-discharge surveillance can be accomplished is not clear at the present time and needs further consideration.

Surveillance of other important nosocomial infections should be considered in the future, possibly including: urinary tract infections in patients with urinary catheters, pneumonia in mechanically ventilated patients and post-operative patients, postpartum endometritis, mastitis, and post-cesarean section wound infections in obstetric patients, and infections in newborn infants.

Written definitions of nosocomial infections are needed. The CDC (Centers for Disease Control and Prevention) Definitions of Nosocomial Infections could be used, although the use of laboratory tests to document infections will need to be improved. If this cannot be achieved, alternative definitions that do not rely as heavily on laboratory tests should be developed.

A written surveillance plan should be developed, reviewed each year, revised as necessary by the Hospital Hygiene Service, and approved by the Hospital Hygiene Committee. The plan should include statements regarding the goal of each surveillance component, methods for case finding, definitions of infections, calculation of rates of infection, and reporting of infection rates. Regular, timely feedback of infection rates to the physicians and nurses involved in patient care, the chiefs of services, the Hospital Hygiene Committee, and the hospital administration is critical.

Except in unusual circumstances (such as point source outbreaks of nosocomial infections), microorganisms recovered from cultures of the environment are not the direct cause of nosocomial infections. Except for the educational purpose of illustrating the role of the hands of health care workers in the indirect transmission of hospital microorganisms, results of hand cultures are rarely, if ever, useful in infection prevention efforts. We recommend that the Hospital Hygiene Service does not establish a routine of environmental or hand culturing.

2. Outbreaks

FINDINGS:

No clusters of nosocomial infections have been detected or investigated.

RECOMMENDATIONS:

Most hospitals experience at least one cluster of nosocomial infections every 12-18 months. The improved surveillance data will probably identify more potential clusters of infections than have been detected in the past. Clusters of nosocomial infections should be completely investigated since important problems with infection prevention efforts are often identified during the course of these investigations, even if they are not the direct cause of the observed infections.

3. Policies and Procedures

FINDINGS:

There are written policies and procedures are governed by some degree by national hospital hygiene regulations/guidelines, although there is reportedly some latitude allowed for implementation in individual hospitals. We did not review written hospital policies and practices or national hospital hygiene regulations/guidelines.

The Hospital Hygienist, the Sanitary Inspector, and another committee member conduct inspections of hospital wards and treatment areas. The frequency of these inspections varies according to the intensity/invasiveness of care provided; Operating Theaters, the Intensive Care Unit, the obstetrics ward and nursery, and other high-risk areas are inspected every 3 months. Other wards are inspected every 6 months and non-patient care areas are inspected yearly. Ad hoc inspections may conducted if the need arises. Inspections include review of relevant written hospital policies and procedures, inspection of facilities, observation of nursing practices, assessment of overall hygiene including personal hygiene, and review of cleaning and disinfection practices. Reports are made to the Chief of the Service, the head nurse, and the hospital management.

RECOMMENDATIONS:

Periodic reviews such as those described above are extremely useful. We do not have any recommendations.

4. Personnel Education and Training

FINDINGS:

There is an orientation program for new hospital personnel. An in-service training program for nurses is conducted. Instruction in infection control (hospital hygiene) is included in these programs.

RECOMMENDATIONS:

Orientation and educational programs such as those described above are extremely important. We do not have any recommendations.

5. Antimicrobial Utilization and Control

FINDINGS:

The utilization of antimicrobial agents is monitored by an antibiotic committee. This committee is in the process of discussing issues regarding utilization and prescription restrictions for antimicrobial agents. There are presently no restrictions on the prescription of antimicrobial agents.

RECOMMENDATIONS:

A plan for optimizing the use of perioperative antimicrobial prophylaxis was developed as a part of the quality improvement project developed at the workshop Dec. 12 - 16. Details of the development of this project, as well as recommendations for implementation and a timeline for tasks associated with this project from January - June, 1995, are included in the overall project report, titled "Quality Improvement/Infection Control Demonstration Project for Hungary: Report for Phases I and II."

The utilization of antimicrobial agents should be monitored and, in the future, it may be necessary to restrict prescription of expensive broad spectrum antimicrobial agents.

6. Antimicrobial Resistant Organisms

FINDINGS:

There is presently no program for monitoring of antimicrobial resistant organisms.

RECOMMENDATIONS:

The frequency of antimicrobial resistant microorganisms should be monitored and specific strategies developed to limit spread of these organisms. Of specific concern are: methicillin resistant *Staphylococcus aureus*, vancomycin and high-level gentamicin resistant *Enterococcus* sp., penicillin resistant *Streptococcus pneumoniae*, and third generation cephalosporin and aminoglycoside resistant gram negative bacteria (especially *Pseudomonas aeruginosa*, *Enterobacter* sp., *Klebsiella* sp., *Serratia* sp., and *Acinetobacter* sp.). A recent summary of antimicrobial sensitivity indicates that more than 50% of *Staph. aureus* strains may be resistant to methicillin. Since susceptibility testing of this microorganism can be complicated, we agree that a collection of these *Staph. aureus* strains should be sent to a reference laboratory for confirmatory testing. We suggest that the infection control (hospital hygiene) service develop a plan in collaboration with the microbiology laboratory for tracking these organisms, identifying infected and colonized individuals, and a strategy for minimizing spread of these organisms.

7. Occupational Health

FINDINGS:

Hepatitis B Vaccine: Hepatitis B vaccine is available to susceptible, at-risk hospital workers free-of-charge through the national public health service. Periodic vaccination campaigns are conducted in the hospital in specific departments. A standard dosing regimen (administered intramuscularly at months 0, 1, and 6) is used. Post-vaccination antibody titers are not checked.

Occupational Exposure to Blood and Potentially Infectious Body Fluids: Percutaneous injuries involving exposure to blood or other potentially infectious body fluids are reportedly uncommon. Hospital personnel are instructed to report occupational exposures to blood and potentially infectious body fluids. If there is clinical evidence of a communicable infection, additional investigation of the source is conducted on a case-by-case basis and prophylaxis or treatment provided, if indicated. There is no protocol for evaluating the source of the exposure for evidence of blood-borne pathogens if the clinical history is not suggestive.

Influenza Vaccine: Influenza vaccine is offered free-of-charge to hospital workers every autumn. Acceptance of the vaccine is variable.

Tuberculosis: There is no specific evaluation for occupational exposure to TB or active tuberculosis among hospital workers within the hospital. Hospital workers are supposed to undergo yearly radiographic examinations for pulmonary tuberculosis as a part of the general screening procedure conducted by the national public health service on the entire Hungarian population.

Other: There are no other vaccines or examinations offered to hospital workers.

RECOMMENDATIONS:

We suspect that there is considerable under-reporting of needlestick injuries and other significant occupational exposures blood or potentially infectious body fluids by hospital personnel. Hospital personnel should be encouraged to report exposures and a mechanism should be established for monitoring frequency, location, and circumstances of the exposure.

Processes of care should be examined to identify situations and practices that increase the risk of an occupational exposure (such as recapping of needles contaminated with blood). Interventions to reduce the risk of exposure should be implemented and included in written procedures.

If an exposure occurs, prompt investigation of the source of the exposure (the person whose blood was involved in the exposure) should be performed to determine if prophylaxis against hepatitis B is necessary (HBsAg testing on the patient and HBsAb testing on the employee). The expense of testing should be borne by the hospital. There is no known effective prophylaxis for infection against HIV so no specific recommendations in this regard are made, except to provide counseling and follow-up serologic testing as is presently performed.

There is good reason for increased concern about the potential for occupational exposure to TB. Even though patients with TB are likely to be referred to other hospitals, the potential for exposure still exists. The most useful approach is to promptly identify patients with TB and initiate effective therapy as soon as possible. If patients with TB are cared for in the hospital, they should be placed in a single room and hospital personnel should wear masks when caring for these patients. Although these precautions will be helpful in reducing the risk of transmission of TB and other airborne infections, some risk will remain given the lack of isolation rooms with special ventilation systems capable of generating negative pressure relative to adjacent hallways. As a long term goal, improved isolation rooms for patients with infections spread by the airborne route are needed (see below, "Facilities").

H. Facilities

FINDINGS:

General Organization: On the Surgery, Traumatology, and Obstetrics/Gynecology wards, most rooms are multiple bed rooms. The Intensive Care Unit is spacious area with several one bed rooms and another multiple bed room. Ultraviolet lights are located in many of the hallways and rooms.

Isolation Rooms: The Infectious Diseases Ward contains a large number of isolation rooms. These rooms have an anteroom but do not have any special ventilation.

Preparation Area for Intravenous Fluids and Medications: Designated rooms or areas are used.

Clean and Dirty Utility Areas: Separate areas are used for clean and dirty equipment.

General Organization of the Operating Theaters: There are 4 operating theaters: General Surgery/Urology/Gynecology, Ophthalmology, Otorhinolaryngology, Obstetrics). In the General Surgery/Urology/Gynecology Operating Theater, patients enter and leave through the same doorway. There is a room for pre-op and post-op patients.

Ventilation in the Operating Rooms: Ventilation is provided by a central air conditioning system. The number of air exchanges per hour provided by this ventilation system is not known.

Hospital Water Supply: We did not assess the source or quality of the hospital water supply.

RECOMMENDATIONS:

As a long term goal, isolation rooms with special ventilation systems capable of generating negative air pressure relative to adjacent hallways are needed.

It is unlikely that the ultraviolet lights contribute to infection control since the source for bacteria causing most nosocomial infections is not the air. Since there is an occupational risk associated with these lights, we recommend that their use be discontinued.

I. Patient Care

1. Handwashing Facilities, Supplies, and Practices

FINDINGS:

Sinks: Functional sinks for handwashing were available at nursing stations and patient care areas. However, the number of sinks for handwashing in patient rooms was not always adequate.

Aerators/Filters on Faucets: Aerators or filters are not used on the faucets.

Soap: Liquid soap in closed, pour top containers or pump dispensers was generally available.

Towels (type and availability): Paper towels were generally available.

Waterless Handwash Agents: An alcohol-based waterless handwashing agent was available in closed, pour top bottles.

Handwashing Practices: It was not possible to perform a systematic assessment of handwashing practices.

RECOMMENDATIONS:

Alcohol-based waterless handwashing agents are very effective antiseptics for reducing the microbial load, especially transient colonizers, on the hands of caregivers. However, these agents should be available in greater supply, particularly for use by doctors and nurses when they move from bed to bed examining patients or performing procedures (i.e., changing dressings). A simple, inexpensive waterless handwashing agent, such as alcohol (70% by weight)/glycerin (1% by weight), can be formulated by the Pharmacy and provided in closed, pour top bottles.

2. Isolation Precautions, Universal Precautions, and General Use of Barriers

FINDINGS:

Written guidelines are available (see above, "Policies and Procedures"). Patients with communicable diseases are usually transferred to the Infectious Diseases Ward where they are cared for in an isolation room (see above). The Infectologist assists in determining whether a patient is likely to have a communicable disease. Gloves, cloth gowns, and synthetic, disposable masks are available. Shoe covers are used on a number of areas, including the Operating Theater and the Intensive Care Unit.

We did not assess the use of appropriate barriers in a comprehensive manner; however, by casual observation it was evident that staff often did not use appropriate barriers (gloves) when handling supplies contaminated with blood or potentially infectious body fluids. In addition, patients with draining wounds are often cared for in the same room as other surgical patients.

RECOMMENDATIONS:

There should be greater awareness of the presence of potential pathogens, particularly antimicrobial resistant microorganisms, in secretions and excretions of all patients. These microorganism can be spread to other patients via direct and indirect transmission (especially on the hands of health care workers). Hospital personnel should be educated on strategies to prevent this transmission through improved compliance with handwashing (see above), use of barriers (gloves, gowns), and appropriate patient placement.

Since there are no data demonstrating the efficacy of shoe covers in preventing nosocomial infections, their use can be discontinued from an infection control perspective.

3. Surgery and Wound Care

FINDINGS:

Pre-op Bath: Performed with standard soap the night before surgery for elective surgeries.

Pre-op Hair Removal: Removed with a disposable razor the night before surgery.

OR Staff Scrub: Wash with soap and water, then wash with Bradoderm (unable to determine active agent) or a povidone iodine preparation or a chlorhexidine-alcohol preparation.

OR Staff Attire: Cloth scrubs and disposable, synthetic hats, masks, and shoe covers.

Gloves: New disposable sterile gloves.

OR Staff Mucus Membrane Protection: We did not assess whether OR staff use mucus membrane protection (goggles or face shields).

Patient Skin Antisepsis: Wash with soap and water, then apply an alcohol-based agent (Dodosept) for surgery involving the chest or abdomen or povidone iodine preparation for surgery on or close to mucus membranes.

Perioperative Antimicrobial Prophylaxis: National Institute of Health guidelines for perioperative antimicrobial prophylaxis are available.

Wound Care Instruments and Supplies: A dressing cart is used for wound care supplies and instruments. Instruments used for dressings are supplied in individual sterile packs. Supplies used for dressings (sterile cotton balls, cotton tipped applicators, and gauze) are supplied in bulk in large sterile containers. Antiseptics used in dressing changes are changed on a variable schedule.

Burn Wound Care: Only patients with small burns are cared for in the hospital. A systematic assessment of the care of burn wounds was not performed.

RECOMMENDATIONS:

An antiseptic which contains chlorhexidine or povidone-iodine should be used since these agents provide residual antibacterial activity on the skin during the surgery. It was not clear whether Dodosept contains either of these agents in addition to alcohol.

Hair should be removed from the patient's skin only if this is necessary. If hair removal is necessary it should be clipped instead of shaved. If shaving is necessary, it should be done immediately before surgery.

A plan for optimizing preoperative preparation of the patient's skin at the site of the incision and for optimizing the use of perioperative antimicrobial prophylaxis was developed as a part of the quality improvement project developed at the workshop Dec. 12 - 16. Details of the development of this project, as well as recommendations for implementation and a timeline for tasks associated with this project from January - June, 1995, are included in the overall project report, titled "Quality Improvement/Infection Control Demonstration Project for Hungary: Report for Phases I and II."

4. Intravascular Catheters, Intravenous Fluids, and Medications

FINDINGS:

Indications for Use:

Peripheral intravenous catheters (PIV) are used for infusion of most intravenous fluids and mediations.

Percutaneous central venous catheters (PCVC) are occasionally used in some patients for hemodynamic monitoring and central venous access.

Peripheral arterial catheters are not used.

The use of umbilical arterial or venous catheters was not assessed.

Duration of Use: Catheters are used for as long as they are needed. There is no routine schedule for removal of catheters.

Personnel Inserting: PIVs are inserted by nurses; PCVCs are inserted by physicians.

Types of Intravascular Catheters (catheter material):

PIV

--Vasofix (Teflon)--short, over-the-needle catheters

PCVC

--Subclavia-Jugular Catheter set (material not stated, ? polyetherethylene)--long, over-the-needle catheters

All catheters are discarded after use.

Skin Antisepsis: Povidone-iodine or an alcohol-based antiseptic.

Insertion Technique: Inserted percutaneously.

Barriers Used During Insertion: Non-sterile gloves are used during insertion of PIVs. Sterile gloves, gowns, masks, and drapes are used for insertion of PCVCs.

Dressing: Gauze and tape is used.

Monitoring of Site Inspection: Insertion sites are monitored regularly by nurses.

Syringes: Only disposable syringes are used; they are discarded after one use.

Needles: Only disposable needles are used; they are discarded after one use.

Types of IV Fluid Containers and Administration Sets: Only commercially manufactured IV fluids are used. These fluids are available in glass bottles with rubber tops which are spiked by the IV infusion tubing. The rubber tops are covered by metal covers; there are no screw tops caps. Connections between the components of the infusion system are compatible and tight connections can be maintained.

IV Fluid and Medication Preparation: Admixture of IV fluid and medications is performed on the

wards by nurses on an "as needed" basis. Single-dose ampoules of electrolyte solutions and medications are used and discarded after opening.

Parenteral Nutrition Preparation: Commercially manufactured parenteral nutrition solutions (dextrose/amino acid/electrolytes/vitamins) and lipid emulsions are used in the Intensive Care Unit, but rarely elsewhere in the hospital. Bottles are used for an individual patients.

Frequency of IV Fluid Container and Administration Set Change: IV fluid bottles and parenteral fluid bottles are changed when they are finished, which is usually within several hours and always within 24 hours. "Keep open" infusions are generally not used. IV infusion tubing is changed every day. Infusion tubing is changed after a blood product infusion.. IV and parenteral nutrition containers and administration sets are disposed after use.

Hemodynamic Monitoring: Hemodynamic monitoring is performed using disposable manometers which are discarded after use.

RECOMMENDATIONS:

IV infusion tubing does not need to be changed every day. In the absence of evidence that nosocomial bloodstream infections are a significant problem, it is reasonable to change IV infusion tubing every 3 days.

5. Indwelling Urinary Catheters and Urine Drainage Systems

FINDINGS:

Indications for Use: Monitoring urine output in severely ill patients, post-operative patients in whom voiding difficulties are expected, irrigation of the bladder after urologic procedures, bladder outlet obstruction, and incontinence.

Duration of Use: Used as long as needed. There is no routine schedule for removal.

Personnel Inserting: Nurse or physician

Types of Catheters: Foley catheters are used. Urinary catheters designed for continuous irrigation of the bladder are used in patients after urologic surgeries, such as transurethral resection of the prostate.

Antiseptic Used to Cleanse the Meatus Prior to Insertion of a Urinary Catheter: Povidone-iodine

Type of Drainage System: Closed drainage systems are used exclusively.

Integrity of Foley Catheter/Drainage System Junction: Foley catheters are not routinely irrigated. Drainage systems are discarded when the drainage bag is full, although it is possible to drain these catheters. This procedure requires disruption of the catheter-drainage system junction. Sometimes, urinary catheters are clamped and disconnected from the drainage system to allow the patient to ambulate without carrying the drainage bag.

Measuring Containers: Measuring containers are not used at the bedside since drainage systems are usually disconnected and discarded (instead of drained) when the drainage bag is full.

RECOMMENDATIONS:

Urine drainage bags can be drained (instead of changing and discarding the entire drainage system) when the bag is full. This will reduce the risk of urinary tract infection since it will significantly reduce the frequency of disruption of the catheter-drainage system junction. To facilitate easier emptying of urine drainage bags, consider purchase of a different type of urine drainage systems with drainage ports on the bottom of the drainage bag.

6. Mechanical Ventilation and Respiratory Equipment

FINDINGS:

Indications for Use: Predominantly for respiratory failure, but also after head trauma with cerebral edema and major surgery.

Duration of Use: As long as necessary. Long term ventilation is not frequently needed.

Monitoring of Oxygenation and Ventilation: Analysis of blood gases is available. Capillary blood samples are used. Pulse oximetry is available.

Ventilator Humidifiers: Bubble-through heated humidifiers are used on all ventilators. Humidifiers are filled with sterile distilled water. Humidifiers are used for the duration of ventilation for an individual patient.

Frequency of Ventilator Tubing Change: Disposable ventilator tubing is generally changed every day.

Suctioning: Suction catheters are used once and discarded. Ampoules (10cc) of sterile saline are used to loosen secretions during suctioning.

Nebulizers: Reusable small volume nebulizers are used to administer inhaled medications and are reprocessed between uses.

RECOMMENDATIONS:

Ventilator circuits do not need to be changed as frequently as every day. There is currently no well-established guideline addressing this issue, but it is reasonable not to change ventilator circuits at all during short term ventilation. During long-term ventilation, it is still not clear that ventilator circuits need to be changed; however, if they are changed it is reasonable to change them no more frequently than once a week.

J. Reprocessing of Supplies and Equipment

FINDINGS:

Location: The Central Sterilization unit performs all steam sterilization and ethylene oxide sterilization for the hospital. Anesthesia equipment used in the Operating Room is reprocessed in Central Sterilization, except for laryngoscope blades and masks which are disinfected in the Operating Room. Respiratory equipment used in the ICUs is reprocessed in Central Sterilization. Upper gastrointestinal endoscopes are reprocessed in the room where endoscopy is performed. Arthroscopes and laparoscopes are reprocessed in the Operating Room.

Separation of Contaminated, Clean, and Sterile Items: The Central Sterilization has adequate separation of contaminated, clean, and sterile items.

Cleaning: Instruments and equipment used on the wards and the Intensive Care Unit receive superficial cleaning before transport to Central Sterilization where they receive additional manual cleaning. Surgical instruments are soaked in Haemosol (a detergent plus a disinfectant) in the Operating Theater, manually cleaned, dried, packaged, and transported to Central Sterilization. Workers wear heavy gloves and an apron during cleaning. Goggles to protect against splashes to the eyes or mouth are not used.

Packaging: Materials for steam sterilization are wrapped in muslin. Materials for ethylene oxide sterilization are sealed in plastic wrapping.

Steam Sterilization: Two large autoclaves are used for steam sterilization in the Central Sterilization unit. Both are automatically operated.

Quality Control of Steam Sterilization: Monitoring gauges are functional and are visually monitored. Chart recorders are functional and record sterilization cycle parameters. Chemical indicator tape is used on the outside of each item. Additional chemical indicators are used inside and outside of individual items once a day. Biologic indicators used every 6 months during the inspection performed by governmental inspectors. Written logs are maintained of cycle parameters and the

results of chemical and biologic indicator test results.

Ethylene Oxide Sterilization: There are two medium size ethylene oxide sterilizers with venting to outside air.

Quality Control of Ethylene Oxide Sterilization: Chemical indicator tape is used on the outside of each item. Additional chemical indicators are used inside and outside of individual items once a day. Biologic indicators used every 6 months during the inspection performed by governmental inspectors. Written logs are maintained of cycle parameters and the results of chemical and biologic indicator test results.

Shelf life: Items are dated and a defined shelf life has been established which varies according to the item and the method of sterilization.

Storage: Sterilized items are stored in the Operating Theater and on the wards and ICUs.

Surgical Instruments: Surgical instruments that can tolerate heat are sterilized using steam sterilization.

Heat/Moisture Sensitive and Delicate Surgical Instruments: Most heat sensitive items are sterilized using ethylene oxide. We did not assess the methods used to sterilize delicate ophthalmologic instruments.

Laparoscopes and Arthroscopes: Washed and sterilized with ethylene oxide.

Endoscopes: Endoscopes used for GI endoscopy are washed after use with soap and water, submerged in 2% glutaraldehyde for 15 minutes, rinsed with tap water, and allowed to drip dry. Biopsy forceps are reprocessed in the same manner.

Ventilator and Respiratory Equipment: Reused ventilator and respiratory equipment is cleaned, submerged in 2% glutaraldehyde for several hours, rinsed, packaged, and sterilized with ethylene oxide.

Anesthesia Equipment: Anesthesia equipment is cleaned, submerged in 2% glutaraldehyde for several hours, rinsed, packaged, and sterilized with ethylene oxide..

RECOMMENDATIONS:

Personnel cleaning instruments should wear heavy duty gloves. Goggles and a mask or a face shield should be used to prevent splashes of contaminated substances to their eyes or mouth. Sharp instruments should not be handled by hand to avoid percutaneous injuries.

We are not familiar with the particular chemical indicators presently in use and are not aware of the efficacy of these tests in ensuring adequate functioning of steam sterilizers. The standard in the U.S. is to monitor the functioning of steam sterilizers once a day using a biologic indicator (a test using bacterial spores). When implantable items are sterilized, the standard in the U.S. is to use a biologic indicator in each load in which these materials are sterilized and to determine that the biologic indicator test is negative (i.e., that sterilization was adequate) before these materials are released for use. Biologic indicators should be wrapped in muslin or, preferably, placed inside an instrument pack.

We are not aware of any data that clearly demonstrates that the use of formaldehyde as it is described above is an adequate method for sterilization. We recommend that critical items (items that will contact sterile tissues or fluids) that cannot be steam sterilized should be sterilized by ethylene oxide. If this is not possible due to time constraints, we recommend that chemical sterilization with glutaraldehyde be used for 10 hours, followed by sterile water rinsing, drying, and packaged in a sterile fashion.

Endoscopes should be meticulously cleaned after use and should have a longer contact time (20-30 minutes) with glutaraldehyde to ensure high-level disinfection. Preferably, endoscopes should be rinsed with sterile water although distilled water is an acceptable alternative if rinsing with sterile water is not possible. The endoscope should be completely dried before reuse. Biopsy forceps used with endoscopes should be sterilized since they may contact sterile tissues. If this is not possible, they should be at least be processed in a manner consistent with high-level disinfection described above.

Respiratory and anesthesia equipment are, in effect, undergoing double disinfection/sterilization. Either high level disinfection with a glutaraldehyde containing solution or ethylene oxide sterilization are adequate.

Depending on the manufacturer's recommendations, glutaraldehyde preparations may be used for periods of 14 to 28 days if kept in a covered basin or tub.

K. Preparation, Distribution, and Monitoring of Antiseptics and Disinfectants Used in Patient Care

FINDINGS:

Preparation of Antiseptics and Disinfectants: Antiseptics and disinfectants are purchased "ready-made."

Distribution of Antiseptics and Disinfectants : Antiseptics and disinfectants are stored in the Pharmacy and dispensed to the wards, ICUs, and Operating Theaters. It is the responsibility of individuals in these areas to fill individual containers with these solutions. Small (<500ml) glass bottles with tops are used for antiseptics used in patient care.

Monitoring of Antiseptics and Disinfectants: Practices for emptying and cleaning of containers of antiseptics and disinfectants used in patient care vary by ward according to extent to which they are used. Bottles of antiseptics are emptied and refilled least every week, but it was not clear whether there is a standard procedures for cleaning antiseptic bottles before they are refilled.

RECOMMENDATIONS:

There are a large number of "ready-made" disinfectants and antiseptics in use. Cost savings may be achieved by reviewing the use of each of these solutions and reducing unnecessary use and by eliminating unnecessary or redundant solutions.

A standard procedure for cleaning antiseptic containers before they are refilled should be developed, if such a procedure is not already in existence. Autoclaving the bottles is desirable, if it can be accomplished easily. If not, cleaning with soap and water followed by thorough drying before refilling is necessary.

L. Environmental Cleaning and Waste

FINDINGS:

General wards: General cleaning on the wards was not assessed.

Operating Room: The operating room table and other surfaces contacted by the patient are wiped with a disinfectant. (Metasept, active ingredient not determined). After surgeries involving abscesses, cleaning is performed the same way but the room is closed for 24 hours, if possible. Cleaning of the walls, cabinets, and fixtures in the Operating Room is performed on a routine basis.

Disposal of Infectious Waste: Potentially infectious waste is discarded in special labeled containers and incinerated outside the hospital.

RECOMMENDATIONS:

Closing the operating room after a surgery involving an infection is not necessary since microorganisms causing these infections are not likely to be spread via the air.

M. Microbiology Laboratory

FINDINGS:

Services: Routine stains and bacterial cultures are performed.

Culture Processing and Identification Procedures: Specimens are inoculated onto standard media. Blood cultures are semi-automated using a device that measures increased air pressure due to carbon dioxide production. Subcultures are made as indicated. Blood cultures are kept

for 10 days and then discarded. Identification of bacteria is performed using basic procedures. Identification of gram negative bacteria is performed using biochemical tests.

Susceptibility Testing: Disk diffusion (Kirby-Bauer) testing is performed. Reference strains with known antimicrobial susceptibilities are obtained from the National Institutes of Health and are used for quality control of antimicrobial susceptibility results.

Reporting: Results are reported via paper slips which are placed in the medical record. Log books are used to record specimens and results. A summary of antimicrobial susceptibility results was recently compiled and discussed with physicians at a conference. Copies of this summary are reportedly available on the wards.

Other Special Cultures: The laboratory does not perform special cultures at the present time. Screening media to identify patients colonized with antibiotic resistant bacteria are not used.

RECOMMENDATIONS:

A yearly summary of antimicrobial susceptibility results should be compiled and distributed to the infection control program and physicians and nurses caring for patients.

Use of selective media (media with antibiotics such as oxacillin or gentamicin) can be relatively easily and inexpensively prepared. This media can be used to screen selected patient populations antimicrobial resistant bacteria.

V. PREVALENCE SURVEY RESULTS

The results of the prevalence survey of nosocomial infections are displayed in Tables 1, 2, 3, and 4. Four wards with a total of 236 beds were surveyed; 166 (70.3%) of the beds were occupied at the time of the survey. Of these 166 patients, 112 (67.4%) had been in the hospital at least 48 hours at the time of the survey or were recently readmitted (nosocomial infections are, by definition, infections which are present after 48 hours of hospitalization and which were not present or incubating at the time of admission).

A total of 3 infections were identified in 3 of these 112 patients. Thus the prevalence of patients with nosocomial infections was 2.7%. The prevalence rate by ward is shown in Table 1. The total numbers of infected patients on each ward are small; consequently, the confidence intervals (which are not displayed) for these prevalence rates are large.

Table 2 displays the specific sites of nosocomial infection by ward.

Table 3 displays data regarding utilization of invasive devices and procedures and the prevalence of specific nosocomial infections in these "at-risk" patients. Again, the total numbers of infected patients in each of these categories is small; consequently, the confidence intervals (which are not displayed) for these prevalence rates are large. These data should not be over interpreted since they represent only the prevalence of active nosocomial infections in the hospital at a particular point in time.

The prevalence of surgical wound infections in post-operative patients was 5.8%. Wound classification or other measures of risk were not recorded so the risk-adjusted prevalence of surgical wound infection is not provided.

Indwelling urinary catheters were used infrequently. The prevalence of urinary tract infections in patients with indwelling urinary catheters was 0%. It is important to remember that the diagnosis of urinary tract infections in catheterized patients is very dependent on laboratory studies (evidence of pyuria determined by positive leukocyte esterase test on urine dipstick or by urinanalysis and urine cultures). If laboratory studies are not ordered for patients in whom infection is suspected or if laboratory data is not documented in the record, the prevalence survey would not detect these infections.

Mechanical ventilation was used only in the intensive care unit. The prevalence of lower respiratory tract infections in mechanically ventilated patients was 0%.

High-risk intravascular catheters (central venous catheters of any kind, hemodialysis catheters, arterial catheters, umbilical catheters, and intravascular catheters placed by cut-down) were used infrequently. The prevalence of bloodstream infections in patients with these high-risk intravascular catheters was 0%.

Table 4 displays the prevalence of use of intravenous antimicrobial agents by ward. The overall prevalence of intravenous antimicrobial agent use was 6.6%. The prevalence of use of expensive, broad spectrum antimicrobial agents (second or third generation cephalosporins, ciprofloxacin, and ampicillin/sulbactam) was 3.0%. No patients were receiving vancomycin.

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TABLE 1
PREVALENCE OF NOSOCOMIAL INFECTIONS BY WARD

WARD	# OF BEDS	# OF PTS (% beds occupied)	# OF PTS IN HOSPITAL >48 HOURS* (% of total patients)	# OF NOSOCOMIAL INFECTIONS*	# OF PTS WITH NOSOCOMIAL INFECTIONS*	PREVALENCE OF PTS WITH NOSOCOMIAL INFECTIONS**
Intensive Care Unit	9	5 (55.6)	4 (80.0)	0	0	0%
Surgery	70	65 (92.9)	34 (52.3)	0	0	0%
Traumatology	34	28 (82.4)	24 (85.7)	2	2	8.3%
Obstetrics/Gynecology	76	46 (60.5)	34 (73.9)	1	1	2.9%
Infectology	47	22 (46.8)	16 (72.7)	0	0	0%
TOTAL	236	166 (70.3)	112 (67.4)	3	3	2.7%

* Only patients hospitalized for >48 hours were evaluated for nosocomial infections.
** The prevalence of patients with nosocomial infections was calculated by dividing the number of patients with nosocomial infections by the number of patients hospitalized for >48 hours and multiplying by 100.

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TABLE 2
NUMBER OF NOSOCOMIAL INFECTIONS BY SITE AND WARD

WARD	# OF NOSOCOMIAL INFECTIONS	SURGICAL SITE INFECTION	URINARY TRACT INFECTION	LOWER RESPIRATORY TRACT INFECTION	BLOOD-STREAM INFECTION	SKIN AND SOFT TISSUE INFECTION	GASTRO-INTESTINAL INFECTION	OTHER
Intensive Care Unit	0	0	0	0	0	0	0	0
Surgery	0	0	0	0	0	0	0	0
Traumatology	2	2	0	0	0	0	0	0
Obstetrics/ Gynecology	1	1	0	0	0	0	0	0
Infectology	0	0	0	0	0	0	0	0
TOTAL	3	3 (100%)	0	0	0	0	0	0

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TABLE 3
NUMBER OF NOSOCOMIAL INFECTIONS IN PATIENTS AFTER INVASIVE PROCEDURES BY WARD

WARD	# POST-OP PTS	# SURGICAL SITE INFECTIONS IN POST-OP PTS (%)	# PTS WITH URINARY CATHETERS	# URINARY TRACT INFECTIONS IN PTS WITH URINARY CATHETERS (%)	# VENTILATED PTS	# LOWER RESPIRATORY TRACT INFECTIONS IN VENTILATED PTS (%)	# PTS WITH HIGH-RISK INTRA-VASCULAR CATHETERS	# BLOOD-STREAM INFECTIONS IN PTS WITH HIGH-RISK INTRA-VASCULAR CATHETERS (%)
Intensive Care Unit	1	0	1	0	1	0	1	0
Surgery	25	0	1	0	0	0	2	0
Traumatology	14	2 (14.3)	0	0	0	0	0	0
Obstetrics/ Gynecology	12	1 (8.3)	0	0	0	0	0	0
Infectology	0	0	2	0	0	0	0	0
TOTAL	52	3 (5.8)	2	0	0	0	0	0

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TABLE 4
PREVALENCE OF INTRAVENOUS ANTIMICROBIAL AGENT USE BY WARD

WARD	# OF PTS	# OF PTS RECEIVING INTRAVENOUS ANTIMICROBIAL AGENT(S) (%)	# OF PTS RECEIVING AN EXPENSIVE, BROAD SPECTRUM ANTIMICROBIAL AGENT* (%)	# OF PTS RECEIVING VANCOMYCIN (%)
Intensive Care Unit	5	2 (40.0)	2 (40.0)	0
Surgery	65	5 (7.7)	3 (4.6)	0
Traumatology	28	0	0	0
Obstetrics/ Gynecology	46	4 (8.7)	0	0
Infectology	22	0	0	0
TOTAL	166	11 (6.6)	5 (3.0)	0

* A broad spectrum antibiotic is defined as a single antibiotic (not a combination of two or more antibiotics) with a broad range of activity against gram-positive and gram-negative bacteria. For the purpose of this survey, second and third generation cephalosporins, ciprofloxacin, and ampicillin/sulbactam were included in this category.

Appendix 2 Summary of Workshop

SUMMARY OF QUALITY IMPROVEMENT/INFECTION CONTROL WORKSHOP

Dec. 12-16, 1994

Faculty:

Donald A. Goldmann, MD
W. Charles Huskins, MD
Carol O'Boyle Williams, MSN, RN, CIC

Workshop Participants:

Flór Ferenc Hopsital

Vértes Tamásné Maria, Nursing Director, Chairperson, Nursing Medical Quality Assurance Committee
Dr. Várnai László, Hospital Hygienist
Dr. Rákay, Assistant Hospital Hygienist
Elek Marta, Sanitary Inspector
Dr. Gyetvan, General Surgeon
Dr. Szabo László, Obstetrics/Gynecology
Zenoné Vertetits Aniko, Operating Room Nurse
Suki Maria, Surgical Ward Nurse, Surveillance Nurse
Simko Aniko, Operating Room Nurse, Surveillance Nurse

Kátai Gábor Hopsital

Mészárosné Hakucsák Erika, Nursing Director, Chairperson, Nursing Medical Quality Assurance Committee
Dr. Hersko Gyula, Obstetrics/Gynecology, Chairperson, Medical Quality Assurance Committee
Dr. Gyarmati Elizabeth, Hospital Hygienist
Igas Esther, Sanitary Inspector
Dr. Dobrai István, General Surgeon
Toth Julia, Operating Room Nurse
Kiss Ambrus Ilona, Surgical Ward Nurse, Surveillance Nurse
Toth Erika, Pharmacy Technician

Monday, Dec. 12

A series of lectures were provided by the workshop faculty covering the following topics:
Concepts underlying quality improvement;
Rationale for using infection control as a model for quality improvement;
Transmission of microorganisms in the hospital environment;
Surgical wound infections (epidemiology, diagnosis, prevention);

Reducing endemic rates of surgical wound infections using quality improvement techniques.

Tuesday, Dec. 13

The lecture series was continued covering the following topics:
Surveillance of nosocomial infections;
Infection control programs (organization, personnel, activity)
Nosocomial urinary tract infection (epidemiology, diagnosis, prevention);
Nosocomial lower respiratory tract infection (epidemiology, diagnosis, prevention);
Nosocomial bloodstream infection (epidemiology, diagnosis, prevention).

After these lectures, a formal critique of the workshop to date was elicited by participants using the delta/plus method (plus = strengths; delta = things to change or improve). Comments are summarized below:

Plus	Delta
Sharing experiences	Need more time to share experiences
Emphasis on measurement and methods	Written handouts in Hungarian
Exposure to practical tools and methods	More specific information practical for use in Hungary
Opportunity to talk and listen	Some influential people (Chiefs of Services) are missing
Reinforced the need to change the attitude of "my house, my castle"	Need a lot of approvals to make improvements
Honesty about difficulties encountered in implementing QI	
Opportunity to work with colleagues in another hospital	
Practical information about surveillance	

The day was concluded was by conducting a brainstorming session for quality improvement projects. The participants were asked to provide their answers to the question, "What would you most like to improve in your hospital?" In response to some of the comments listed above, one of the participants served as a facilitator and the entire session was conducted in Hungarian (with translation to English only for the faculty) using group process techniques.

Wed., Dec. 14

A final lecture was provided on epidemiology/study design and basic biostatistics. In response to comments made the previous day, the case study "Surgical Wound Infection Outbreak" was canceled in order to allow greater time for development of specific projects for each of the participating hospitals.

The participants divided into groups according to their hospital and began working on their projects. They were asked to use the following (Nolan) guideline for project development.

1. What do we want to improve?
   What is the specific goal?

2. How will we know that change is an improvement?
   What are useful measurements of outcome (e.g., surgical wound infection/100 surgeries)?
   What are useful measurements of process (e.g., appropriate choice and timing of perioperative antimicrobial prophylaxis)
   How will we gather the data required for these measurements?
   What do we need to do to be able to collect this data?

3. What are the first steps we need to take to make changes?
   Who needs to participate in the process of improvement?
   Who needs to be on the multidisciplinary team?
   What is the system involved in the process we want to change? (Document this system with a flow chart)
   What steps in the system are the most important to change? Where is there unnecessary work, an unnecessary "hand-off," or unnecessary delay?
   What tests (experiments) can we run?

The workshop faculty provided considerable guidance regarding this process. This included better definition of the aim of the project and the specific outcomes and processes of interest.

Two projects were defined:
1. A project to reduce the rate of surgical wound infection
2. A project to optimize perioperative antimicrobial prophylaxis

Critique of the day's activity was again elicited by participants using the delta/plus method. Comments are summarized below:

Plus	Delta
Practical information	More time to listen and learn
Principles of good evaluation	
Exposure of new way of thinking	
Good group process	
Can speak freely	

Thu., Dec. 15

Clinical practice guidelines (critical pathways) were discussed. Several specific examples of clinical practice guidelines developed and in use at Children's Hospital, Boston were presented.

The previous days' work on quality improvement projects were briefly reviewed and an overall plan for development and implementation was presented and discussed. The participants discussed one of the processes involved in this project (ordering and administration of perioperative antimicrobial prophylaxis) and constructed a detailed flow chart of this process.

Fri., Dec. 16

The participants worked on developing a written proposal for their project with the assistance of the faculty. Proposals were developed using the following format:

- General Aim
- Specific Goals
- Background and Significance
- Preliminary Data
- Methods (described for each specific goal)
  - Measures of process and outcome
  - Data Collection
  - Data Analysis (including calculation of rates)
  - Reporting
- Strategy for Implementation (including multidisciplinary team members)
- Timeline
- Necessary Resources

The general aim and specific goals for the project were (note some modification from Wed., Dec. 14):

General Aim: Cost-effective reduction in surgical wound infection rates

Specific Goals:

1. Introduce a surgical wound infection surveillance system
2. Provide confidential feedback to surgeons regarding surgical wound infections and procedure-specific duration of surgery
3. Reduce the length of preoperative stay
4. Optimize cost-effectiveness of perioperative antimicrobial prophylaxis
5. Review and improve preoperative preparation of surgical patients

Written preliminary recommendations were provided to and discussed with senior hospital administrators and infection control/quality assurance personnel.

Appendix 3 Hungarian NIH PAP Guidelines

Ajánlás a műtéti szisztémás antibiotikum profilaxisra
(Szisztémás antibiotikum profilaxis = SZAP)

1. Bevezetés

1.1. A műtéti SZAP célja: a műtéti fertőzéses szövődmények számának csökkentése. Ennek elérésére a műtét idejére szisztémásan antibiotikumokat adagolunk. Általában egy adagnál többre nincs szükség e cél eléréséhez.

1.2. Kontrollált klinikai vizsgálatok mutatják, hogy a SZAP helyes indikációja és alkalmazása esetén bizonyos műtétek infekciós aránya csökken, ezáltal a morbiditás, a kórházi kezelés ideje , költsége és talán a szepszishez társuló lethalitás is csökkenthető.

1.3. A SZAP előnyeit mérlegelni kell a gyógyszer okozta toxikus, allergiás reakciók lehetőségével valamint a rezisztens baktériumok szelekciójának és a felülfertőződés lehetőségének potenciális veszélyével szemben.Helyesen végzett szisztémás antibiotikum profilaxissal a kórházi antibiotikum felhasználás csökkenthető.

2. Szisztémás műtéti antibiotikum profilaxis javallata

A javallat felállításánál tekintetbe kell venni a műtét nozokomiális környezetét, a műtéttel kapcsolatos speciális kockázati tényezőket ill. a beteggel kapcsolatos szempontokat. Bizonyos kisérő betegségek a beteg teherbíróképességének csökkentése és infekció fokozott veszélye miatt SZAP -t indokolhatnak olyan esetekben is , amikor egyébként a műtét a műtét ezt egyértelműen nem tenné szükségessé.

2.1. Műtétek csoportosítása a kontamináció mértéke szerint

2.1.1.TISZTA (aszeptikus technika, gyulladásos folyamat nincs, nem nyílt meg a légző-,bél-,urogenitális traktus.) Az infekciós ráta 5% alatt van.

2.1.2. TISZTA KONTAMINÁLT (a légutak vagy gasztrointesztinum megnyitása, a műtéti terület jelentős kontominációja nélkül)Az infekció gyakorisága 5-10% között van.

2.1.3. KONTAMINÁLT (a műtéi terület jelentős expozíciója béltartalommal, fertőzött epévelvagy vizelettel.) Kb. 20% az infekció gyakorisága.

2.1.4. FERTŐZÖTT (súlyos bakteriális infekció, bélperforáció vagy sebészeti tályog megnyitás által, nekrotikus szövet jelenléte.) 40% a fertőzés kialakulásának gyakorisága.

A tiszta műtéteknél SZAP általában nem indokolt. Kivételt képeznek azok a műtétek, ahol a fertőzéses szövődmény jóvátehetetlen következményekkel járna a betegre nézve.
A tiszta-kontaminált csoportba tartozó műtéteknél SZAP javasolt.
A kontaminált csoport műtétjeinél a SZAP végzése kötelező.
A fertőzött műtéteknél antibiotikum adása szükséges, de mivel már eleve kialakult fertőzésről van szó, profilaxis nem végezhető, terápia indokolt.

2.2. A SZAP-t indokló <u>egyéb műtéti kockázati tényezők</u>

2.2.1. Nagy inplantátumok behelyezése (szívbillentyű, nagy izületi protézisek)

2.2.2. Elhúzódó műtét.

2.2.3. Nagy szövetroncsolással járó műtét.

2.2.4. Reoperáció

2.2.5. Akut műtét, ahol a szokásos - a műtét biztonságát fokozó - előkészítés, idő hiányában nem végezhető (pl. akut hasi műtétek).

2.3. Antibiotikum profilaxist indokló, a <u>beteggel kapcsolatos kockázati tényezők</u> (olyan műtéteknél, ahol a műtét jellegéből adódóan SZAP-t nem végeznénk).

2.3.1. SZAP kötelező.

2.3.1.1. Infekciós endokarditisz kialakukása szemponjából veszélyeztetett betegek

2.3.1.2. Implantátumok jelenléte (műbillentyű, izületi protézis, ventriculo-atrialis shunt).

2.3.2. SZAP ajánlott ill. mérlegelés tárgya.

2.3.2.1. Immunszupprimált beteg

a) Leukopénia (abszolut granulocita szám $1x10^9$ (liter alatt).

b) Tartós szteroid kezelés
c) Citotasztikus kezelés

2.3.2.2. Kísérőjelenségek: diabetes mellitus, obesitas, rosszul tápláltság, súlyos májműködési zavar, veseelégtelenség, alkoholizmus, gyógyszerabúzus.

3. A műtéti szisztémás antibiotikus profilaxis hatékonyságának feltételei.

3.1. A gyógyszerválasztás szempontjai a feltételezett kórokozók figyelembevételével.

3.1.1. A hatékony profilaxisnak a fertőzést legnagyobb valószínűséggel okozó baktériumok ellen kell irányulnia és nem kell hatékonynak lennie minden lehetséges kórokozóval szemben.

3.1.3. A műtéti fertőzést okozhatja a beteg környezetében előforduló baktérium (exogén flóra), vagy a beteg adott testájékán vagy testüregében előforduló baktérium (endogén flóra). A környezetben ill. a műtétttel kapcsolatos testájékon előforduló baktériumok határozzák meg az anitbiotikum választást profilaxis céljára.

3.1.2.1. Környezeti flóra
Staphylococcus aureus - koaguláz-negatív staphyloccocusok, colifarmok (L.coli), Pseudomonas spp., citobacter spp., Enterobacter, Clostridium spp.

3.1.2.2. Endogén flóra
a) Orr: Staphylococcus aureus, Streptococcus pneumaniae, corinebacterium spp., zöldítő streptococcusok.
b) Felső légutak: S.pneumoniae, Haemophilus influenzae.
c) Száj/garat: S.pneumoniae, straptococcusok (és haemolyzáló) Cscherichia coli, Bacteroide oralis, melaninogenicus, fusobacterium, peptostreptococcusok, Actinomyces.

d) Colorectalis (fecalis) flóra: Escherichia coli, Klebsiella, Enterobacter, Bacteroides fragilis, peptostreptococcusok, clostridiumok.
e) Epeutak: Eschericia coli, Klebsiella, Proteus, clostridiumok.
f) Húgyutak: normál flóra nincs (gyakori kórokozók: E.coli, Klebsiella, Proteus, Enterobacter).
g) Genitális traktus (női): Streptococcusok, staphylococcusok, gram negatív pálcák, bacteroides csoport, Chamydia trachomatis.
h) Bőr: Staphylococcus aureus, koaguláz-negatív staphylococcus, Propionibacterium acnes, diphteroidok.

3.2. Ideális anibiotikum a profilaxis céljára:
- hatékony a feltételezett kórokozóval szemben
- hatékony koncentrációban van jelen a műtéti területen (szérumszint, penetráció, a gyógyszer kiürülésének sebessége a műtét időtartamára megfelel)
- nem indukál rezisztenciát
- nem toxikus
- olcsó

3.3. A gyógyszer adagolásának módja többnyire parenterális (iv., esetleg im.) és néhány körülhatárolt esetben per os (colorectalis sebészet, endocarditis profilaxis).

3.4. <u>Az antibiotikum adagolásának időzítése</u> profilaxis céljára.

3.4.1. A műtét teljes időtartamára (Bőrmetszéstől bőrzárásig) hatékony antibiotikum koncentrációra van szükség.

3.4.2. A műtét utáni antibiotikum alkalmazásra a profilaxis folytatásaként réitkán van szükség. A posztoperatív antibiotikum adagolás fenntartása rezisztens baktériumok szelektálásával és szuperinflekcióval veszélyeztet.

3.4.3. A leggyakrabban javasolt un. "1 dózist" a műtét kezdete előtt 15-60 perccel - az anesztézia indukciójakor - célszerű adni.

3.4.4. A műtét teljes időtartamára kiterjedő hatékony védelem eléréséhez bizonyos esetekben a kezdő dózis interaoperatív ismétlésére van szükség.

a) elhúzódó műtét esetén (Ha az alkalmazott antibiotikum szérum felezési idejét a műtét időtartama jelentősen meghaladja, több mint kétszerese, pl. 60 percnél rövidebb szérum felezési idővel rendelkező szer esetén a kezdő dózis után 2 óránként ismétlés szükséges.)

b) Műtét alatt jelentkező masszív vérzés esetén a csökkenő szérum koncentráció miatt indokolt ismételt dózist adni.

3.5. A kórelőzményben szereplő azonnali típusú <u>penicillin allergiára</u> utaló adat a profilaxisban penicillin vagy penicillin származék adását ellenjavalja.
A cefalosporinokkal szembeni, várhatóan 10% gyakoriságú keresztallergia lehetősége miatt profilaxis céljára ebben az esetben cefalosporin sem javasolható, penicillin allergia esetén a sémában feltüntetett alternetív rezsimek alkalmazandók.

4. <u>Műtéi szisztémás antibiotikum profilaxisra ajánlott rezsimek műtéti típusok ill. kórállapotok szerint.</u>

4.1. Fej - nyak sebészet (oropharynx megnyílásával).

a) amoxicillin + klavulánsav
vagy
ampicillin + szulbaktám

b) clindamycin + aminoglikozid

Időtartam: 1 dózis

4.2. Mellkassebészet

4.2.1. Tüdőműtétek a hörgőrendszer megnyílásával

4.2.2. Nyelőcső műtétek

a) amoxicillin + klavulánsav
b) ampicillin + szulbaktám
c) penicillin allergia esetén
fluorokinolon + clindamycin

Időtartam: 1 dózis

4.2.3. Cardiovascularis műtétek

a) II. generációs cephalosporin
b) penicillin allergia esetén
Vancomycin

Időtartam: 24-48 óra.

4.3. Hasi sebészet

4.3.1. Gyomor-, gastroduodenális műtétek
(benignus elváltozásoknál csak rizikófaktor esetén, malignus elváltozásnál mindig)
rizikófaktorok : akut vérzés,H2 receptor blokkoló egyidejű adása, hypochlorhydria.

a) II. gen.cefalosporin (cefamandol, cefuroxim)
tartós pangás esetén : +metronidazol.
b) Penicilin allergia eseté clindamycin+aminoglikozid
Időtartam : 1 dózis.

4.3.2. Epeutak sebészete.
Rizikófaktorok esetén: 70 év felett, icterus,cholecystitis, choledocholithiasis.

a) II.gen. cefalolosporin (cefamadol,cefuroxim)
b) penicillin allergia esetén fluorokinolon.

Időtartam: 1 dózis

4.3.3. Hasnyálmirigy sebészet

a) III. gen.cefalosporin (cefotaxim,ceftriaxon)
b) penicillin allergia esetén fluorokinelon.

Időtartam: 1 dózis

4.3.4. Appendectomia

a) II. gen. cefalosporin (cefamandol, cefuroxim)
b) Penicillin allergia esetén aminoglikozid + metronidazol

Időtartam: 1 dózis (műtéti lelettől, a kórkép súlyosságától függően az antibiotikum terápia folytatása lehet szükséges)

4.3.5. Colorectalis sebészet

a) elektiv
műtét előtti napon:
- mechanikus béltisztítás / pl.: polyetilén glycolelektrolit oldat, vagy mannit per os ill. beöntések előző nap.

- neomycin 1 g + erythromycin 1 g per os délután 1, 2 és 10 órakor
  (alternative neomycin 1 g + metronidazol 500 mg háromszor)

Szisztémás Antibiotikum adása:
III. gen. cefalosporin (cefotaxim, ceftriaxon) + metronidazol.
Időtartam: anesztézia kezdetekor 1 dózis.
Folytatás: j. o. hemicolectomiánál 12 h.
b. o. " 24 h.

b) akut
Szisztémás antibiotikum profilaxis
Az anasztézia kezdetekor:
III. gen. cefalosporin (cefotaxim, ceftriaxon) + metronidazol
Folytatás: j. o. hemicolectomiánál 12 h.
b. o. " 24 h.
(Peritonitissel járó elváltozásoknál a terápia a klinikai kép függvényében folytatandó.)
Penicillin allergia esetén:
aminoglikozid + clindamycin vagy
aminoglikozid + metronidazol
Időtartam: mint fent.

4.3.6. Akut hasi katasztrófa, tompa hasi sérülés, lövés, szúrás áthatoló sérülése.
Antibiotikum választás mint 4.3.5. (colorectalis sebészet) esetében akut ellátáskor.
Időtartam: 24 óra vagy műtéti lelettől függően (peritonitis esetén) terápia több napon át.

4.3.7. Érsebészet.
Csak protézis behelyezése esetén javasolt
a) II. generációs cefalosporin
b) clindamycin
Időtartam: 1 dózis

4.4. Szülészet- nőgyógyászat.
Akut ill. elektív császármetszés.
Hüvelyi méhkiirtás
a) II. generációs cefalosporin + metronidazol
b) amoxycillin + klavulánsav

c) ampicillin + szulbaktám
d) penicillin allergia esetén, clidamycin + aminoglikozid
Időtartam : 1 dózis

4.5. Urológiai műtétek.
Steril vizelet mellett SZAP értéke kétséges.
Bacteriuria esetén elektiv esetben preoperativ kezelés, ha ez nem lehetséges ill. akut esetben SZAP
Hólyagkatéter bevezetése önmagában SZAP-t nem indokol
a) fluorokinolon
b) II. generációs cefalosporin+ aminoglikozid.
Időtartam: 1 dózis

4.6. Idegsebészet

4.6.1. Gerincsebészet(flavotomia, laminectomia SZAP-t nem indokol !
Nagy gerincműtétek esetén, ha az intézeti infekciós ráta magas (5%).
a) II. generációs cefalosporin : cefuroxim!
b) penicillin allergia esetén vancomycin.

4.6.2. Craniotomia.
(Reoperácoó vagy fokozott kockázat esetén)
a) II. generációs cefalosporin : cefuroxim
b) penicillin allergia esetén vancomycin.

4.6.3. Liquorcsorgás esetén
- Konzervatív terápia mellett szoros klinikai és mikrobiológiai kontroll szükséges. SZAP bizonytalan hatékonysága és rezisztens kórokozók szelekciója miat nem javasolt.
- Liqourcsorgás mellett vagy annak megszüntetésére végzett idegsebészeti vagy maxillo-facialis műtét esetén
  a) amoxicillin + klavulánsav
  b) ampicillin + szulbaktám
  c) szulfonamid + trimetoprim
  d) cefuroxim
  Időtartam : 24 óra.
  Fenti esetekben jellemzően az orr-garat gram pozitiv kórokozói fordulnak elő, de

kolonizáció lehetséges gram negatív kórokozókról ill. koaguláz negatív staphylococcussal, ezen esetekben a rezsim megváltoztatűsa szükséges.)

4.7. Ortopéd- traumatológiai műtétek

4.7.1. Izületi protézis implantáció
(+ nagy csöves csontok osteosynthesisei, medencén végzett műtétek, gerincsebészet mint fent)
a) II. generációs cefalosporin
b) penicillin allergia esetén vancomycin
Időtartam: 1 dózis (+ műtét alatti ismétlés szükség esetén.)

4.7.2. Nyílt törések, lágyrészek súlyos lacerációja.
a) II. generációs cefalosporin + metronidazol
b) ampicillin + szulbaktám
c) amoxicillin + klavulánsav
d) penicillin allergia esetén clindmycin + aminoglikozid.
Időtartam: 48 óra.
SZAP kezdete a beteg felvételkor azonnal.
Késedelmes kezdés és /vagy késői műtéti ellátás esetén nem profilaxis hanem terápia végzése indokolt.

4.7.3. Végtagamputáció
a) II. generációs cefalosporin + metronidazol
b) penicilin allergia esetén clindamycin
Időtartam: 24 óra.

4.7.4. Harapott seb (emberi, állati eredetű)
(korokozók: emberi orális flóránál említetteken kívül állati harapásnál Pasteurella multocida.)
a) amoxicillin + klavulánsav
b) ampicillin + szulbaktám
c) penicilin allergia esetén erythromycin.
Időtartam: 48-72 óra.

4.8. Szemészeti műtétek.
SZAP nem indokolt.

4.9. Fül-, orr-gégészet (4.1. alatt részletezett fej-, nyaksebészethez sorolható eseteket leszámítva nem indokolt.)

4.10. Infekciós endocarditis profilaxis.
Az Országos Kardiológiai Intézet 1992-ben kiadott módszertani levele az irányadó.

Megjegyzés:

A hatékony perioperatív antibiotikum profilaxis végzéséhez az országos rezisztencia adatok és az Intézet rendszeres vizsgálata szükséges a nozokomiális infekciókat előidéző kórokozók ismeretére, s azok lehetséges antibiotikum rezisztenciájára. Ennek figyelembevétele szükséges - különösen hosszabb idejű preoreratív kórházi tartózkodás esetén - az előbbiekben javasolt profilaktikus rezsimek alkalmazásakor. Rezisztens kórokozók kolonizációja, különösen intenzív osztályon ápolt beteg esetén speciális gyógyszerek adását teheti szükségessé. A rendszeres mikrobiológiai értékelés az egyébként bevált rezsimek időnkénti változtatását is indokolhatja.
A részletezett ajánlásokból lehetőség szerint cefalosporint részesítsük általában előnyben. Az egyéb gyógyszerek kiegészítéseképpen, a spektrum szélesítrésére ill. alternatívaként szerepelnek. Az aminoglikozidok alkalmazását kerüljük.
Ahogy a fenti ajánlásból és a függelékben feltüntetett antibiotikum listából kiderül az ajánlásból igyekeztünk kizárni az életmentő antibiotikumokat és azokat a kritikusan súlyos infekció kezelésére tartalékolni.

Függelék a SZAP Útmutatóhoz

A részletes ajánlásban szereplő gyógyszerek ill. gyógyszercsoportok jelenleg hozzáférhető gyári készítményei és ajánlott felnőtt adagjai:

Cefamandol,	Mandokef	2g	719.-Ft
Cefuroxime,	Zinacef	1,5g	902.-Ft
Cefoxitin,	Mefoxin	2g	1.029.-Ft

III. gen. Cefalosporinok

Cefotaxime,	Claforan	2g	911.-Ft
Ceftriaxon,	Rocephin	2g	2 .028.-Ft
Cefoperazon,	Cefobid	2g	1.335.-Ft

Penicillinszármaték + beta laktanáz gátlók

Amoxicillin + klavulánsav,	Augmentin	1,2g	454.-Ft
Ampicillin + szulbaktám	Unasyn	1,5(3)g	1.555.-Ft

Egyéb

Doxycycline		200 mg	566.-Ft
Erythromycin		300-600 mg	172.-Ft
Vancomycin,	Vancocyn	1g	2.784.-Ft
Clindamycine,	Dalacin C	600 mg	605.-Ft
Metronidazol,	Klion	500 mg	280.-Ft

Kinolonok

Ofloxacin,	Tarivid	200 mg	93.-Ft
Pefloxacin,	Peflacine	400 mg	106.-Ft
Ciprobay		200 mg	2.704.-Ft

Aminoglikozidok (profilaxisra, adásuk csak rendkívűl körülhatárolt esetben indokolt!!)

Gentamycin		3mg / tkg / kb. 240 mg/	179.-Ft
Netilmycin,	Netromycin	300 mg	865.-Ft
Tobramycin,	Brulamycin	3mg / kg / kb. 240 mg/	488.-Ft

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Appendix 4 US Literature: PAP

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ANTIMICROBIAL PROPHYLAXIS IN SURGERY

Antimicrobial prophylaxis can decrease the incidence of infection, particularly wound infection, after certain operations, but this benefit must be weighed against the risks of toxic and allergic reactions, emergence of resistant bacteria, and superinfection (AB Kaiser in GL Mandell et al, eds, *Principles and Practice of Infectious Diseases*, 3rd ed, New York:Churchill Livingstone, 1990, page 2245). Medical Letter consultants generally recommend antimicrobial prophylaxis only for procedures with high infection rates and those involving implantation of prosthetic material.

The special problem of antimicrobial prophylaxis to prevent bacterial endocarditis when patients with prosthetic heart valves, rheumatic heart disease, or other cardiac abnormalities undergo dental or surgical procedures was discussed in *The Medical Letter Handbook of Antimicrobial Therapy*, 1992, page 53.

TIMING — With many antimicrobials, a single dose given just before the procedure provides adequate tissue concentrations throughout the operation. When surgery is prolonged or massive blood loss occurs, or when an antimicrobial with a short half-life is used, such as cefoxitin *(Mefoxin)*, a second dose may be advisable during the procedure. Postoperative doses of prophylactic drugs are generally unnecessary.

CARDIAC — Prophylactic antibiotics can decrease the incidence of infection after open-heart surgery, including valvular procedures and coronary artery bypass grafts (RE Ariano and GG Zhanel, DICP Ann Pharmacother, 25:478, 1991). Single doses appear to be as effective as multiple doses, provided that high concentrations are maintained in the blood throughout the operation. Prophylaxis may not be necessary for pacemaker implantation in centers with a low incidence of infection.

NON-CARDIAC THORACIC — Controlled trials of antimicrobial prophylaxis have produced conflicting results in pulmonary resection; some have shown a decrease in wound infection, but not in pneumonia or empyema (R Aznar et al, Eur J Cardiothorac Surg, 5:515, 1991; CC Hopkins, Rev Infect Dis, 13 suppl 10:S869, 1991). Prophylactic antimicrobials may prevent empyema after closed-tube thoracostomy for chest trauma, but the evidence is limited (WF Fallon, Jr and RL Wears, J Trauma, 33:110, 1992).

VASCULAR — Preoperative administration of a cephalosporin decreases the incidence of postoperative wound infection after arterial reconstructive surgery on the abdominal aorta,

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vascular operations on the leg that include a groin incision, and amputation of the lower extremity for ischemia (CJL Strachan, J Antimicrob Chemother, 31 suppl B:65, 1993). Many clinicians also recommend prophylaxis for implantation of any vascular prosthetic material, including grafts for vascular access in hemodialysis.

ORTHOPEDIC — Prophylactic antistaphylococcal drugs can decrease the incidence of both early and late infection in prosthetic joints following total hip replacement (RH Fitzgerald, Jr, Infect Dis Clin North Am, 3:329, 1989; AF Heath, Pharmacotherapy, 11:157, 1991). They also decrease the rate of infection when hip and other fractures are treated with internal fixation by nails, plates, screws or wires. Medical Letter consultants disagree on whether patients with indwelling prosthetic joints should receive antimicrobial prophylaxis routinely when undergoing dental, gastrointestinal, or genitourinary procedures; for long procedures, surgery in an infected area, or other procedures with a high risk of bacteremia, administration of an antistaphylococcal agent may be advisable.

NEUROSURGERY — Studies of antimicrobial prophylaxis for implantation of cerebrospinal fluid shunts have produced conflicting results (EM Brown, J Antimicrob Chemother, 31 suppl B:49, 1993). In spinal surgery, the post-operative infection rate after conventional lumbar discectomy is so low that antibiotics have not been shown to be effective; infection rates are higher after spinal procedures involving fusion or prolonged spinal surgery, and use of prophylactic antibiotics is common, but controlled trials of such use are lacking. An antistaphylococcal antibiotic may decrease the incidence of infection after craniotomy (B van Ek et al, Scand J Infect Dis, 22:345, 1990; M Djindjian et al, J Neurosurg, 73:383, 1990).

OPHTHALMIC — Data are limited on the effectiveness of antimicrobial prophylaxis for ophthalmic surgery, but postoperative endophthalmitis can be devastating. Most ophthalmologists use antimicrobial eye drops for prophylaxis, and many also give a subconjunctival injection at the end of the procedure.

HEAD AND NECK — Prophylaxis with antimicrobials has decreased the high incidence of wound infection after head and neck operations that involve an incision through the oral or pharyngeal mucosa (RS Weber and DL Callender, Ann Otol Rhinol Laryngol, 101:16, 1992). Gentamicin eardrops may decrease the incidence of purulent otorrhea after placement of a tympanostomy tube (RS Baker and RA Chole, Arch Otolaryngol, 114:755, 1988).

GASTRODUODENAL — The risk of infection after gastroduodenal surgery is high when gastric acidity and gastrointestinal motility are diminished by obstruction, hemorrhage, gastric ulcer or malignancy, or by therapy with H_2-blockers, such as cimetidine *(Tagamet)*, ranitidine *(Zantac)*, nizatidine *(Axid)*, or famotidine *(Pepcid)*. Preoperative use of a cephalosporin can decrease the incidence of postoperative infection in these circumstances, and also after gastric bypass surgery for obesity or percutaneous endoscopic gastrostomy (NK Jain et al, Ann Intern Med, 107:824, 1987).

BILIARY TRACT — Antimicrobials are recommended before biliary tract surgery only for patients with an increased risk of infection — those more than 70 years old and those with acute cholecystitis, obstructive jaundice, or common duct stones.

COLORECTAL — Preoperative antibiotics can decrease the incidence of infection after colorectal surgery; for elective operations, an oral regimen appears to be as effective as

parenteral drugs (SL Gorbach, Clin Infect Dis, 15 suppl 1:S313, 1992). Whether a combination of oral and parenteral agents would be more effective than either alone is unclear. The prophylactic regimen should include antimicrobials effective against both facultative gram-negative bacilli and anaerobes such as *Bacteroides fragilis*.

APPENDECTOMY — Preoperative antimicrobials can decrease the incidence of infection after appendectomy. Regimens with activity against both facultative gram-negative bacilli and anaerobes are more effective than those active against either alone (W Browder et al, J Infect Dis, 159:1088, 1989).

GYNECOLOGY AND OBSTETRICS — Antimicrobial prophylaxis decreases the incidence of infection after vaginal hysterectomy and possibly after abdominal hysterectomy (DL Hemsell, Rev Infect Dis, 13 suppl 10:S821, 1991). Peri- or preoperative antimicrobials can prevent infection after emergency cesarean section in high-risk situations such as active labor or premature rupture of membranes, after first-trimester abortion in high-risk women, and also after mid-trimester abortions (ET Houang, Drugs, 41:19, 1991).

UROLOGY —Infectious disease experts do not recommend antimicrobials before urological operations in patients with sterile urine. When the urine culture is positive or unavailable, patients should be treated to sterilize the urine before surgery or receive a single preoperative dose of an appropriate agent (CM Kunin, *Detection, Prevention and Management of Urinary Tract Infections*, 4th ed, Philadelphia:Lea & Febiger, 1987, p 361).

OTHER PROCEDURES — Prophylaxis with antimicrobial drugs is not routinely recommended for cardiac catheterization, gastrointestinal endoscopy, arterial puncture, thoracentesis, paracentesis, repair of simple lacerations, or outpatient treatment of burns.

"DIRTY" SURGERY — "Dirty" surgery, such as that for a perforated abdominal viscus, a compound fracture, or a laceration due to an animal or human bite, is often followed by infection; use of antimicrobial drugs for these operations is considered treatment rather than prophylaxis and should be continued postoperatively for several days.

CHOICE OF A PROPHYLACTIC AGENT — An effective prophylactic regimen should be directed against the most likely infecting organisms, but need not eradicate every potential pathogen; rather, the goal is to decrease their numbers below critical levels necessary to cause infection. For most procedures, cefazolin (*Ancef*; and others), which has a moderately long serum half-life, has been effective. In institutions where methicillin-resistant *S. aureus* or methicillin-resistant coagulase-negative staphylococci have become important pathogens, vancomycin (*Vancocin*, and others) should be used. For colorectal surgery and appendectomy, Medical Letter consultants prefer cefoxitin *(Mefoxin)* or cefotetan *(Cefotan)* because they are more active than cefazolin against bowel anaerobes, including *Bacteroides fragilis*. For other abdominal and pelvic procedures, including obstetrical and gynecological operations, cefazolin has been equally effective and is less expensive. Third-generation cephalosporins, such as cefotaxime *(Claforan)*, ceftriaxone *(Rocephin)*, cefoperazone *(Cefobid)*, ceftazidime *(Fortaz; Tazicef; Tazidime)*, or ceftizoxime *(Cefizox)*, should not be used for surgical prophylaxis. They are expensive, their activity against staphylococci is often less than that of cefazolin, their spectrum of activity against facultative gram-negative bacilli includes organisms rarely encountered in elective surgery, and their widespread use for prophylaxis promotes emergence of resistance to these potentially valuable drugs.

PREVENTION OF WOUND INFECTION AND SEPSIS IN SURGICAL PATIENTS

Nature of operation	Likely pathogens	Recommended drugs	Adult dosage before surgery[1]
CLEAN			
Cardiac			
Prosthetic valve, coronary artery bypass, other open-heart surgery, pacemaker implant	*Staphylococcus epidermidis, S. aureus, Corynebacterium,* enteric gram-negative bacilli	cefazolin or cefuroxime *OR* vancomycin[3]	1-2 grams IV[2] 1 gram IV
Vascular			
Arterial surgery involving the abdominal aorta, a prosthesis, or a groin incision	*S. aureus, S. epidermidis,* enteric gram-negative bacilli	cefazolin *OR* vancomycin[3]	1-2 grams IV 1 gram IV
Lower extremity amputation for ischemia	*S. aureus, S. epidermidis,* enteric gram-negative bacilli, clostridia	cefazolin *OR* vancomycin[3]	1 gram IV 1 gram IV
Neurosurgery			
Craniotomy	*S. aureus, S. epidermidis*	cefazolin *OR* vancomycin[3]	1 gram IV 1 gram IV
Orthopedic			
Total joint replacement, internal fixation of fractures	*S. aureus, S. epidermidis*	cefazolin *OR* vancomycin[3]	1-2 grams IV 1 gram IV
Ophthalmic	*S. aureus, S. epidermidis,* streptococci, enteric gram-negative bacilli, *Pseudomonas*	gentamicin *OR* tobramycin *OR* neomycin-gramicidin-polymyxin B cefazolin	multiple drops topically over 2 to 24 hours 100 mg subconjunctivally at end of procedure
CLEAN-CONTAMINATED			
Head and neck			
Entering oral cavity or pharynx	*S. aureus,* streptococci, oral anaerobes	cefazolin *OR* clindamycin	1-2 grams IV 600-900 mg IV
Abdominal			
Gastroduodenal	Enteric gram-negative bacilli, gram-positive cocci	*High risk, gastric bypass, or percutaneous endoscopic gastrostomy only:* cefazolin	1 gram IV
Biliary tract	Enteric gram-negative bacilli, enterococci, clostridia	*High risk only:* cefazolin	1 gram IV
Colorectal	Enteric gram-negative bacilli, anaerobes	*Oral:* neomycin + erythromycin base[4] *Parenteral:* cefoxitin *OR* cefotetan	 1 gram IV
Appendectomy	Enteric gram-negative bacilli, anaerobes	cefoxitin *OR* cefotetan	1 gram IV
Gynecologic			
Vaginal or abdominal hysterectomy	Enteric gram-negatives, anaerobes, Gp B strep, enterococci	cefazolin	1 gram IV
Cesarean section	same as for hysterectomy	*High risk only:* cefazolin	1 gram IV after cord clamping
Abortion	same as for hysterectomy	*First trimester high risk:*[5] aqueous penicillin G *OR* doxycycline *Second trimester:* cefazolin	 1 million units IV 300 mg PO[6] 1 gram IV
DIRTY SURGERY			
Ruptured viscus[7]	Enteric gram-negative bacilli, anaerobes, enterococci	cefoxitin *OR* cefotetan either ± gentamicin *OR* clindamycin + gentamicin	2 grams IV q6h 1-2 grams IV q12h 1.5 mg/kg IV q8h 600 mg IV q6h 1.5 mg/kg IV q8h
Traumatic wound[7,8]	*S. aureus,* Gp A strep, clostridia	cefazolin	1-2 grams IV q8h

1. Parenteral prophylactic antimicrobials can be given as a single intravenous dose just before the operation. Cefazolin can also be given intramuscularly. For prolonged operations, additional intraoperative doses should be given q4-8h for the duration of the procedure.
2. Some consultants recommend an additional dose when patients are removed from bypass during open-heart surgery.
3. For hospitals in which methicillin-resistant *S. aureus* and *S. epidermidis* frequently cause wound infection, or for patients allergic to penicillins or cephalosporins. Rapid IV administration may cause hypotension, which could be especially dangerous during induction of anesthesia. Even if the drug is given over 60 minutes, hypotension may occur: treatment with diphenhydramine (*Benadryl*, and others) and further slowing of the infusion rate may be helpful (DG Maki et al, J Thorac Cardiovasc Surg, 104:1423, 1992). For procedures in which enteric gram-negative bacilli are likely pathogens, such as vascular surgery involving a groin incision, cefazolin should be included in the prophylaxis regimen.
4. After appropriate diet and catharsis, one gram of each at 1 PM, 2 PM, and 11 PM the day before an 8 AM operation.
5. Patients with previous pelvic inflammatory disease, previous gonorrhea, or multiple sex partners.
6. Divided into 100 mg one hour before the abortion and 200 mg one half hour after.
7. For "dirty" surgery, therapy should usually be continued for five to 10 days.
8. For bite wounds, in which likely pathogens may also include oral anaerobes, *Eikenella corrodens* (human), and *Pasteurella multocida* (dog and cat), some Medical Letter consultants recommend use of amoxicillin-clavulanic acid *(Augmentin)* or ampicillin-sulbactam *(Unasyn)*.

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INFECTIOUS DISEASES SOCIETY OF AMERICA QUALITY STANDARDS FOR INFECTIOUS DISEASES

Purpose of Quality Standards for Infectious Diseases

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The following quality standards have been developed by the Quality Standards Subcommittee of the Clinical Affairs Committee of the Infectious Diseases Society of America (IDSA). The goal is to make available to infectious disease specialists and other physicians clear, logical, discrete standards that can be applied without controversy in most hospital settings to the review of the care of patients with certain infectious disease problems. Members of the subcommittee represent the IDSA (Peter A. Gross, Chairman, and John E. McGowan, Jr.), the Society for Hospital Epidemiology of America (Richard P. Wenzel), the Surgical Infection Society (E. Patchen Dellinger), the Pediatric Infectious Diseases Society (Peter J. Krause), the Centers for Disease Control and Prevention (William J. Martone), the Obstetrics and Gynecology Infectious Diseases Society (Richard L. Sweet), and the Association of Practitioners of Infection Control (Trisha L. Barrett). The standard is endorsed by the IDSA.

Rather than writing a comprehensive guideline covering all aspects of care for a particular topic, we have emphasized important, incontestable aspects. In most instances, the standard we have chosen is analogous to a single indicator or a few branch point indicators of a practice guideline.

Table 1. Categories reflecting the strength of each recommendation for or against its use.

Category	Definition
A	Good evidence to support a recommendation for use
B	Moderate evidence to support a recommendation for use
C	Poor evidence to support a recommendation for or against use
D	Moderate evidence to support a recommendation against use
E	Good evidence to support a recommendation against use

NOTE. Table is adapted from [1].

Table 2. Categories reflecting the quality of evidence on which recommendations are based.

Grade	Definition
I	Evidence from at least one properly randomized, controlled trial
II	Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies (preferably from more than one center), from multiple time-series studies, or from dramatic results in uncontrolled experiments
III	Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

NOTE. Table is adapted from [1].

Since many practice guidelines are difficult to implement, we have focused on implementation, proposing mechanisms for implementation that are likely to succeed but also leaving room for the variability that will be encountered in local circumstances. We will update these standards periodically.

Our goal was not to offer an exhaustive list of references; instead, we have included only essential and recent publications. We have classified the strength of each recommendation and the quality of the evidence supporting that recommendation according to the scheme shown in tables 1 and 2, respectively [1]. Finally, we have adapted an abstract format from a recent article on abstracts for clinical practice guidelines [2]. Other quality standards are being planned.

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Quality Standard for Antimicrobial Prophylaxis in Surgical Procedures

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Objective. The objectives of this quality standard are (1) to provide an implementation mechanism that will facilitate the reliable administration of prophylactic antimicrobial agents to patients undergoing operative procedures in which such a practice is judged to be beneficial and (2) to provide a guideline that will help local hospital committees formulate policies and set up mechanisms for their implementation. Although standards in the medical literature spell out recommendations for specific procedures, agents, schedules, and doses, other reports document that these standards frequently are not followed in practice.

Options. We have specified the procedures in which the administration of prophylactic antimicrobial agents has been shown to be beneficial, those in which this practice is widely thought to be beneficial but in which compelling evidence is lacking, and those in which this practice is controversial. We have examined the evidence regarding the optimal timing of drug administration, the optimal dose, and the optimal duration of prophylaxis.

Outcomes. The intended outcome is more uniform and reliable administration of prophylactic antibiotics in those circumstances where their value has been demonstrated or their use has been judged by the local practicing medical community to be desirable. The result should be a reduction in rates of postoperative wound infection in conjunction with a limitation on the quantities of antimicrobial agents used in circumstances where they are not likely to help.

Evidence. Many prospective, randomized, controlled trials comparing placebo with antibiotic and comparing one antibiotic with another have been conducted. In addition, some trials have compared the efficacy of different doses or methods of administration. Other papers have reported on the apparent efficacy of administration at different times and on actual practice in specific communities. Only a small group of relevant articles found through 1993 are cited herein. When authoritative reviews are available, these—rather than an exhaustive list of original references—are cited.

Values. We assumed that reducing rates of postoperative infection was valuable but that reducing the total amount of antimicrobial agents employed was also worthwhile. The cost of and morbidity attributable to postoperative wound infections should be weighed against the cost and potential morbidity associated with excessive use of antimicrobial agents.

Benefits, harms, and costs. More reliable administration of antimicrobial agents according to recognized guidelines should prevent some postoperative wound infections while lowering the total quantity of these drugs used. No harms are anticipated. The costs involved are those of the efforts needed on a local basis to design and implement the mechanism that supports uniform and reliable administration of prophylactic antibiotics.

Recommendations. All patients for whom prophylactic antimicrobial agents are recommended should receive them. The agents given should be appropriate in light of published guidelines. A short duration of prophylaxis (usually <24 hours) is recommended.

Validation. More than 50 experts in infectious diseases and 10 experts in surgical infectious diseases and surgical subspecialties reviewed the standard. In addition, the methods for its implementation were reviewed by the American Society of Hospital Pharmacists.

Sponsors. The Quality Standards Subcommittee of the Clinical Affairs Committee of the Infectious Diseases Society of America (IDSA) developed the standard. The subcommittee was composed of representatives of the IDSA (P.A.G. and J.E.M.), the Society for Hospital Epidemiology of America (R.P.W.), the Surgical Infection Society (E.P.D.), the Pediatric Infectious Diseases Society (P.J.K.), the Centers for Disease Control and Prevention (W.J.M.), the Obstetrics and Gynecology Infectious Diseases Society (R.L.S.), and the Association of Practitioners of Infection Control (T.L.B.). Funding was provided by the IDSA and the other cooperating organizations. The standard is endorsed by the IDSA.

Statement of Purpose

Our purpose is to standardize the use of prophylactic antimicrobial agents in association with surgical procedures and thus to reduce the incidence of wound infections and minimize the expenses and adverse reactions attributable to overuse of antibiotics.

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Background Information

Wound infections are among the most common nosocomial infections among hospitalized surgical patients and are the second or third most common nosocomial infections among all hospitalized patients [1–3]. Surgical wound infections result in the administration of more antibiotics, an increase in the cost of care, and a prolongation of hospital stay [4]. Additional antibiotic use increases environmental pressure favoring the emergence of antimicrobial resistance. Extensive medical literature documents that the appropriate perioperative prophylactic use of antimicrobial agents can reduce the incidence of postoperative wound infections [5–11].

Since early reports of this effect, research has focused on the delineation of the specific surgical procedures in which antimicrobial prophylaxis is beneficial, the optimal agents, and the optimal timing and duration of administration of those agents. It is widely agreed that antimicrobial prophylaxis is beneficial in operations entailing entry of the gastrointestinal tract, with the consequent exposure of the surgical wound to endogenous intestinal bacteria. A single exception is elective surgery on the stomach for duodenal ulcer disease; in this situation the highly acidic environment results in a very low endogenous bacterial density, and thus rates of postoperative infection are low. Antimicrobial prophylaxis is recommended for high-risk gastroduodenal surgical procedures. These high-risk procedures include operations for cancer, gastric ulcer, bleeding, obstruction (including pyloric stenosis), and perforation as well as surgery involving patients who have received effective acid-reducing therapy, whether medical (H2 blockers, proton pump inhibitors) or surgical [5–11]. Prophylaxis is also recommended for gastric operations when the patient is morbidly obese [5–11]. The biliary tract is normally sterile, with only a low rate of colonization when elective operations for stone-related disease are undertaken in young patients; accordingly, antimicrobial prophylaxis in biliary surgery has been recommended only for high-risk patients—defined as those who are >60 years old or who have had common duct stones, bile duct obstruction, recent acute cholecystitis, or prior operations on the biliary tract [5–11].

For elective surgical procedures on the colon, rates of infection are high when antimicrobial prophylaxis is not used [11–13], and such prophylaxis is not controversial. For most other types of surgical procedures, parenteral administration is standard when prophylaxis is opted for. However, for colon procedures, oral (luminal) and/or parenteral administration may be used. Studies have demonstrated the efficacy of either route, but the benefit of the two combined has not been firmly established [13]. The most common practice in the United States is oral antibiotic administration along with mechanical bowel cleansing the evening before the operation and parenteral antibiotic administration in the operating room just before incision [13, 14].

Other procedures that do not require entry into the gastrointestinal tract but that are associated with a high rate of infection (e.g., lower-extremity vascular procedures, hysterectomy, and primary cesarean section), with devastating consequences of infection (e.g., joint replacement or other prosthetic hardware placement, cardiac procedures, and aortic vascular grafting), or with both (craniotomy) have been widely accepted as indications for antimicrobial prophylaxis [5–11]. Whether the benefits outweigh the risks has been questioned for "clean," low-risk procedures such as hernia repair, breast operations, and skin surgery [15–24]. It may be that the benefits exceed the risks in these procedures when a risk index or some other information indicates an increased probability of postoperative wound infection [10, 25, 26]. The advantages of prophylaxis are especially evident when the risk of infection is high.

Urologic and gynecologic procedures that involve the intestinal tract are covered by the guidelines listed above for general surgical procedures. Like hysterectomies, gynecologic procedures entailing entry of the vagina probably all merit prophylaxis. Urologic procedures that do not involve entry into the intestine and that do involve patients with sterile urine are clean operations. If the urine is infected, it is preferable to sterilize it before beginning an elective procedure on the genitourinary tract [11]. If that is not possible, then antimicrobial therapy targeting the responsible pathogens should be initiated before the procedure and continued until the urinary tract infection has resolved.

The selection of an antimicrobial agent can be confusing. Literally dozens of agents have been reported to be effective in reducing rates of wound infection following most procedures. Hundreds of articles on trials of antimicrobial prophylaxis in surgical procedures have been published in the past decade. In general terms, the agent chosen should be effective against the pathogens most often recovered from infections occurring after that specific procedure and against the endogenous flora of the region of the body being operated upon. In practical terms, the most common recommendation is the use of cefazolin for operations that do not involve the distal ileum, appendix, or colon [5–11]. Operations on the latter sites require the use of an agent—or combination of agents—with activity against both aerobic and facultative enteric bacteria and against the obligate anaerobes of the colon, including *Bacteroides fragilis* [13]. Cefotetan or cefoxitin is recommended. Newer, "advanced-generation" agents have not been proved to be more effective than cefazolin, cefoxitin, or cefotetan for prophylactic purposes [11]. While *Enterococcus* species are frequently present in the endogenous bowel flora, no reports have described a greater reduction in surgical-site infections for antimicrobial regimens with specific activity against the enterococci than for regimens lacking such activity. Regimens active against enterococci (ampicillin, amoxicillin, or vancomycin combined with gentamicin) are, however, recommended for prophy-

laxis of endocarditis when a patient with certain cardiac lesions undergoes genitourinary or gastrointestinal tract procedures [27].

Studies of animals have demonstrated that antimicrobial drugs are most effective for preventing postoperative infection when they are administered before the operation begins. In nearly all recent clinical trials, the administration of prophylactic agents has been initiated within 120 minutes before incision. Recent reports have confirmed the importance of this timing [20, 21, 28]. Indeed, pharmacokinetic data indicate the desirability of administration as close to the time of incision as is practical—e.g., at anesthesia induction [29, 30]. If a drug with a short half-life is given 120 minutes before incision, its levels may be very low during most of the procedure. Postoperative initiation of antimicrobial "prophylaxis" is still relatively common in practice [28, 31–33] but is not recommended, nor is the administration of the first dose after incision desirable. (Cesarean section is a specific exception, as discussed below.)

The necessary duration of antimicrobial prophylaxis is not clear. In the earliest clinical trials, the duration was 12 hours. Reports of trials employing longer durations have continued to appear periodically, and considerably longer durations are common in clinical practice [28, 31–33], although their benefit has not been proved. While a single report suggests greater efficacy of a longer course of prophylaxis in certain high-risk patients undergoing peripheral vascular procedures [34], most of the published data support a short duration [11, 21, 35].

The Standard

Throughout this standard, the strength of each recommendation and the quality of the evidence supporting it are given in bold type: these ratings are defined in tables 1 and 2, respectively, of "Purpose of Quality Standards for Infectious Diseases" on page 421 of this issue [36] and are adapted from McGowan et al. [37].

Procedures

Parenteral antimicrobial prophylaxis should be administered for the following surgical procedures: procedures that entail entry into the gastrointestinal tract (**A, I**), whether esophageal, gastric,* small intestinal, biliary,† colonic,‡ or appendiceal§; head and neck procedures that entail entry into the oropharynx (**A, I**); abdominal and lower-extremity vascular procedures (**A, I**); craniotomy (**A, I**); orthopedic procedures with hardware insertion (**A, I**); cardiac procedures with median sternotomy (**A, I**); hysterectomy (**A, I**); primary cesarean section or other cesarean sections involving prolonged rupture of membranes‖ (**A, I**); and procedures that include the implantation of permanent prosthetic materials# (**B; III**).

Parenteral antimicrobial prophylaxis is optional for the following procedures: breast and hernia procedures** (**B, I**); other "clean" procedures in which the clinical setting indicates an increased risk of infection** (**B, III**); ordinarily clean procedures in which contamination takes place# (**C, III**); and low-risk gastric and biliary procedures** (**B, III**).

"Minimally invasive" procedures (**C, III**). No available data indicate how these recommendations should be applied to so-called minimally invasive procedures, such as laparoscopic cholecystectomy and laparoscopically assisted bowel resection. Pending further data, it seems safest to apply the standards that would be used for the same procedure done through a traditional incision.

Open urologic procedures (**B, III**). Open urologic procedures that involve the bowel are covered by the guidelines that have been developed largely for general surgical procedures. The literature for transurethral procedures is large and controversial. It seems prudent to eradicate bacteriuria before undertaking any urinary-tract procedure when clinical circumstances permit. Beyond that, local guidelines for implementation of the standard should reflect local practice.

* "High-risk" patients, defined as patients undergoing gastric procedures for cancer, gastric ulcer, bleeding, or obstruction; morbidly obese patients; or patients with iatrogenic or natural suppression of gastric acid secretion.

† "High-risk" patients, defined as those >60 years old, those with recent symptoms of acute inflammation, common duct stones, or jaundice; or those who have previously undergone biliary surgery.

‡ Oral prophylaxis with neomycin plus erythromycin or another proven regimen, administered for 18 hours preoperatively, is sufficient for scheduled colon operations in which the bowel can be effectively cleansed. When cleansing is impossible because of obstruction or another emergency condition or when the surgeon wants to provide extra prophylactic protection to a high-risk patient, parenteral antimicrobial agents may also be administered. An agent effective against Enterobacteriaceae and organisms of the *B. fragilis* group should be used.

§ If the appendix is freely perforated or associated with an abscess, then antimicrobial administration is considered therapeutic and not prophylactic and should be continued until an appropriate clinical response is elicited. An agent effective against Enterobacteriaceae and organisms of the *B. fragilis* group should be included in the regimens used for both prophylaxis and therapy.

‖ For cesarean section, standard practice is to administer the prophylactic antimicrobial agent immediately after the cord is clamped [7, 11, 38].

This standard is widely recommended and practiced, although specific data for the wide range of prosthetic devices in common use are not available. The list includes various CNS shunts, vascular-access devices, prosthetic mesh for hernia repair, and many other types of devices in addition to specific devices, such as orthopedic hardware and cardiac valves, that are covered in other standards.

** Many authorities believe that these procedures do not require antimicrobial prophylaxis. Certain clinical factors increase the risk of postoperative infection and may increase the motivation to administer prophylactic agents [12]. These factors include an American Society of Anesthesiologists preoperative assessment of 3, 4, or 5 [28]; the diagnosis of three or more major preoperative conditions [27]; and the expectation that an operation will last longer than 2 hours [27] or longer than the 75th percentile for that procedure [28]. (See specific references for details.) An undesirable local rate of wound infection may also increase the benefits conferred by antimicrobial prophylaxis.

Procedures involving newborns (**C, III**). It is common practice among pediatric surgeons to administer broad-spectrum antimicrobial prophylaxis for most operative procedures involving infants <30 days old. No specific data address the necessity for or effectiveness of this practice.

Choice of Antimicrobial Agents

Many antimicrobial agents have been demonstrated to be effective for perioperative prophylaxis. The drug chosen should be active against the pathogens most commonly associated with wound infections following the specific procedure and against the pathogens endogenous to the region of the body being operated upon. For procedures involving the distal ileum, colon, or appendix, the drugs used should always be active against both the Enterobacteriaceae and the common enteric anaerobic species, especially the *B. fragilis* group [5–11, 13]. Although infections following gynecologic operations (especially hysterectomy) often involve anaerobic bacteria, combinations including drugs specific for anaerobes have not been shown to be superior to cefazolin alone [5, 11, 38–41]. An acceptable option is to use cefotetan or cefoxitin for operations involving the distal ileum, appendix, or colon and to use cefazolin for all other procedures (**A, I**).

Vancomycin can be given instead of cefazolin to patients who are allergic to cephalosporins or in settings where infections with methicillin-resistant *Staphylococcus aureus* (MRSA) are prevalent. Since vancomycin provides no activity against faculative gram-negative bacilli, which may be involved in settings such as upper gastrointestinal surgery, lower-extremity vascular surgery, or hysterectomy, another agent with gram-negative activity should be added to the regimen under these circumstances. If vancomycin is being given because of concern over MRSA, cefazolin can be administered in addition. If allergy to cephalosporins is the concern, aztreonam or an aminoglycoside can be administered with vancomycin. An aminoglycoside can be combined with either clindamycin or metronidazole, or aztreonam can be combined with clindamycin to substitute for cefoxitin or cefotetan for the treatment of allergic patients undergoing a colonic procedure. Aztreonam should not be used in a two-drug combination with metronidazole because this combination lacks activity against gram-positive cocci and may permit a higher rate of infection caused by *S. aureus* [42]. If this combination is used, an agent with activity against gram-positive cocci must also be included. Unfortunately, data on the efficacy of these alternative regimens are not available (**C, III**).

Dose

Few reports have focused on the appropriate dose for antimicrobial prophylaxis [43]. The prophylactic dose should never be smaller than the standard therapeutic dose of a drug. In light of the short duration of administration recommended for prophylaxis and the safety profile of most prophylactic antimicrobial agents, it is reasonable to use a dose on the high side of the usual therapeutic range (e.g., 1–2 g of cefazolin, cefoxitin, or cefotetan for adults and 30–40 mg/kg for children) (**C, III**).

Timing

The goals in prophylaxis are to achieve inhibitory antimicrobial levels at incision and to maintain adequate levels for the duration of the procedure. Agents used for parenteral perioperative prophylaxis should be administered intravenously during the interval beginning 60 minutes before incision [30]. Administration up to the time of incision—or as close as possible to that time—is preferred (**A, I**) [29].

For cesarean section, antimicrobial prophylaxis should be delayed until the umbilical cord is clamped and then should be initiated immediately (**A, I**) [5, 9, 38].

Duration

The optimal duration of perioperative antimicrobial prophylaxis is not known. Many reports document effective prophylaxis with a single dose of drug (**B, II**). It is likely that no further benefit is conferred by the administration of additional doses after the patient has left the operating room. Thus, pending further data, postoperative administration is not recommended (**C, III**). Antimicrobial prophylaxis should certainly be discontinued within 24 hours of the operative procedure (**B, III**).

The optimal duration of prophylaxis for cardiac operations is still being debated, and many investigators believe that longer durations are needed (**C, III**) [44]. However, the continuation of prophylaxis until all catheters and drains have been removed is not appropriate.

Repeated Doses During the Surgical Procedure

The need to administer additional doses of a prophylactic antimicrobial agent during an operative procedure of long duration has not been clearly defined. A number of references, however, document a reduced rate of effectiveness of antimicrobial prophylaxis in lengthy procedures [45–47] and when levels of drug in serum or tissue are low during a procedure [48, 49]. Current information indicates that additional intraoperative doses of an antimicrobial agent should be given at intervals of one or two times the half-life of the drug[††] so that adequate levels are maintained throughout the operation (**C, III**).

[††] Representative half-lives (with normal renal function) of the antimicrobial agents usually recommended for prophylaxis are as follows: cefazolin, 1.8 hours; vancomycin, 3–9 hours; cefoxitin, 40–60 minutes; cefotetan, 3–4.6 hours; aztreonam, 1.6–2.1 hours; aminoglycosides, 2 hours; clindamycin, 2.4–3 hours; and metronidazole, 8 hours.

Implementation

The standard should be implemented by incorporating the administration of perioperative prophylactic antimicrobial drugs into the routine procedures executed in the operating room by either the anesthesiologist or the circulating nurse. For example, a standard check-off box on the medical record forms could be routinely completed by either of these individuals or by the nurse in the preoperative holding area. The dose, route, and exact time of administration of a parenteral agent—or the surgeon's specific instruction not to give such an agent—would be noted. For cases in which no parenteral antimicrobial agent was administered, the form would be checked to indicate that oral antimicrobial drugs had previously been given for a scheduled colon procedure, that the surgeon had determined that prophylaxis was not indicated, or that the patient was receiving therapeutic antibiotics at the time of the procedure.

It might be helpful to develop preprinted standing orders for antimicrobial prophylaxis from each surgical division for all operations in its specialty in which prophylaxis is deemed appropriate. The forms should be developed by a joint committee of surgeons, anesthesiologists, and nurses, with participation of the hospital's operating room, pharmacy and therapeutics, and infection control committees, and should include recommendations about the usual drug choices (including a reminder about the need for anaerobic coverage in cases involving the colon). Provision should be made for administering antimicrobial agents other than those usually chosen, and the reason for such a choice should be delineated. Standard antimicrobial choices can be listed with their usual doses and half-lives, and the form can include the recommendation that an additional dose be administered if the duration of the operation exceeds approximately twice the half-life of the drug being used. The form should record the time of antimicrobial administration and the time of incision. The operating room should stock the usual prophylactic drugs listed on the standard form, and the standard drug in the standard dose should be provided to the anesthesiologist along with the anesthetic agents. The presence of a satellite pharmacy in the operating-room area may be helpful in this respect.

Alternative programs that accomplish the same goals may be developed and instituted on the local level. In fact, levels of compliance and implementation will probably be highest with locally developed procedures. A sample form should be developed as a model by the Quality Standards Subcommittee of the IDSA and should be modified by local institutions as needed. The quality assurance committee of the individual hospital should conduct periodic surveys to determine that initial doses are being administered before incision and that additional doses are being given during the operation if necessary.

The guidelines should encourage the administration of prophylactic antibiotics for a total of ≤24 hours; to this end, a standard prophylaxis order could specify automatic discontinuation of prophylaxis at the time determined by the individual hospital committee developing the local guidelines. The quality assurance committee of the hospital should be encouraged to conduct periodic surveys of the records of surgical patients to determine whether prophylaxis has indeed been discontinued within 24 hours. If the incidence of prophylactic drug administration after 24 hours is high, a program should be developed to reduce long-term antibiotic use.

Compliance with the principles of prophylactic antibiotic administration should be reviewed at least annually by the hospital's infection control or quality assurance committee or by another designated body within the hospital. Data on prophylactic antibiotic use should be summarized by type of procedure, surgeon (coded anonymously), and service. Summary data should be reported periodically to the appropriate committees and persons, including the operating room, quality assurance, and pharmacy and therapeutics committees and the chiefs of surgical services. The surgical chiefs should have access to data regarding individual surgeons. If the results are not satisfactory, the chief should take corrective action. The implementation and continued monitoring of this standard would be an ideal quality-assurance project. If the infection control committee is monitoring postoperative wound infections, their occurrence can be studied in relation to the appropriate use of prophylactic antimicrobial agents.

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Appendix 5 Antibiotic Order Form and Reference

Improved Antibiotic Usage Following Introduction of a Novel Prescription System

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• We investigated the impact of a novel antibiotic prescription system on antibiotic use. After a two-month baseline monitoring period, an antibiotic prescription form was introduced on surgical and medical wards, which obliged physicians to categorize antibiotic use as prophylactic, empirical (culture results unavailable), or therapeutic. Depending on the category, administration of antibiotics was automatically discontinued after two days (prophylactic), three days (empirical), or seven days (therapeutic) unless the physician renewed the order or specified an alternate duration of administration. In the subsequent two-month intervention period, 233 (60%) of 390 surgical patients received prophylactic antibiotics compared with 281 (68%) of 413 in the baseline period. Mean duration of prophylaxis was reduced from 4.9±2.4 days to 2.9±1.6 days. In the intervention period, 11% of patients received their first prophylactic dose postoperatively, compared with a 30% baseline rate. The percentage of urology patients receiving appropriate therapy for urinary tract infection increased from 38% to 89%. No significant changes in antibiotic use were noted on the medical service. This antibiotic prescription system may have a substantial impact on antibiotic use.

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THE USE of antibiotics in American hospitals has increased dramatically during the past two decades.[1,2] This trend has been noted in pediatric as well as adult populations; recent studies indicate that approximately 35% of infants and children admitted to hospitals receive antibiotics.[4,5] The indications for antibiotic administration are not always clear,[6] and the duration of antibiotic therapy is often longer than generally recommended.[7] These studies prompted us to evaluate antibiotic usage in our hospital and to consider possible methods for identifying and limiting excessive or inappropriate antibiotic administration.

A variety of strategies for controlling the unwarranted use of antibiotics has been suggested, including physician education,[8,9] control of antibiotic release by the infectious disease service,[2,10] removal of drugs from the formulary,[11] peer audit of prescribing practices,[11] and monitoring of antibiotic use by a clinical pharmacist.[11] Unfortunately, these approaches either are impractical for many hospitals, are not efficacious, or have not been subjected to adequate study.

We elected to evaluate another approach based in part on the limited experience of other investigators who noted reduced antibiotic use when physicians were compelled to explain their use of antibiotics and to reorder antibiotics frequently.[14] We introduced an antibiotic prescription form that required the physician to indicate the rationale for antibiotic administration. The pharmacy automatically discontinued antibiotics after a predetermined number of days depending on the indication for therapy designated on the prescription form. This report summarizes the favorable impact of this prescription system on antibiotic usage in our hospital.

METHODS

Baseline Study

For two months in the winter of 1978 to 1979, we collected baseline information on antibiotic usage in medical and surgical patients at our hospital. Four surgical wards with 70 beds for general surgery, urology, plastic surgery, and otolaryngology patients were surveyed. Surveillance was also performed on a cardiac surgery unit of ten beds and on the largest and most representative pediatric floor, a general infant and toddler ward with 31 beds. Orthopedic and neurosurgery wards were not monitored, since a preliminary survey had disclosed that in contrast to other divisions, almost all patients undergoing surgery on these services received a standard course of antibiotic prophylaxis for 48 hours or less.

A data sheet was completed by one of the investigators for each patient admitted to the study wards. Recorded information was obtained solely by review of medical records, medication sheets, and laboratory reports and included the patient's name, age, diagnosis, operative procedures, antibiotic therapy, culture and

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antibiotic susceptibility results, serum antibiotic levels, WBC counts, and liver function test and renal function test results. Antibiotic data included the drugs that were administered, dosage, time of first dose, dosage interval, and duration of therapy. While performing their surveillance, the investigators did not discuss antibiotic use with physicians or nurses.

Intervention Period

One month after completion of baseline surveillance, an antibiotic prescription form was introduced in the same six wards (Fig 1). Meetings were held with all house staff physicians (who write all orders at our hospital), nurses, and pharmacists who would be using the form to explain the mechanics of the study. For the next two months (intervention period), only antibiotic orders that were written on this prescription form were honored by the pharmacy and nursing staff. When writing antibiotic orders, physicians were required to categorize their use of antibiotics as prophylactic, empirical, or therapeutic and to write their prescription in the corresponding section of the form. These prescription categories were defined as follows: Prophylaxis referred both to perioperative antibiotic therapy given to prevent the development of infections related to surgery as well as to chronic antibiotic prophylactic or suppressive therapy (principally for recurrent or chronic urinary tract or middle ear infections). Empirical therapy was given for patients with suspected or known infection for which bacteriologic confirmation was unavailable at the time antibiotic therapy was initiated. Therapeutic antibiotics were selected when the site and microorganism of an infection were known. Each time antibiotic therapy was changed, a new order was written in the appropriate section of the form.

Depending on the category of antibiotic therapy chosen, physicians were asked, but not required, to record basic clinical information, such as the planned surgical procedure, the suspected site of infection, and the culture results. These data were requested to encourage physicians to review the information on which they would be making their therapeutic decisions.

When the antibiotic prescription form was received in the pharmacy, an automatic antibiotic discontinuation date was assigned, depending on the category of use selected by the physician. Surgical prophylaxis was discontinued at two days, a duration consistent with or exceeding the recommendation of most authorities.[1,2,3] Empirical antibiotic therapy was automatically discontinued after three days, a time at which culture and antibiotic susceptibility results are usually available.

ANTIBIOTIC PRESCRIPTION FORM

INSTRUCTIONS
- Select appropriate category - I, II, or III
- Any interval up to 7 days may be elected in any category
- No order will automatically lapse on Sunday or Holiday

PATIENT'S WEIGHT _____

I. PROPHYLACTIC ANTIBIOTICS (For Surgery or Chronic Infection)

OPERATION OR CONDITION _____

DATE	ANTIBIOTIC	ORDERED BY	TRANSCRIBED BY	ORDER STARTED DATE TIME NAME

NOTE: ORDERS FOR PROPHYLACTIC ANTIBIOTICS FOR SURGERY WILL LAPSE AFTER 7 DAYS UNLESS REORDERED

II. EMPIRIC ANTIBIOTICS (For suspected infection or known infection caused by unknown pathogen)

CULTURES ORDERED: ☐ NONE ☐ BLOOD ☐ URINE ☐ CSF ☐ WOUND ☐ SPUTUM ☐ OTHER _____

SITE OF INFECTION: _____ ☐ GRAM STAIN

DATE	ANTIBIOTIC	ORDERED BY	TRANSCRIBED BY	ORDER STARTED DATE TIME NAME

NOTE ORDERS FOR EMPIRIC ANTIBIOTICS WILL LAPSE AFTER 3 DAYS UNLESS REORDERED

III. THERAPEUTIC ANTIBIOTICS (For known infection - known pathogen)

SITE: _____ PATHOGEN(S): _____

RELEVANT SENSITIVITIES _____

DATE	ANTIBIOTIC	ORDERED BY	TRANSCRIBED BY	ORDER STARTED DATE TIME NAME

NOTE ORDERS FOR THERAPEUTIC ANTIBIOTICS WILL LAPSE AFTER 7 DAYS UNLESS REORDERED

ROUTING COPY 1 - MEDICAL RECORD SUCCESSIVE COPIES - PHARMACY

TEMPORARY FORM (EXPIRES 09/01/81) - APPROVED BY MEDICAL RECORDS COMMITTEE AND STAFF EXECUTIVE COMMITTEE 01/79 (6M 02/79)

Fig 1.—Antibiotic prescription form.

Administration of therapeutic and long-term prophylactic antibiotics was discontinued after seven days, as are all medications at our hospital.

Several safeguards were built into this antibiotic prescribing system to ensure that antibiotic therapy was not inadvertently or prematurely discontinued. Most important, physicians always had the option of overriding automatic discontinuation by writing orders for the precise duration of antibiotic administration they desired. Furthermore, a prominent "antibiotic expiration" sticker was placed in the progress notes of the patient's chart by a pharmacist 24 hours before automatic discontinuation, thus giving the physician ample time to renew or rewrite the order. Last, a physician-investigator made daily rounds to be certain that no patient who clearly needed antibiotics had therapy inadvertently terminated.

During the two-month intervention period, data were compiled for all patients admitted to the study wards. The data collected and the methods used were the same as in the baseline survey.

RESULTS

Comparability of Baseline and Intervention Periods

The baseline and intervention periods were similar with respect to the number of patients admitted to the surgical wards. During the baseline period, 413 patients underwent elective surgery (general surgery, 142; otolaryngology, 71; plastic surgery, 76; cardiac surgery, 53; urology, 71),

Antibiotic Prophylaxis for Elective Surgery						
	No. (%) of Patients Receiving Antibiotics for Surgery		No. (%) of Patients Receiving First Dose Postoperatively		Duration of Antibiotic Therapy, Days (±SD)	
Service	Baseline	Intervention	Baseline	Intervention	Baseline	Intervention
General surgery	75(53)	55(41)	42(56)	7(13)	4.6±2.6	3.2±2.1
Otolaryngology	34(48)	32(46)	29(85)	17(53)	ND*	ND
Plastic surgery	51(67)	35(49)	14(27)	2(6)	5.5±2.3	3.0±1.5
Cardiac surgery	53(100)	49(100)	1(2)	0(0)	4.8±2.2	2.3±0.8
Urology	68(96)	62(93)	0(0)	0(0)	ND	ND
Total	281(68)	233(60)	85(30)	26(11)	4.9±2.4	2.9±1.6

*ND indicates not determined.

compared with 390 in the study period (general surgery, 133; otolaryngology, 70; plastic surgery, 71; cardiac surgery, 49; urology, 67). The distribution of types of procedures performed was similar in both periods (data available on request from the authors). The number of patients admitted to the medical ward was slightly greater during the winter baseline period (152) compared with the spring intervention period (134), and seasonal variation was noted for some diagnoses, such as asthma and bronchiolitis. There was a 15% turnover of surgical house staff during the study, while there was a 50% turnover in medical house staff. There were no changes in surgical attending staff during the study, whereas there was a complete turnover of the medical attending staff. There were no formal lectures concerning the proper use of antibiotics.

Impact on Surgical Use of Antibiotics

The antibiotic prescription system had a clear impact on the use of prophylactic antibiotics on surgical services. There was a significant decrease in the number of patients receiving perioperative antibiotics; 68% received antibiotics during the baseline period compared with 60% during the intervention period (χ^2=5.99, P<.05) (Table).

The percentage of patients receiving their first dose of prophylactic antibiotics postoperatively decreased from 30% in the baseline period to 11% in the intervention period (χ^2=27.4, P<.001) (Table).

The mean duration of antibiotic prophylaxis was significantly reduced on the plastic, cardiac, and general surgical services (Wilcoxon rank sum test, P<.001 for each) (Table). The overall mean duration of therapy on these services was reduced from 4.9±2.4 days in the baseline period to 2.9±1.6 days in the intervention period (P<.001) (Fig 2). Moreover, there was a significant reduction in the number of patients receiving prophylaxis for more than two days (χ^2=7.7, P<.01 for general surgery; χ^2=16.4, P<.001 for plastic surgery; and χ^2=42.0, P<.001 for cardiac surgery; χ^2=58.3, P<.001 for all three services combined). Overall, the percentage of patients receiving surgical prophylaxis for more than two days was reduced from 85% to 44%. Data concerning the duration of prophylactic therapy for urology and otolaryngology patients were not obtained, since these patients almost always were still receiving antibiotics at discharge.

When physicians were required to use the antibiotic prescription form, they tended to specify the precise duration of prophylaxis at the time postoperative antibiotic orders were first written rather than postponing the decision until the automatic 48-hour discontinuation time; the duration of prophylaxis was designated at the time postoperative orders were written for 144 of 233 patients (62%) in the intervention period vs 48 of 281 patients (17%) in the baseline period (χ^2=108.9, P<.001).

The introduction of the antibiotic prescription system had an impact on the therapy of urinary tract infections in urology service patients undergoing elective surgery. These children all had urine cultures performed routinely on admission. During the baseline period, the cultures from 13 patients had significant growth of a pathogen, but in only five cases did the physician respond to the report by prescribing an antibiotic to which the microorganism was susceptible. In contrast, during the intervention period, nine patients had cultures showing significant growth and in only one instance did the physician fail to prescribe an appropriate antibiotic (P=.02, Fisher's exact test, two-tailed test).

The antibiotic prescription system did not have an impact on a number of other parameters of antibiotic usage. The specific antimicrobial agents prescribed and the number of antibiotics administered to a given patient, either concurrently or sequentially, were similar in the baseline and intervention periods. During both periods, 90% of patients received an appropriate antibiotic dosage, as judged by recent publications.[17-19] There was no change in the thoroughness with which patients receiving therapeutic antibiotics were monitored for toxic conditions.

Impact on Medical Use of Antibiotics

The institution of the antibiotic prescription form and the automatic discontinuation policy had little effect on antibiotic administration on the medical ward. Sixty-six percent of patients received antibiotics in both baseline and intervention periods. The number of patients receiving multiple antibiotics, the specific antimicrobial agents prescribed, the dosage and duration of therapy, and monitoring for drug-associated toxic conditions were similar before and after the intervention. All but three courses of antibiotics were administered for suspected or documented infections. Three patients during the baseline period and two patients in the intervention period received antibiotics without a rational indication; in all other patients, the selection, dose and duration of therapy, and the frequency of toxic condition monitoring were judged to be acceptable.

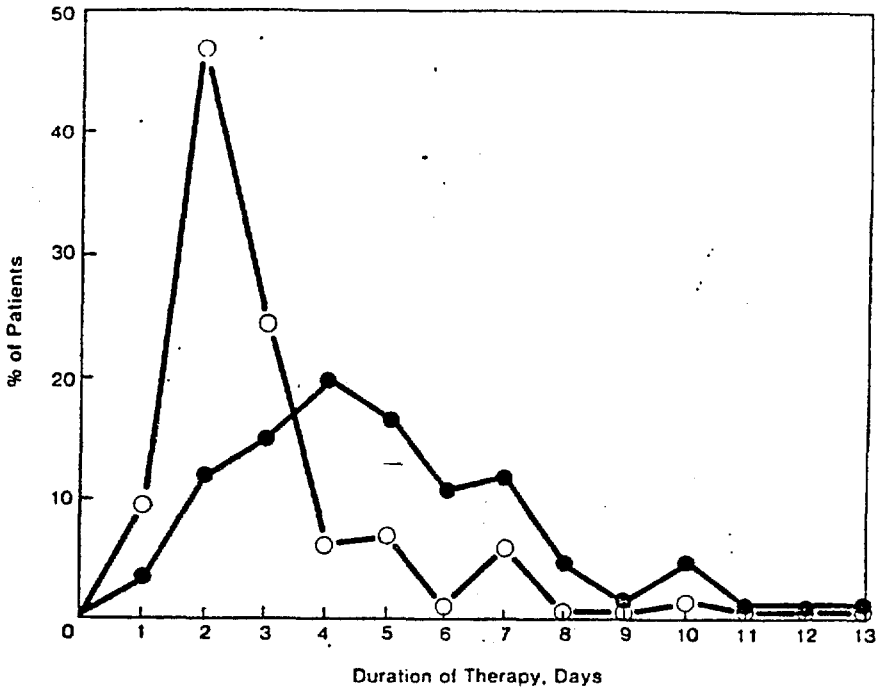

Fig 2.—Impact of prescription system on duration of antibiotic prophylaxis for elective surgery. Solid dots indicate baseline period; open dots, intervention period.

Compliance and Acceptance

Compliance with mandatory aspects of the antibiotic prescription system was complete. In addition, 80% of prescriptions included clinical background information (planned surgical procedure, suspected site of infection, etc), which was requested but not required. The system was well received by pharmacy, nursing, medical, and surgical personnel. It took a pharmacist about 30 minutes per day to maintain an automatic discontinuation date logbook and to place the antibiotic expiration stickers on patient charts. The paperwork involved in dispensing antibiotics was simplified because the length of therapy could be recorded as soon as the prescription form was received.

The physician monitor noted no inadvertent discontinuation of antibiotics during the intervention period.

COMMENT

Antibiotic misuse results in part from physician ignorance of basic principles of sound antibiotic therapy.[20] However, although we do not disagree that the average physician's knowledge of proper antibiotic use should be improved, the development of our antibiotic prescription system was based on an alternative hypothesis. We believe that some misuse of antibiotics occurs not out of ignorance, but rather because the busy physician may not take the time to critically examine the treatment plan or may inadvertently neglect to terminate antibiotic therapy after a reasonable period of administration. This hypothesis is supported by a recent study of antibiotic use in randomly selected Pennsylvania hospitals in which it was found that the duration of antibiotic administration was frequently determined by the patient's length of stay rather than by a physician's conscious decision.[7] Our antibiotic prescription form was designed to encourage the physician to review basic clinical and laboratory information and to categorize the rationale for antibiotic administration. The automatic antibiotic discontinuation policy encouraged, but did not force, the physician to limit the duration of antibiotic administration and to review the antibiotic orders periodically.

The most dramatic impact of the antibiotic prescription system was on antibiotic prophylaxis for elective surgery. The duration of antibiotic administration was significantly reduced from a mean of 4.9 to 2.9 days, which is within the generally recommended maximum of 72 hours,[17] and the percentage of patients receiving prophylaxis for more than two days was reduced by nearly half. We also noted a reduction in the number of patients receiving prophylactic antibiotics. Although the reduction was statistically significant, the absolute magnitude of the decrease was a modest 8%. Moreover, physicians continued to administer antibiotics for procedures (eg, hypospadias repairs, tympanoplasties, and uncomplicated laparotomies) for which authorities such as the Veterans Administration Interdisciplinary Advisory Committee on Antimicrobial Drug Usage would not consider prophylaxis to be indicated.[17] It should be noted, however, that the use of prophylactic antibiotics in many surgical procedures has not been adequately evaluated and that very few prospective trials of antibiotic prophylaxis have been performed in pediatric surgical patients. We are therefore more concerned that the surgeon who decides to administer prophylaxis chooses an appropriate antibiotic in a proper dosage, initiates treatment before the operation, and discontinues therapy shortly after surgery.

Two unanticipated changes in antibiotic administration practices on the surgical service were noted after the antibiotic prescription system was introduced. The percentage of surgical patients who (inappropriately) received their first dose of prophylactic antibiotics following surgery decreased significantly, from 31% to 11%. Also, during the intervention period, physicians on the urology service were more likely to prescribe appropriate antibiotic therapy for patients with urinary tract infection. Since the antibiotic prescription form did not contain information concerning the timing of prophylactic antibiotics or the therapy of urinary tract infections, we conclude that the antibiotic prescription program raised physicians' consciousness and encouraged them to more consistently apply sound principles of antibiotic usage that were already known to them.

It is not surprising that the antibiotic prescription system did not have an impact on antimicrobial use on the medical service. There were small numbers of patients in each diagnostic category, and, given the great variety of potential antibiotic regi-

mens, it would have been difficult to document changes in prescribing practices without performing a much longer study. More important, medical patients received empirical or therapeutic, rather than prophylactic, antibiotic regimens. On our medical service, antibiotic therapy for suspected or proved infection is usually ordered after exhaustive discussion, and antibiotic orders are frequently revised. Such carefully crafted decisions are not likely to be altered by an antibiotic prescription form or automatic antibiotic discontinuation policy. However, it is possible that an antibiotic prescription system would have an impact in hospitals in which there is no pediatric or medical house staff or where physicians do not have the luxury of thoroughly discussing decisions during rounds with a group of their peers.

We conclude that an antibiotic prescription system such as the one we have described may have a substantial impact on prescribing practices, particularly in the area of surgical prophylaxis. The system compares favorably with other strategies for the control of inappropriate antibiotic usage in terms of its ease of installation and maintenance, ready acceptance by physicians, and limited demands on specialized personnel. Although our study was subject to all the potential pitfalls of a longitudinal comparative trial, we were unable to identify any factors other than intervention with the prescription system that might have influenced antibiotic usage. Additional studies are indicated to verify our findings and to assess the long-term impact of this antibiotic prescription system.

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Appendix 6 NNIS SSI reference

Nosocomial Infections in Surgical Patients: Developing Valid Measures of Intrinsic Patient Risk

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For surgeons or hospitals to compare their rates of wound infection meaningfully, the analysis must first control for the mix of intrinsic infection risk of their patients. Research over the past century has led to the development of several intrinsic risk indexes that can be used to stratify the wound infection rates so that valid comparisons can be made within risk strata. For an intrinsic risk index to be useful for comparing rates, it must control for all of the important intrinsic risk constructs; merely being statistically associated with infection rates does not ensure that a risk index will be useful. Understanding how a risk index can be both parsimonious and comprehensive requires consideration of the competing principles of multicollinearity and orthogonality. Various techniques of multivariate analysis are used to develop multivariate risk indexes, but the success of the process depends on having all of the important orthogonal risk constructs represented in the pool of predictor variables available for the analysis, either directly by variables in the pool or by demonstrated multicollinearity. Despite recent advances in risk measurement, many important questions remain.

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One of the great advances of the latter years of the 20th century is the idea of using statistical feedback to change maladaptive behavior in the high-technology workplace. In the health care field, feedback has been best explored in reporting wound infection rates to surgeons to assist them in their efforts to reduce the risk of wound infections.

It has long been appreciated that for surgeon-specific analysis to be insightful to the surgeons (some say "to be fair"), the analysis must control for the intrinsic risk of the patients, usually by stratifying the rate tables by a risk index or classification. This allows surgeons to compare their own wound infection rates with those of other surgeons in comparable patients, that is, the "apples-to-apples condition" is met.

This review will summarize the history of risk indexes for wound infection, the principles of how they work and why we need them, suggestions for how they should be developed, and, finally, a list of open questions that must be answered in the upcoming decade.

HISTORY OF WOUND INDEXES

The idea of controlling for intrinsic risk in wound infection reporting is far from new. In 1895, Brewer fed back wound infection rates in clean surgery to his surgeon colleagues and observed a 95% reduction in rates [1]. Experience with wound classification in the 1920s and 1930s [2] led ultimately to the development of a five category classification of probable wound contamination in the National Research Council's study of ultraviolet light in the operating room [3]. That system, later endorsed by the American College of Surgeons, became the familiar "NRC classification," the "wound contamination classes" or, simply, "wound class" [4].

In the 1970s Cruse and Foord [5] again demonstrated the usefulness of reporting surgeon-specific wound infection rates for reducing rates in clean wounds and popularized the practice among surgeons. About the same time, Lidwell [6] and Davidson *et al* [7] performed the first multivariate analyses of risk factors for surgical wound infection but did not focus the findings into a risk index.

A decade later, Ehrenkranz [8] and Simchen *et al* [9] extended these multivariate analyses to include other risk factors, and Nichols *et al* [10] performed the first multivariate analyses in trauma surgery. To control for the mix of patient risk factors in the Study on the Efficacy of Nosocomial Infection Control (SENIC project), Hooton et al [11] used the chi-square automatic interaction detection (CHAID) technique to develop a series of complex, site-specific, multivariate risk indexes capturing the interactions of many risk factors [11], but they were considered too complex for use in hospitals. At the completion of SENIC, Haley *et al* [12] developed a simplified multivariate risk index for wound infection that could be assigned easily by operating room personnel. Subsequently, Christou *et al* [13] derived an index that included skin testing and blood studies to represent patients' nutritional status and host defense mechanisms more directly.

In the late 1980s, research into methods for comparing hospital mortality rates and reimbursement formulas has led to interest in so-called severity of illness measures as well as a renewed interest in the older systems for subjective prediction of mortality risk, most notably the McCabe-Jackson system and the American Society of Anesthesiology (ASA) physical status classification [14].

WHY MEASURE INTRINSIC RISK?

Intrinsic patient risk is the patient's underlying probability of infection conferred by his or her presenting illness or illnesses and by the tests and treatments that these normally entail. This is the component of risk that is already present or determined before the patient arrives at the hospital. It does not include the component of risk conferred later by the *quality* of care the patient receives from the physicians and nurses.

We want to measure this intrinsic risk to control for the patient's underlying probability of infection so that the *residual variation* in rates will reflect differences in the quality of care given. For this to work validly, however, the measure of underlying risk must truly measure *all* (or almost all) of that underlying risk. Otherwise, surgeons or hospitals high in some unmeasured risk factor will be singled out unfairly as outliers—spurious outliers. This has undesirable consequences regardless of the context, for example, in a punitive system (strongly to be discouraged), those who care for the most difficult cases tend to be unfairly penalized, whereas in a nonpunitive system spurious feedback may prompt unproductive, or even destructive, changes in practice or behavior.

HOW TO MEASURE INTRINSIC RISK

How can we ensure that our measure of underlying risk is good enough to prevent unfairly singling out an individual who simply cares for more high-risk patients? Two competing principles apply.

First is the *principle of multicollinearity* [15]. Fortunately, many risk factors are intercorrelated and overlap in their representation of the true underlying risk constructs. This is due to the fact that patients with one particular risk factor often have certain others as well. This allows one risk variable to represent many others in an index. The principle is best demonstrated in multivariate analyses predicting wound infection; even though a large number of risk factors may be associated with infection in the first step, after the first three or four variables enter the model, the rest are usually no longer significantly associated.

Second is the *principle of orthogonality* [15]. Unfortunately, some risk factors are largely orthogonal to each other. One might think of this as their being perpendicular conceptually. Two variables may be measuring two unrelated, uncorrelated risk constructs. In a multivariate analysis, even after one of these variables has entered the model, the other will remain significantly associated. In this case, both of these largely uncorrelated (orthogonal) variables *must* be represented in the final index, or the index will be highly misleading in practice, that is, physicians or hospitals treating more patients high in the missing orthogonal factor will be spurious outliers.

How does one know which risk factors are collinear and which are orthogonal? This is the reason for doing multivariate analysis. The multivariate statistical methods most commonly used for studying the associations and interactions of several risk factor variables with a binary indicator of the presence or absence of infection are multiway cross-tabulation, stepwise logistic regression analysis, and CHAID [11,15–17]. No amount of multivariate analysis will suffice, however, if the pool of predictor variables available to the modeling program does not contain predictors that represent all of the important orthogonal risk constructs. A satisfactory risk index, therefore, must be developed through multivariate analysis of a pool of variables representing all of the important underlying risk constructs.

This fundamental tenet has not been widely appreciated. A common assumption is that, if a risk variable or index is strongly associated with the outcome (e.g., nosocomial infection or mortality), it must be adequate for controlling for underlying risk. **Figure 1** provides two provocative examples that will inspire a healthy skepticism

about mere associations. Notice that the duration of urinary catheterization not only predicts the risk of nosocomial urinary tract infection (UTI), but it also predicts the risk of surgical wound infection almost as well. However, for UTI, it has face validity, that is, one can see why it predicts and understand how it is working. Why it predicts wound infection is a mysterious jumble of intercorrelation with a web of surgical risk factors (multicollinearity), but who knows what important orthogonal risk contructs it does *not* control for? Similarly, we are comfortable with the ability of the duration of surgery to predict the underlying risk of wound infection, but its strong association with UTI is mysterious. Would we be willing to use the duration of surgery as a UTI risk index? The healthy skeptic concludes, "Stairsteps do not necessarily a useful index make."

One might ask what difference these two principles make; why not use just any predictive index? The continuing efforts of the Health Care Financing Administration (HCFA) to identify hospitals with excessively high mortality rates provides a graphic illustration of the pitfalls of using incomplete risk measures. Green et al [18] demonstrated that when patients' severity of illness on admission (an orthogonal construct) was incorporated into the HCFA mortality prediction model, virtually all of the hospitals earlier singled out by HCFA as high or low outliers were no longer outside the predicted range. The comprehensiveness of a risk index really does make a difference in the validity and usefulness of its results.

HOW TO DEVELOP A RISK INDEX

The preceding ideas illustrate the thinking that led to the development of our simplified multivariate risk index for wound infection [12]. A review of the steps used in developing that index might prove useful in future efforts to improve on this index or to develop indexes for other outcomes. However, risk index development is an art that demands creativity beyond any simple list of steps.

First, we consciously undertook to develop an index for use in assisting surgeons and hospitals to make meaningful comparisons of wound infection rates. The temptation to adapt indexes developed for other purposes must be resisted, because one may not know what variables were included in the predictor pool, whether there was a reasonable attempt to represent all of the key underlying risk constructs, and whether the final weights on the included variables are appropriate for the new use. This is the reason for extreme caution in the use of the so-called severity of illness measures. Most were developed to predict length of stay, resource

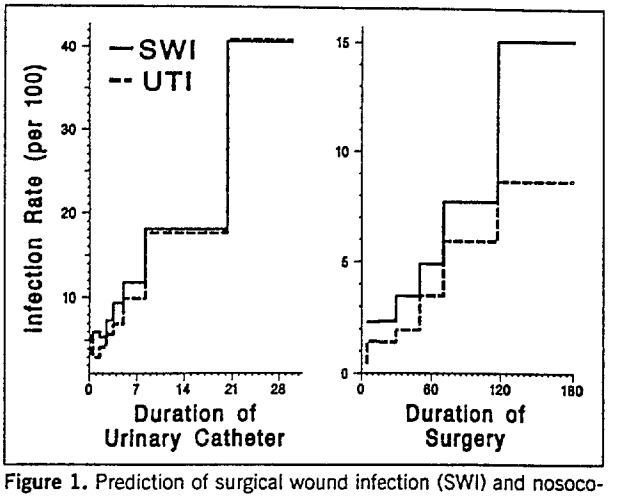

Figure 1. Prediction of surgical wound infection (SWI) and nosocomial urinary tract infection (UTI) rates by the duration of indwelling urinary catheterization (in days) and the duration of the operation (in minutes). Nationwide estimates from the SENIC project, 1975–1976 [33].

utilization, or mortality; some are applicable only to special care areas (e.g., APACHE); for some, there was little published scientific validation before they were released for use (e.g., MEDISGRPS); and for some, the formulas for combining the variables are closely guarded proprietary secrets (e.g., MEDISGRPS and APACHE). These realities raise worrisome questions. For example, what exactly do they measure that is relevant to wound infection? More importantly, what orthogonal risk constructs are left out? Are the combining weights, derived for predicting financial outcomes or mortality, appropriate for predicting wound infection? Again, "stairsteps do not necessarily a useful index make."

Second, we collected and analyzed risk factors for all the known constructs, or dimensions, of wound infection risk [11,12]. Some variables were excluded from the pool on the basis of demonstrated multicollinearity in the first risk analysis, [11] and the rest were included in the final pool for developing the simplified index [12]. Simply put, we were satisfied that we had the right variables in the regression pool. The more recent work of Christou *et al* [13], however, suggests additional, possibly orthogonal factors, such as nutritional status, that may not have been adequately represented.

Third, we formulated the variables in such a way that they could be feasibly obtained at the end of the operation, so that the index would be practical to use. Since then, however, there has been some discussion about the practicality of obtaining the number of underlying diagnoses from the medical record at the end of the operation, and this may have to be replaced by another measure of the

TABLE I

Prediction Equation for a Simplified Index Predicting the Logit of the Probability of a Surgical Wound Infection Among 58,498 Randomly Selected Patients Hospitalized in 1970

Indicator Variable	Order of Entry	Exact Coefficient	Rounded Coefficient	p
Constant		−4.48		
Abdominal operation	1	1.12	1	<0.0001
Operation lasting > 2 hours	2	1.04	1	<0.0001
Contaminated or dirty-infected operation by the traditional wound-classification system	3	1.04	1	<0.0001
Having ≥ 3 diagnoses	4	0.86	1	<0.0001

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complexity of the patient's underlying condition. Some have suggested that it can be replaced with the ASA Physical Status score [19], but whether the two are measuring the same underlying risk construct remains unstudied, and the reliability of the ASA score has been questioned [20]. Similarly, Christou *et al* [13] noted the difficulty of obtaining routine skin testing with which to measure nutritional status for their index. These debates emphasize the necessity of deriving practical variables for use in the indexes.

Fourth, we performed stepwise logistic regression analyses to reduce the set of variables to the fewest orthogonal factors that would represent all of the strong underlying risk constructs. We found that virtually all of the predictive power of the 10 variables in the pool of predictors was contained in the four variables in the final model, illustrating the principle of multicollinearity, but that the four included variables were all independently important, illustrating the principle of orthogonality (**Table I**).

Fifth, we translated the risk weights into a simple additive scale that could be applied practically in the operating room. In this particular index, the regression weights on the four variables were all close to 1.0, allowing a simple additive scaling for the final index (Table I). Had their weights differed more, a more cumbersome weighting scheme might have been necessary for the final index.

Sixth, after developing the index on 58,000 patients in one data base, we tested its predictive ability on another data set of the same size. This is important to avoid overfitting the index to the particular set of data in which the index was developed. Overfitting occurs when a statistical model is developed on a relatively small data set and the computer program is allowed to overreact to sampling variation in the data. The risk of overfitting is minimized either by using large data sets (i.e., tens of thousands of operations) for initial development or by testing the model on a second set of data, and preferably by both. The completeness and quality of the data (e.g., standard definitions, postdischarge follow-up) are important as well.

Finally, we quantified the index's predictive power with appropriate statistics, in this case, the Goodman-Kruskal nonparametric correlation coefficient, and compared its relative power with that of the traditional wound class system, using the nonparametric matched partial correlation procedure, MATPAR (**Table II**) [21–23]. There are advantages to the widespread adoption of a standard index and continuing its use over many years: personnel become familiar with how to classify patients and use the index; longitudinal trends are not interrupted; and interhospital comparisons will be more feasible if most hospitals are using the same index or indexes. These advantages place a burden on index developers to use valid methods to demonstrate the superiority of new indexes over the older, established ones before urging a change.

OPEN QUESTIONS

Great progress has been made in the technology of risk indexes, yet many open questions remain. The following are some of immediate interest.

First, are changes needed in the simplified multivariate index before it can be used widely? We need to study whether the main diagnosis and the number of comorbidities can be obtained with reasonable accuracy at the end of the operation? The original binary variable in the index distinguished between one or two versus three or more discharge diagnoses (excluding diagnoses of nosocomial infection); discounting the patient's primary diagnosis, as suggested by Munoz *et al* [24], this variable is distinguishing between relatively uncomplicated patients (none or one comorbid condition in addition to the main diagnosis) and more complicated patients (two or more comorbid conditions). Assuming that the risk of wound infection is overwhelmingly determined by the condition of the patient and the wound at the time of the operation, it seems unlikely that additional conditions appearing later in hospitalization would add much to the predictive power of the index for wound infection. This suggests that the number of discharge diagnoses might be replaced by a count of the number of diagnoses recorded in the "impressions" section of the surgeon's admitting note or in the operative summary, which are available at the end of the operation. The variability in recording both admis-

TABLE II

Surgical Wound Infection Rates Among 59,352 Randomly Selected Patients Hospitalized in 1975–1976, Categorized by the Traditional Wound-Classification System and by Our Simplified Multivariate Risk Index

Traditional Wound-Classification System*	Simplified Risk Index†					
	Low Risk	Medium Risk	High Risk			
	0	1	2	3	4	All
Clean	1.1 (56)‡ (68§	3.9 (33) (55)	8.4 (10) (33)	15.8 (1) (14)		2.9 (100) (55)
Clean-contaminated	0.6 (41) (32)	2.8 (34) (37)	8.4 (18) (41)	17.7 (7) (51)		3.9 (100) (36)
Contaminated		4.5 (25) (2)	8.3 (51) (6)	11.0 (20) (8)	23.9 (4) (11)	8.5 (100) (2)
Dirty-infected		6.7 (26) (6)	10.9 (46) (20)	18.8 (19) (27)	27.4 (9) (89)	12.6 (100) (7)
All	1.0 (46) (100)	3.6 (32) (100)	8.9 (16) (100)	17.2 (5) (100)	27.0 (1) (100)	4.1 (100) (100)

*The Goodman-Kruskal nonparametric correlation statistic G (± SE), measuring the association between a patient's traditional wound class and whether he or she developed a surgical wound infection, is 0.364 (±0.016), and the partial G controlling for the simplified risk index is −0.028 (± 0.023).
†G measuring the association between a patient's simplified risk index value and wound infection is 0.666 (± 0.010), and the partial G controlling for the traditional wound class is 0.638 (± 0.012).
‡Row percentage.
§Column percentage.
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sion and discharge diagnoses calls for additional research to clarify their role in risk estimation.

Alternatively, one might consider replacing the number of diagnoses with a measure of "severity of illness" (e.g., APACHE, Computerized Severity Index, MEDISGRPS) or a predictor of the risk of postanesthesia death (e.g., ASA Physical Status score). Whereas it is quite probable that these measures will be associated with postoperative wound infection ("stairsteps"), it is unclear whether they are at least partially collinear substitutes for the number of diagnoses or perhaps orthogonal measures of some other underlying risk constructs. These questions call for the generation of large surgical data bases containing all of these variables along with accurate ascertainment of wound infections, so that the joint analysis of all of them can answer these questions empirically.

Second, what is the role of severity of illness measures apart from their potential use in a multivariate risk index? All of these measures appear to be measuring a single underlying risk construct—severity of illness—however ill-defined the concept is at present. Although this construct is undoubtedly correlated to some unknown degree with the other orthogonal risk factors for wound infection, it is unlikely that the multicollinearity is very complete. Thus, pending strong evidence to the contrary, severity of illness measures should not be used alone to control for underlying infection risk when assisting surgeons or hospitals in comparing their wound infection rates. Their usefulness as components in multivariate risk indexes along with other orthogonal risk factors, although more likely to prove fruitful, awaits empirical validation. The usually high cost of generating these measures and the proprietary secrecy of their formulations, however, are likely to inhibit their validation and ultimate acceptance [13]. Measures of nursing workload, such as the *GRASP*, Medicus, and *PRN* systems, routinely collected in many hospitals for nursing management, may prove more useful for this purpose [25].

Third, can we use the multivariate risk index developed for wound infection to adjust for intrinsic risk in analyses of postoperative *pneumonia*? The principle of multicollinearity would entice one to do it, but the principle of orthogonality would caution that some important construct (e.g., chronic lung disease) might not be sufficiently represented.

Fourth, should risk indexes be individualized to specific types of surgery? Recent studies from the Centers for Disease Control's (CDC) National Nosocomial Infections Surveillance (NNIS) System suggest that indexes tailored to specific classes of operations might be useful [26], and studies from at least two trauma centers suggest that separate risk indexes might be needed for trauma operations [10,27]. Further experience is needed to determine if the benefits from the specificity of procedure-specific analyses justify sacrificing the greater statistical power afforded by including all procedures in one analysis stratified by a risk index.

Fifth, despite the widespread use of the traditional wound contamination classification, questions remain over how the wound classes should be defined. Despite its long use, the system has never been defined in detail, and the various published definitions differ on important specifications, so that they are undoubtedly classifying some operations differently [3,4,28,29]. An important source of disagreement is whether a break in technique, a quality of care issue, should be allowed to reclassify an operation to a higher wound class. When the wound classification was being used in clinical research to control for all extraneous factors in evaluating a new treatment (e.g., ultraviolet light), this made sense [3,30–32]. When surgeons use it to compare the quality of their technique, however, they should probably not reclassify operations on breaks in technique. Is it possible to classify operations on the *expected* degree of wound contamination based simply on the procedures performed, e.g., a simple recode of the International Classification of Disease, 9th revision, diagnosis and procedure codes? A consensus conference to define the wound contamination classification in detail, perhaps with different versions for research and feeding back rates, would be useful.

Finally, should surgeon-specific rates be limited to clean operations? In support of this practice, it has been argued that "clean wounds should not get infected, and almost all wounds in higher classes do." The epidemiologic evidence, however, does not support this view. In fact, application of the simplified multivariate risk index proved that some groups of patients with clean operations are expected to have infection rates as high as 15%, whereas 70% or more of the patients with contaminated or dirty-infected operations do not get infections [3,12,28–33]. Moreover, there is ample evidence that feedback of wound infection rates and other preventive measures lead to reductions in rates in all wound contamination classes, in high-risk patients and in low-risk patients [29–33]. Consequently, there seems to be no valid rationale for limiting surveillance or reporting to clean wounds. In the future, it is likely that all operations involving an incision through skin and primary or secondary closure will be included in surveillance and reporting and that surgeons will rely on a good multivariate risk index (or indexes) to control for differences in intrinsic risk.

In conclusion, measuring the intrinsic risk of wound infection and expressing it in a simple, practical risk index appears to be an essential technique for making the reporting of wound infection rates useful to surgeons and hospitals. Just as using the wound contamination classes alone as the risk index is no longer tenable, the idea of substituting another simple or arbitrary variable, or set of variables, without rigorous demonstration of validity, is likewise untenable. Risk indexes of the future will have to represent all of the underlying risk constructs considered important, either through explicit variables in the model or by demonstrated multicollinearity. Initial multivariate risk indexes are presently in everyday use, and the race is on to improve upon them. Researchers have an obligation to use established methods for developing and validating new indexes and to compare them with the established ones before they are recommended for widespread use.

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Surgical Wound Infection Rates By Wound Class, Operative Procedure, and Patient Risk Index

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To perform a valid comparison of rates among surgeons, among hospitals, or across time, surgical wound infection (SWI) rates must account for the variation in patients' underlying severity of illness and other important risk factors. From January 1987 through December 1990, 44 National Nosocomial Infections Surveillance System hospitals reported data collected under the detailed option of the surgical patient surveillance component protocol, which includes definitions of eligible patients, operations, and nosocomial infections. Pooled mean SWI rates (number of infections per 100 operations) within each of the categories of the traditional wound classification system were 2.1, 3.3, 6.4, and 7.1, respectively. A risk index was developed to predict a surgical patient's risk of acquiring an SWI. The risk index score, ranging from 0 to 3, is the number of risk factors present among the following: (1) a patient with an American Society of Anesthesiologists preoperative assessment score of 3, 4, or 5, (2) an operation classified as contaminated or dirty-infected, and (3) an operation lasting over T hours, where T depends upon the operative procedure being performed. The SWI rates for patients with scores of 0, 1, 2, and 3 were 1.5, 2.9, 6.8, and 13.0, respectively. The risk index is a significantly better predictor of SWI risk than the traditional wound classification system and performs well across a broad range of operative procedures.

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This decade will see increased attention being given to measuring clinical outcomes as one component of comprehensive quality assurance programs [1]. A significant impediment to developing meaningful nosocomial infection rates that can be used for intrahospital and interhospital comparisons has been the lack of an adequate means of adjusting for case mix. For surgical wound infections (SWI), the traditional wound classification system, which stratifies each wound into one of four categories—clean, clean-contaminated, contaminated, and dirty-infected—has been recognized and recommended since 1964 [2–4]. Limitations of this system of risk stratification are well recognized. One of the major problems is its failure to account for intrinsic patient risk. A composite risk index that captures the joint influence of this and other risk factors is required before meaningful comparisons of SWI rates can be made among surgeons, among institutions, or across time.

As a start, a simple index was developed during the Study on the Efficacy of Nosocomial Infection Control (SENIC) project [5] by analyzing 10 potential risk factors using logistic regression techniques. Since the final model contained four risk factors having nearly equal regression coefficients, the SENIC index consisted of counting the number of risk factors present among the four factors: (1) an operation that involved the abdomen, (2) an operation lasting longer than 2 hours, (3) an operation classified as either contaminated or dirty-infected, and (4) a patient having three or more diagnoses at discharge.

With the last factor serving as a proxy for intrinsic patient risk, the SENIC index proved to be a better predictor of SWI risk than the traditional wound classification system. In this article we report on a modification of the SENIC risk index and the results of applying it to the data collected by ongoing infection surveillance and control programs.

METHODS

The surveillance protocols used by hospitals in the Centers for Disease Control (CDC) National

TABLE I

Distribution of Duration of Surgery by NNIS Operative Procedure Category

Procedure Category	Number of Operations	Percentiles (Minutes) 25th	50th	75th	Cut Point T (hours)
Coronary artery bypass graft	7,553	190	240	293	5
Cardiac surgery	1,042	134	204	285	5
Other cardiovascular system	1,032	38	62	110	2
Thoracic surgery	1,191	67	105	160	3
Other respiratory system	170	25	50	86	1
Appendectomy	1,569	32	49	70	1
Bile duct, liver, or pancreatic surgery	210	105	149	224	4
Cholecystectomy	4,508	50	73	110	2
Colon surgery	2,285	84	125	180	3
Gastric surgery	802	55	95	152	3
Small bowel surgery	533	80	125	199	3
Laparotomy	2,630	45	75	113	2
Other digestive system	638	58	94	150	3
Limb amputation	1,292	31	55	85	1
Spinal fusion	5,657	65	100	150	3
Open reduction of fracture	4,419	50	82	130	2
Joint prosthesis	5,696	82	123	165	3
Other musculoskeletal system	5,552	40	75	123	2
Cesarean section	7,171	35	45	57	1
Abdominal hysterectomy	4,002	70	90	120	2
Vaginal hysterectomy	847	59	83	118	2
Other obstetrical procedures	27	20	35	60	1
Nephrectomy	321	99	137	188	3
Prostatectomy	402	80	156	235	4
Other genitourinary system	4,549	30	55	90	2
Head and neck surgery	935	60	105	225	4
Other ear, nose, mouth, pharynx	1,061	55	100	150	3
Craniotomy	1,247	103	170	257	4
Ventricular shunt	725	46	65	95	2
Other nervous system	521	38	58	95	2
Herniorrhaphy	2,916	40	65	95	2
Mastectomy	1,779	55	95	135	2
Organ transplant	609	190	305	425	7
Skin graft	1,169	40	68	110	2
Splenectomy	172	70	94	144	2
Vascular surgery	4,982	80	132	202	3
Other endocrine system	335	60	95	143	2
Other eye	941	56	80	115	2
Other hemic and lymphatic systems	233	41	71	108	2
Other integumentary system	1,815	26	50	90	2

NNIS = National Nosocomial Infections Surveillance.

Nosocomial Infection Surveillance (NNIS) System have previously been described [6]. Under the detailed option of the surgical patient surveillance component, all patients undergoing operations in one or more preselected operative procedure categories are monitored, at least until discharge, for postoperative infections. Standard definitions for nosocomial infections are used [7]. Approximately 30% of hospitals collecting SWI surveillance data have developed programs for postdischarge surveillance; however, no formal postdischarge surveillance protocol is followed. The data for this report were from 44 NNIS hospitals, each of which followed the detailed option of the surgical patient component for one or more months during the period January 1987 through December 1990. Altogether, these hospitals reported to the CDC information on 84,691 operations and 2,376 subsequent SWIs.

The NNIS surgical patient risk index consists of scoring each operation by counting the number of risk factors present among these three:

1. A patient having an American Society of Anesthesiologists (ASA) preoperative assessment score of 3, 4, or 5
2. An operation classified as either contaminated or dirty-infected
3. An operation with duration of surgery more than T hours, where T depends on the operative procedure being performed.

The ASA score is itself an index, designed to assess preoperatively the overall physical status of the patient, and ranges from 1 for an otherwise normally healthy patient to 5 for a patient not expected to survive the next 24 hours [8–10]. Instead of using a constant 2-hour cut point for duration of surgery, as in the SENIC index, the distribution of duration of surgery for the different operative procedures was determined. The 75th percentile of each distribution was identified, rounded to the nearest whole number of hours, and used as the cut point, T, for distinguishing between operations of short and long duration.

TABLE II

Surgical Wound Infection Rates Among 84,691 Operations by Traditional Wound Classification or ASA Score

Risk Factor	Percent of Operations	SWI Rate*
Wound class (G† = 0.30, SE = 0.02)		
Clean	58	2.1
Clean-contaminated	36	3.3
Contaminated	4	6.4
Dirty-infected	2	7.1
ASA score (G = 0.34, SE = 0.01)		
1	26	1.5
2	37	2.1
3	26	3.7
4	11	5.5
5	0.4	7.1

ASA = American Society of Anesthesiologists.
*Number of surgical wound infections (SWI) per 100 operations.
†Goodman-Kruskal correlation coefficient and its standard error (SE).

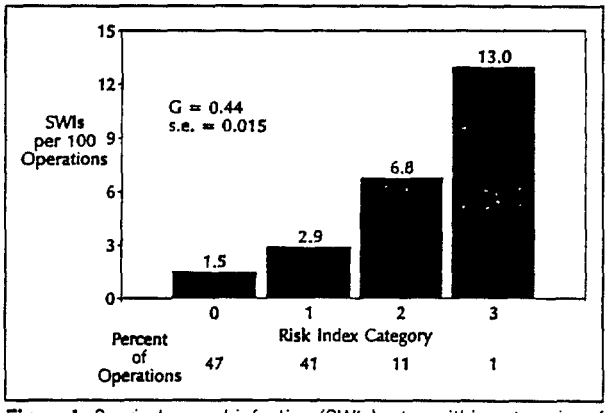

Figure 1. Surgical wound infection (SWIs) rates within categories of the surgical patient risk index. G = Goodman-Kruskal correlation coefficient; s.e. = standard error.

The list of the various NNIS operative procedure categories, the number of operations reported, the quartiles of the distribution of duration of surgery, and the cut point, T, are given in **Table I.** The cut point ranges from 1 hour for appendectomy, limb amputation, and cesarean section, to 5 hours for coronary artery bypass graft and cardiac surgery, to 7 hours for organ transplant.

To summarize the strength of the association between a potential risk factor, or the composite risk index, and a patient's risk of developing an SWI, we calculated the Goodman-Kruskal G statistic [11]. Ranging from −1 to +1, this nonparametric correlation coefficient is most useful for comparing the relative predictive power of different risk factors or comparing a risk factor with the composite index.

RESULTS

Wound class remained a moderately effective predictor of SWI risk (**Table II**). However, as a single predictor of SWI risk, the ASA score was at least as good as the traditional wound classification system. Considerable improvement was obtained in predicting SWI risk when all three risk factors were combined into the composite index (**Figure 1**). SWI rates ranged from 1.5 wound infections per 100 operations for patients with none of the risk factors, to a high of 13.0 for patients with all three of the risk factors present. The presence of each additional risk factor nearly doubled the SWI risk.

Within each category of the traditional wound classification system, SWI rates increased dramatically with the number of risk factors present (**Figure 2**). Of the 49,333 patients with clean operative procedures, 44% had none of the risk factors, 46% had one risk factor, and the remaining 10% had both operations of long duration and an ASA score of 3, 4, or 5. The increase in SWI rates from 1.0 to 5.4 infections per 100 clean operations demonstrated that all clean wounds do not carry the same SWI risk. A similar increase in rates with the number of risk factors present was seen for each of the other three wound classes. Also, patients with the same number of risk factors present had roughly the same risk of wound infection, irrespective of the wound classification. For example, among patients with one risk factor, the SWI rates ranged only from 2.3 to 4.0, that is, a contaminated or dirty-infected operation of normal duration performed on an otherwise healthy patient carried with it only a slightly higher wound infection risk than a clean surgery of long duration or one performed on a patient with an ASA score of 3, 4, or 5.

In all but six of the operative procedure categories from which data were collected, namely, vaginal hysterectomy, ventricular shunt, nephrectomy, limb amputation, "other cardiovascular system procedures," and "other nervous system procedures," we found that SWI rates increased significantly ($p < 0.05$) with the number of risk factors present (**Table III**).

Although developed to predict SWI risk, the index also predicted reasonably well the risks of postoperative infections at other sites (**Figure 3**). Finally, we found that patients in each of risk categories 1, 2, and 3 were more than twice as likely to develop a secondary bloodstream infection following a primary wound infection (risk was 5.2%, 7.8%, and 8.3%, respectively) than were patients with none of the risk factors (risk was 2.3%, $p < 0.003$).

COMMENTS

A number of studies have reported a decline in the incidence of SWI when surveillance programs have been implemented that included the feedback

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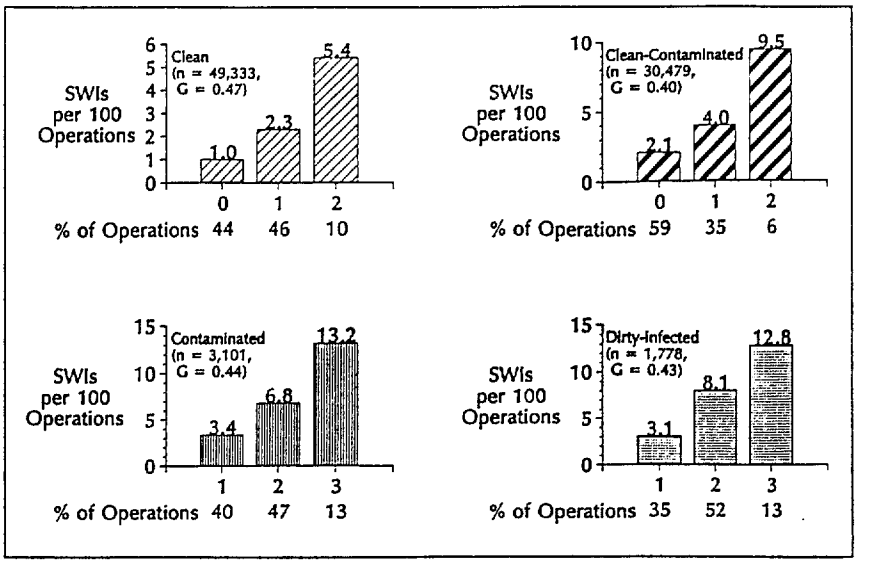

Figure 2. Surgical wound infection (SWIs) rates, by traditional wound classification and risk index. G = Goodman-Kruskal correlation coefficient.

TABLE III

Surgical Wound Infection Rates by Operative Procedure Category and Risk Index

	Number of Risk Factors								
	0		1		2		3		
Procedure Category	No.*	Rate†	No.	Rate	No.	Rate	No.	Rate	G‡
Coronary artery bypass graft	381	1.05	5,595	3.49	1,574	6.67	3	33.33	0.37 (0.05)
Cardiac surgery	61	1.64	773	1.94	204	5.39	4	25.00	0.47 (0.16)
Other cardiovascular system	152	0.66	698	1.00	175	0.57	7	0.00	−0.06 (0.30)§
Thoracic surgery	351	0.57	641	2.18	195	4.62	4	0.00	0.52 (0.13)
Other respiratory system	9	0.00	108	3.70	50	10.00	3	0.00	0.49 (0.23)
Appendectomy	797	2.38	603	2.32	138	9.42	31	9.68	0.33 (0.12)
Bile duct, liver, or pancreatic surgery	67	0.00	109	11.93	31	29.03	3	0.00	0.74 (0.07)
Cholecystectomy	2,506	1.36	1,596	2.01	380	7.11	26	11.54	0.44 (0.08)
Colon surgery	754	3.18	1,039	8.47	447	16.11	45	22.22	0.49 (0.05)
Gastric surgery	287	4.88	386	6.48	120	15.00	9	0.00	0.31 (0.11)
Small bowel surgery	150	4.00	219	6.85	141	11.35	23	13.04	0.33 (0.12)
Laparotomy	1,202	1.50	1,028	4.09	364	14.01	36	13.89	0.62 (0.05)
Other digestive system	243	0.82	311	5.79	82	8.54	2	50.00	0.61 (0.10)
Limb amputation	103	3.88	502	4.58	544	5.51	143	6.99	0.13 (0.10)§
Spinal fusion	3,995	0.70	1,380	1.88	278	3.96	4	50.00	0.53 (0.08)
Open reduction of fracture	1,933	1.03	2,062	1.84	397	3.53	27	3.70	0.34 (0.09)
Joint prosthesis	2,895	1.21	2,461	2.64	337	4.75	3	0.00	0.40 (0.07)
Other musculoskeletal system	2,988	0.40	2,153	0.65	384	2.34	27	0.00	0.41 (0.13)
Cesarean section	5,400	4.22	1,657	5.85	114	11.40	—	—	0.21 (0.06)
Abdominal hysterectomy	2,634	1.37	1,206	4.06	156	5.13	6	0.00	0.48 (0.07)
Vaginal hysterectomy	580	1.03	248	1.21	19	0.00	—	—	0.02 (0.34)§
Other obstetrical procedures	20	0.00	5	20.00	2	0.00	—	—	0.82 (0.12)
Nephrectomy	131	1.53	140	2.86	50	2.00	—	—	0.16 (0.29)§
Prostatectomy	201	1.00	161	3.73	40	5.00	—	—	0.51 (0.20)
Other genitourinary system	3,360	0.65	1,033	0.87	152	9.87	4	50.00	0.59 (0.09)
Head and neck surgery	475	1.26	348	3.45	111	9.01	1	100	0.58 (0.11)
Other ear, nose, mouth, pharynx	703	0.28	313	0.32	42	4.76	3	33.33	0.67 (0.23)
Craniotomy	358	0.56	651	2.46	234	2.56	4	0.00	0.36 (0.14)
Ventricular shunt	234	3.85	410	4.39	77	2.60	4	0.00	−0.04 (0.17)§
Other nervous system	334	0.90	150	1.33	34	2.94	3	0.00	0.29 (0.34)§
Herniorrhaphy	1,789	0.95	1,010	1.88	116	5.17	1	0.00	0.41 (0.12)
Mastectomy	905	0.77	791	2.40	82	1.22	1	0.00	0.43 (0.15)
Organ transplant	3	0.00	115	4.35	342	6.73	149	18.12	0.48 (0.11)
Skin graft	464	1.51	507	4.54	172	6.98	26	23.08	0.52 (0.09)
Splenectomy	52	1.92	87	1.15	31	16.13	2	50.00	0.72 (0.21)
Vascular surgery	967	1.55	2,740	2.08	1,248	6.09	27	14.81	0.46 (0.06)
Other endocrine system	163	0.00	143	0.70	29	3.45	—	—	0.89 (0.10)
Other eye	583	0.00	325	0.00	33	0.00	—	—	—
Other hemic and lymphatic systems	108	0.00	107	2.80	17	5.88	1	0.00	0.82 (0.08)
Other integumentary system	906	1.32	735	1.77	165	6.06	9	11.11	0.39 (0.13)

*Number of operations.
†Number of surgical wound infections per 100 operations.
‡Goodman-Kruskal correlation coefficient (standard error).
§Z = G/se(G) not significant at p = 0.05.

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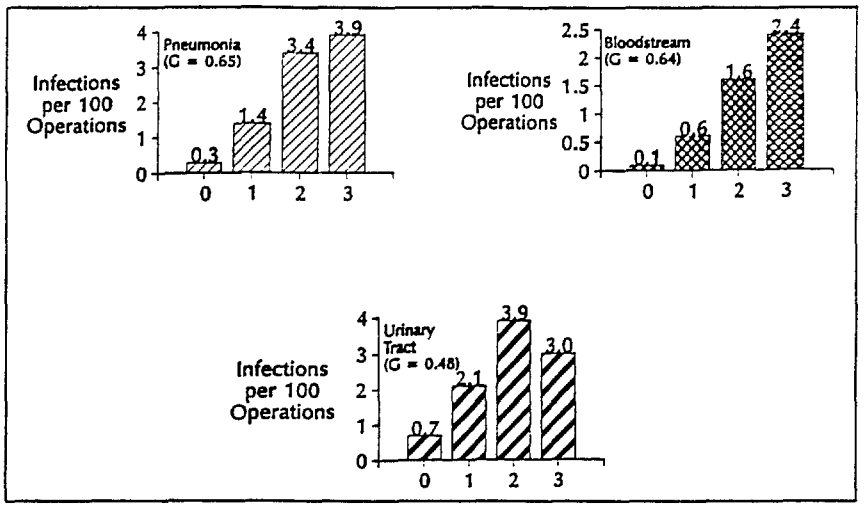

Figure 3. Postoperative pneumonia, bloodstream, and urinary tract infection rates, by surgical patient risk index. G = Goodman-Kruskal correlation coefficient.

of postoperative wound infection rates to practicing surgeons [12–15]. Indeed, the SENIC project showed such feedback to be an essential component of an effective infection control program [16]. Nevertheless, the pace of adoption of this practice has been slow [17]. This may be due in part to hospital and surgeon anxieties regarding potential liability claims. Proper warnings have been sounded regarding an overly simplistic approach to the calculation and comparison of surgeon-specific wound infection rates [18]. For example, emphasis has often been placed on the feedback of clean wound infection rates, on the assumption that these rates should be very low and that a high incidence of such infections can be reduced by assessment and modification of operating techniques. In contrast, infection rates related to intrinsic contamination (clean-contaminated, contaminated, and dirty-infected wounds) are expected to be higher and not as likely to be reduced by modifications in technique. However, a number of studies have called into question some of these assumptions. The results of the SENIC project showed that highly effective infection control programs that included the reporting of SWI rates to surgeons were as effective in reducing SWI risk among high-risk patients (primarily nonclean wounds) as among low-risk patients (primarily clean wounds) [16]. Moreover, a number of studies have previously demonstrated a wide variation in clean wound infection rates when patients undergoing such operations have been stratified by other risk factors or proxies for them [2,5,13,15].

Since it was not developed by a multivariate modeling technique, the NNIS SWI risk index is best viewed as an adaptation of the SENIC risk index. The results of applying this index to NNIS data reaffirm the general conclusions drawn from the SENIC risk index. When applied to a more recently collected set of data—one subject to the normal interhospital variations in case-finding methods, diagnostic accuracy, and risk factor misclassification error—the NNIS index strongly supports the need to incorporate risk factors other than the traditional wound classification into a composite index of SWI risk before attempting to compare infection rates among surgeons, among institutions, or across time. The ASA score is a critical component of the index, included in an attempt to measure intrinsic host susceptibility. Somewhat analogous to the number of discharge diagnoses used in the SENIC index, the ASA score has the advantage of being readily available at the time of surgery.

Although the approximate 75th percentile was arbitrarily chosen to provide the index with additional discriminatory power when applied to specific operative procedures, such as coronary artery bypass grafts, there may be further grounds for its justification. For many procedures, plots of SWI rates as a function of duration of surgery were convex, that is, the rates increased slowly at first and then more sharply when the duration of surgery was very long. Often, the inflection point of these curves was near the 75th percentile, suggesting that perhaps extremely long duration of surgery may serve as a marker for the complexity of the individual case, some aspect of surgical technique, and for certain procedures, the possible diminished effects of antimicrobial prophylaxis. Unfortunately, these data are not collected in NNIS and will require investigation in future studies.

The results in Table III can be used by hospitals in several ways. For each surgeon, procedure-specific SWI rates can be calculated in one or more of the risk categories and compared against the corresponding rates in Table III using a simple Z-test or Fisher's exact test [19]. In many hospitals, the number of procedures performed by an

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individual surgeon in some of the risk categories may be small. In that event, a single surgeon-procedure rate can be obtained by calculating a weighted average of two or more of the specific risk category rates, a process often referred to as direct standardization [20]. Then, applying the same weights to the specific risk category rates in Table III, a single rate for that procedure can be calculated and used as the standard for comparison with the surgeon-procedure rate using a Z-test.

We pooled all of the procedure categories in Table III in order to evaluate the overall performance of the NNIS risk index in Figures 1 and 2. However, a few procedures in Table III had rates that were significantly higher than the rates of other procedures within the same risk category, for example, the SWI rate following cesarean section was 4.22 in risk category 0. It may be tempting to combine the procedures and risk categories that had similar SWI rates into risk strata, for example, by combining all procedure-risk categories with rates less than 2% into a low-risk group. However, more data from more hospitals are required before the validity of such a strategy can be established.

The apparent success of the NNIS index in capturing the risk of developing postoperative pneumonia, bloodstream, or urinary tract infections suggests that the index is a general expression of the propensity to develop infection and probably reflects the general nature of the risk factors that comprise the index. Better risk indices for these infections can be expected by including factors that directly measure utilization of specific devices, that is, mechanical ventilation, central intravascular lines, and urinary catheters, the primary risk factors for these infections. The general applicability of the NNIS index within a broad range of operative procedure categories is encouraging, but there remains room for improvement. Almost certainly, additional important risk factors for specific procedures need to be identified and incorporated into such an index [21], such as antibiotic prophylaxis in those procedures where it has been shown to be effective.

It is important to keep in mind the limitations of any risk index. A statistically significant difference between a risk index adjusted SWI rate for a cohort of patients and an appropriate comparison group merely indicates the presence of a potential problem, one generally worthy of further investigation. In the case of the NNIS index, two of the risk factors in the index, wound class and duration of surgery, may indirectly reflect quality of care. Adjustment for them may mask rather than elucidate a potential problem. For example, a surgeon whose operation time consistently exceeds the 75th percentile for a procedure may have an acceptable SWI rate within each risk category but actually may be unnecessarily increasing the SWI risk of his patients. Therefore, when analyzing the postoperative wound infection experience of individual surgeons, it is important to analyze the distribution of patients among the risk index categories as well as the SWI rates within each category.

As we move forward in developing measures of health care quality, it is critical that risk indices also be developed so that valid comparisons of rates can be performed. The SWI risk index presented here provides a better means of comparing SWI rates among surgeons, among institutions, and across time than by stratifying patients using the traditional surgical wound classification alone.

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Appendix 7 Workshop Materials

Quality Improvement Lecture - - Hungary
December 1994

Donald Goldmann, M.D.

Agenda

- Describe the role of a hospital epidemiologist, past and present
- Discuss the importance of applying epidemiological principles and methods to QI
- Discuss the synergistic impact of infection control/hospital epidemiology and QI on reducing the risk of surgical site infections

Epidemiology

The study of the distribution and determinants of disease frequency in human populations

or

Patterns of disease occurrence in human populations and factors that influence these patterns

Epidemiology - - A Practical Definition

The use of data to describe what's going on, determine why things are the way they are, and determine or predict the impact of the current situation on future events

SHEA

- Society for Hospital Epidemiology of America
- Society for Healthcare Epidemiology of America

Sensitivity

The probability of testing positive if disease is truly present

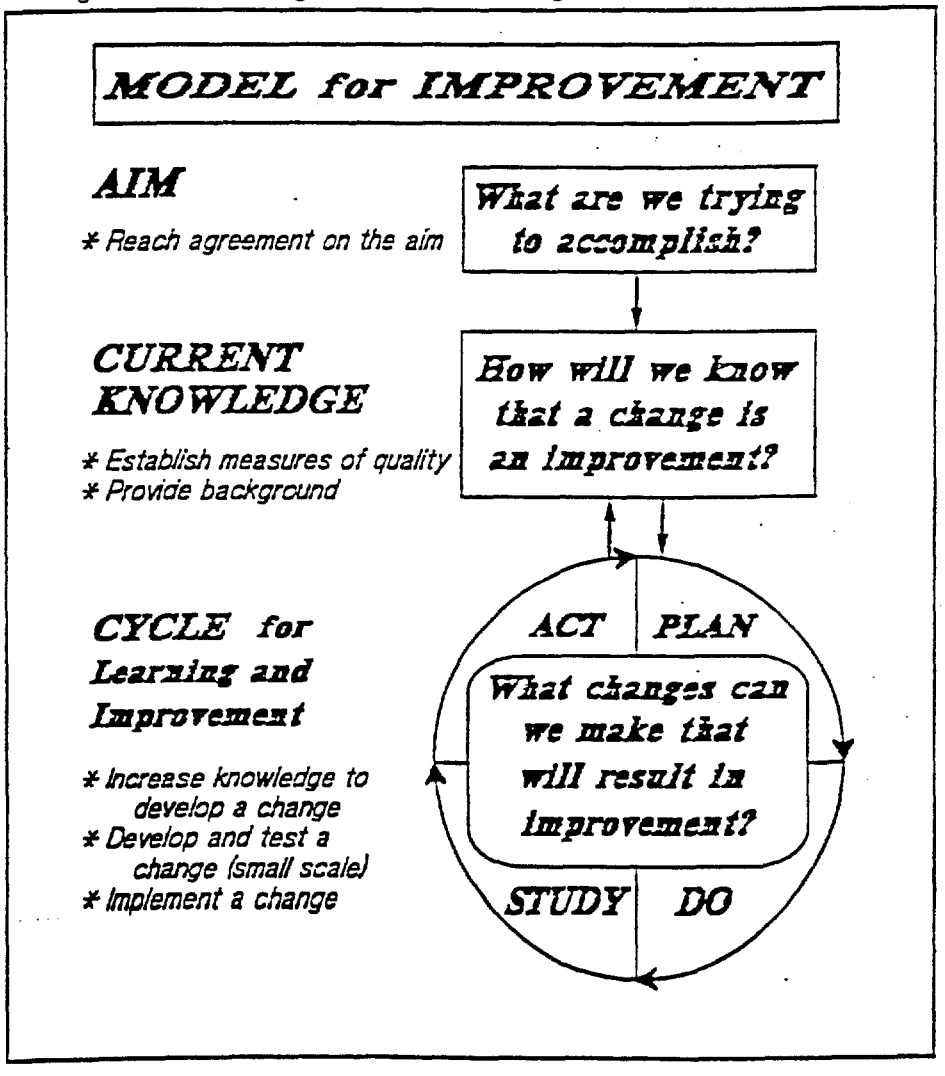
The higher the sensitivity, the less the chance that persons who have a disease will be classified incorrectly as not having the disease (false-negative)

Specificity

The probability of testing negative if the disease is truly absent

The higher the specificity, the less the chance that persons who do not have the disease will be classified incorrectly as having the disease (false-positive)

Figure 1: Answering the Fundamental Questions



Cohort Study

- Two or more groups of people initially free of the outcome (or disease) in question, and that differ according to exposure to a potential cause of disease, are compared for occurrence of the outcome. It is then possible to see how initial characteristics (exposures) relate to subsequent outcomes (disease).

Types of Cohort Studies

Prospective (concurrent):

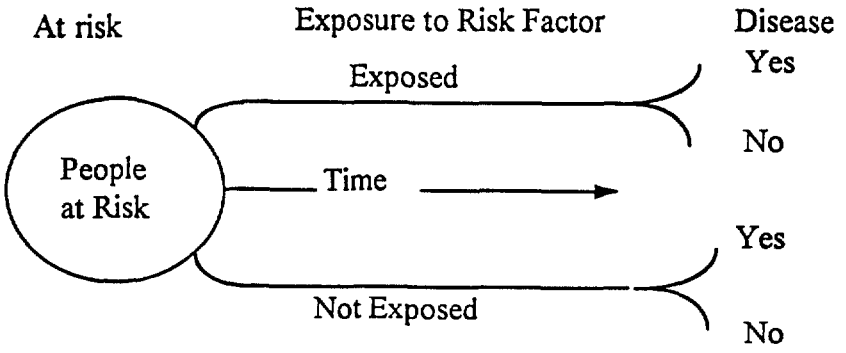
- Exposed and unexposed subjects enrolled (either randomly or by presence and absence of specific exposure(s) before the outcome is apparent)

Retrospective (historical):

- Subjects assembled according to exposure after the outcome has already taken place

Regardless, if one is comparing outcomes, it's a cohort study

Design of a cohort study of risk



Cohort Study- Advantages

1. Intuitive appeal: if persons are exposed, do they get the disease?
2. Required data can be defined ahead of time and collected completely and accurately
3. Absolute rates of exposures and outcomes usually are available, so the incidence (absolute risk) can be measured directly
4. Exposures can be elicited without the bias that might occur if outcomes were already known
5. Can evaluate wide range of outcomes from a single type of exposure, or a wide range of exposures for a single outcome

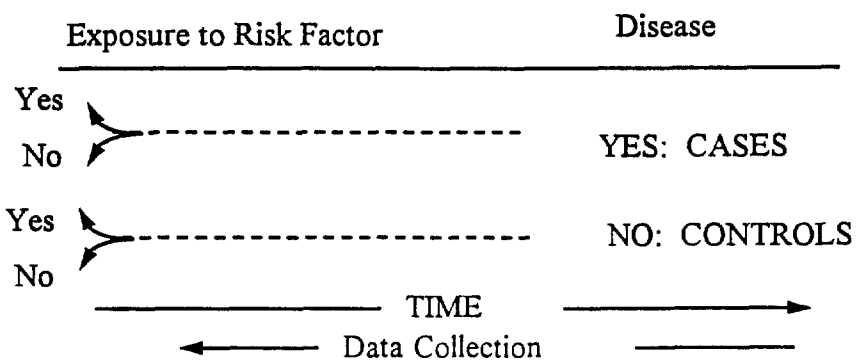
Cohort Study - Disadvantages

1. Can be inefficient and expensive if outcome is rare and many subjects have to be enrolled who do not have outcomes of interest
2. Outcome may be very delayed, so subjects may be lost and results unavailable for a long period
    - Less of a problem in historical studies, but data quality may be poor

Case-Control (Case-Referent) Study

Cases and non-cases are entered into the study and then compared for their exposures

The design of case control studies



Case-Control Study - Advantages

1. Excellent for rare diseases
2. Answer available quickly
   - Method of choice in Outbreak Situations
3. Hypothesis generation
4. Even if large cohort is available, it may be more economical to conduct a small case-control study within the cohort ("nested" case-control study)

Case-Control Study- Disadvantages

1. Only one outcome can be studied
2. Exposure data of interest may not be available or accurate
3. Recall bias
4. Sampling bias
5. Unavailability of enough controls

Selecting Controls to Avoid Sampling Bias

The main objective in selecting controls is to select subjects who represent those who might have become cases in the study. If the cases are selected from one hospital in the city, the controls should represent those people who, had they developed the disease under study, would have gone to the same hospital. Such people may be vastly different from the general population.

Rothman

More on Selecting Controls

- Both cases and controls must be selected independently of the exposure of interest.
- Controls should have navigated the same pathway of selection forces as the cases had they been ill.

Confounding

Any systematic differences between cases and controls that might be related to exposure could distort (confound) the conclusion, making it an inaccurate assessment of the true risk.

after Fletcher

Confounding

Stated another way:

Confounding is the distortion of the estimate of the magnitude of the effect of one exposure, or cause, of the outcome when it is mixed with the effect of other exposures, or causes, of the outcome.

Don't Over-Match!

Estimated average number of extra days, average amount of extra charges per infection, and deaths caused by and contributed to by nosocomial infections - -United States

Type	Extra Days	Extra Charges	Death Directly caused by Infections		Death to which Infections Contri	
			Total	%	Total	%
Surgical Wound Infection	7.3	$3,152	3,251	(0.6)	9,726	(1.9)
Lower Respiratory Tract Infection	5.9	$5,683	7,087	(3.1)	22,983	(10.1)
Bloodstream Infection	7.4	$3,517	4,496	(4.4)	8,844	(8.6)
Urinary Tract Infection	1.0	$680	947	(0.1)	6,503	(0.7)
Other Types	4.8	$1,617	3,246	(0.8)	10,036	(2.5)
All Types	4.0	$2,100	19,027	(0.9)	58,092	(2.7)

Distribution of Post-surgical Infections, NNIS 1986-1992

Site of Infection	%
Surgical site infection	37
• Incisional	24
• Organ/Space	13
Urinary tract infection	27
Pneumonia	15
Bloodstream (primary)	7
All other sites	15

From Horan et al. Infect Control Hosp Epidemiol 14:73, 1993

Superficial Incisional Infection

- Infection occurs within 30 days after the operative procedure, and
- Involves only skin and subcutaneous tissue, and
- Patient has at least one of the following:
  - Purulent discharge
  - Organisms isolated from culture of fluid or tissue
  - At least one of the following: pain or tenderness, localized swelling, redness, or heat, and superficial incision is deliberately opened by surgeon, unless incision is culture-negative
  - Surgeon or attending physician diagnoses infection

Sensitivity of Surveillance Methods

Duplicate surveys, record review, bedside exam, labs (reference std)	UVA, BCH, CDC	1.00
Record review, bedside exam, labs	BCH	0.98
M.D. self-reports	CHIP	0.14-0.34
Micro lab reports	CHIP	0.33-0.65
Micro lab reports	UK	0.71
Kardex clues	UVA	0.69-0.85
Record review	UVA	0.90
Kardex clues	UK	0.49
Ward liaison	UK	0.58
ICDA coded dx	BCH	0.02-0.35
ICDA coded dx	YALE	0.57
SENIC pilot record review	CDC	0.66-0.80

Possible Risk Factors for Surgical Site Infection-1

- Age
- Obesity
- Diabetes
- Malnutrition (decreased albumin)
- Diabetes
- Steroids/immunosuppression
- Malignancy
- Prolonged hospitalization pre-op
- Infection at another site

Possible Risk Factors for Surgical Site Infection-2

Delayed wound closure
Prolonged surgery
Open drains
Closed drains
Urgency of surgery
Foreign body
Skill of surgeon
Intra-operative wound contamination

Measures to Decrease Skin Colonization

- Chlorhexidine washes
- Mupirocin
- Hair removal
- Skin prep
- Drapes

Operating Room Staff

- Surgical scrub
- Gloves
- Gowns
- Caps and beard guards
- Masks
- Shoes and "booties"

Shedding

Wound Classification System

- Clean wound: Uninfected operative wound; no inflammation encountered; respiratory, alimentary, genital infected urinary tracts not entered
- Clean-contaminated wound: respiratory, alimentary, genital, infected urinary tracts entered under controlled conditions without unusual contamination
- Contaminated wound: open, fresh wound with major breaks in aseptic technique or gross spillage from GI tract; or incisions in which acute, non-purulent inflammation encountered
- Dirty (infected) wound: old wound with retained devitalized tissue; existing clinical infection or perforated viscera

NNIS Surgical Wound Infection Risk Index

- ASA Score of 3, 4, or 5
- Wound class (contaminated or dirty)
- Operation lasted longer than the 75th percentile for that procedure in NNIS hospitals

TABLE 3
SURGICAL WOUND INFECTION RATES* AMONG 84,691 OPERATIONS BY TRADITIONAL WOUND CLASSIFICATION AND NNIS RISK INDEX

Wound Class	Risk Category 0	1	2	3	(G†)	All Operations
Clean	1.0	2.3	5.4	—	(0.47)	2.1
Clean-contaminated	2.1	4.0	9.5	—	(0.40)	3.3
Contaminated	—	3.4	6.8	13.2	(0.44)	6.4
Dirty	—	3.1	8.1	12.8	(0.43)	7.1
All operations	1.5	2.9	6.8	13.0		

* No. surgical wound infections per 100 operations.
† Goodman-Kruskal correlation coefficient.

Indicator IC-1

Surgical Wound Infection

Rate of infection for selected inpatient and outpatient surgical procedures detected by surveillance during the 21 days following the procedure

Surgical Wound Infection Indicator Key Features

- Requires post-discharge surveillance
- Uses CDC definitions of infection
- Requires collection of additional data elements that may be useful for further interpretation of the indicator
  - NNIS infection risk index
  - SENIC infection risk index
  - Use and timing of prophylactic antibiotics

Bloodstream Infection Rates and Central Venous Catheter Use for Individual Hospitals

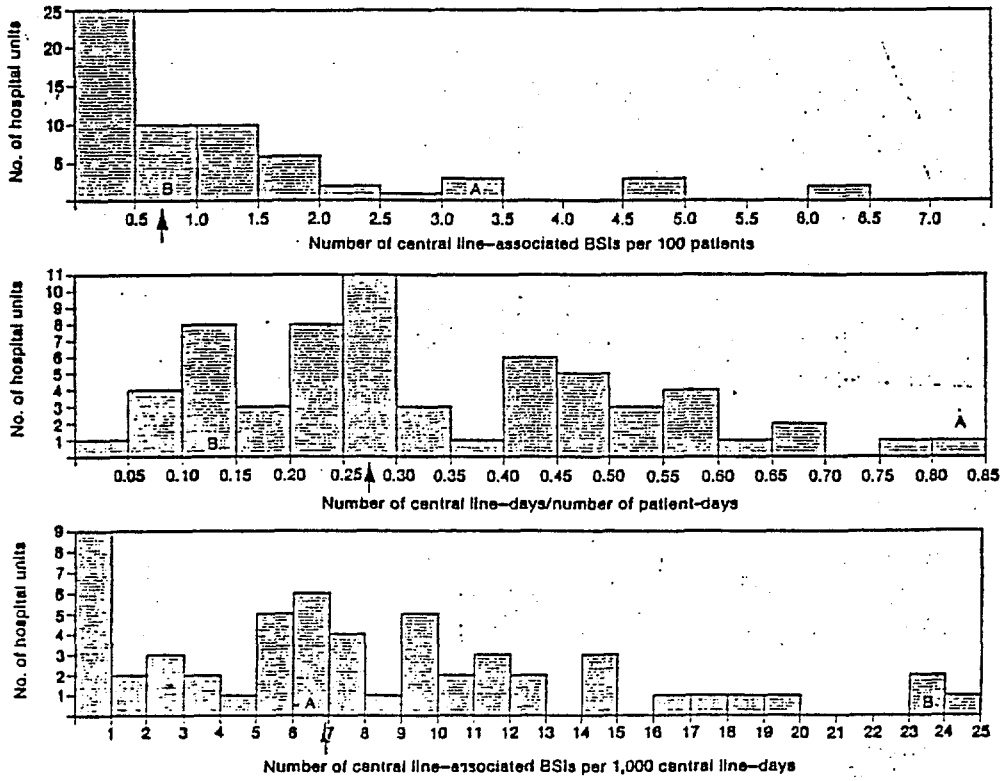


Fig. 5-3. Comparison of the distribution of bloodstream infection (BSI) rates (patient-based and central line–days–based) and central line utilization in combined coronary and medical intensive care units. National Nosocomial Infection Surveillance (NNIS) System, Intensive Care Unit Component, October 1986–December 1990. A and B indicate the specific location of individual hospital unit rates. Arrows indicate median.

ICU Severity of Illness Indices

- APACHE
- PSI
- PRISM
- SNAP
- CRIB

Percentage of Nosocomial Infections Prevented by the Most Effective Program- SENIC

Type of Infection	Components of most effective program	% Prevented
Surgical wound infection (SWI)	An organized hospital-wide program with intensive surveillance and control including reporting SWI rates to surgeons	20
	plus: A trained hospital epidemiologist	35

Percentage of Nosocomial Infections Prevented by the Most Effective Program- SENIC

Type of Infection	Components of most effective program	% Prevented
Lower respiratory tract infection:		
Postoperative	An organized hospital-wide program with intensive surveillance and ICP per 250 beds	27
In medical patients	An organized hospital-wide program with intensive surveillance and control	13
All types	An organized hospital-wide program with intensive surveillance and control with all the components listed above	32

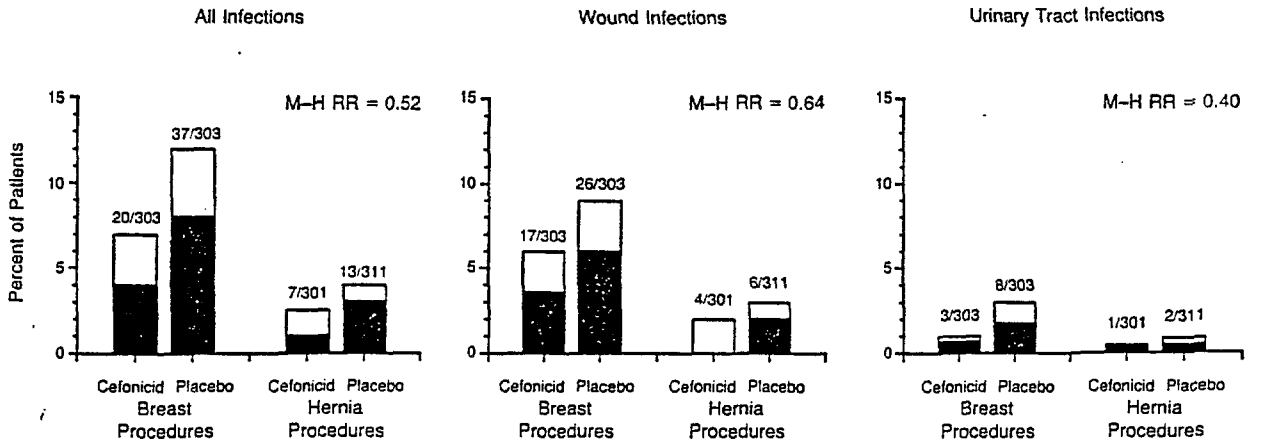


Figure 1. Percentages of Patients in the Cefonicid and Placebo Groups with Infections of Any Type, Wound Infections, and Urinary Tract Infections after Breast or Hernia Procedures.

"All infections" includes wound infections, urinary tract infections, bacteremia, pneumonia, and other types of infections categorized as potentially related to the surgical procedure. One cefonicid recipient undergoing breast surgery had both a wound infection and a urinary tract infection; she is listed as having had a single infection in the count of all infections but is counted separately in both the middle and the right-hand panels. Definite infections are denoted by the solid bars, and probable infections by the open bars. M–H RR denotes the Mantel–Haenszel risk ratio. The numbers at the top of each bar indicate the number of patients with the specified infection and the total number of patients in the respective group.

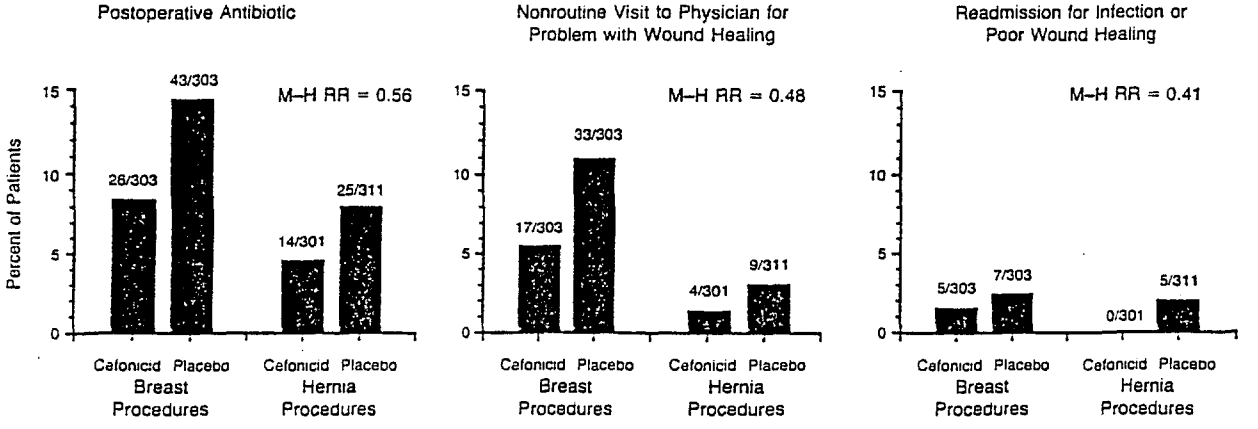


Figure 2. Percentages of Patients in the Cefonicid and Placebo Groups Who Received Postoperative Antibiotic, Had an Unscheduled Visit to a Physician for a Problem with Wound Healing, or Required Readmission for Infection or Poor Wound Healing after Breast or Hernia Procedures.

The numbers at the top of each bar indicate the number of patients in each of the three categories and the total number of patients in the respective group. M–H RR denotes the Mantel–Haenszel risk ratio.

Impact of Cefonocid Prophylaxis

- Routine use for breast surgery would prevent:
  - 56 infections
  - 23 definite wound infections
  - 16 UTIs
    - per 1,000 patients
- Routine use for herniorrhaphy would prevent:
  - 19 infections
  - 13 definite wound infections
    - per 1,000 patients

from: Platt et al. NEJM. 322:153,1990.

Cost of Cefonocid Prophylaxis

Assuming $10 per course:

$ 178 to prevent one breast infection

$ 539 to prevent one herniorrhaphy infection

$ 1,515 to prevent one readmission for breast infection

$ 622 to prevent one readmission for herniorrhaphy

From: Platt et al. NEJM 322:153, 1990.

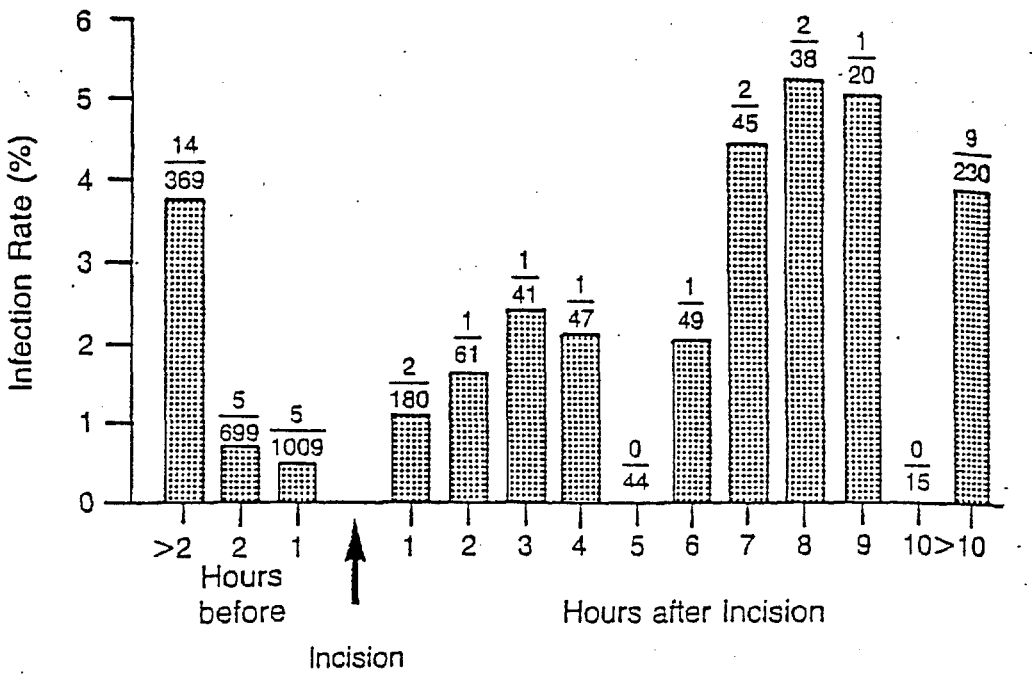


Figure 1. Rates of Surgical-Wound Infection Corresponding to the Temporal Relation between Antibiotic Administration and the Start of Surgery.

The number of infections and the number of patients for each hourly interval appear as the numerator and denominator, respectively, of the fraction for that interval. The trend toward higher rates of infection for each hour that antibiotic administration was delayed after the surgical incision was significant (z score, = 2.00; $P<0.05$ by the Wilcoxon test).

Temporal Relation between the Administration of Prophylactic Antibiotics and Rates of Surgical-Wound Infection

Time of Administration	No. of Patients	No. (%) of Infections	Relative Risk (95% CI)
Early	369	14 (3.8)	6.7 (2.9-14.7)
Preoperative	1708	10 (0.59)	1.0
Perioperative	282	4 (1.4)	2.4 (0.9-7.9)
Postoperative	488	16 (3.3)	5.8 (2.6-12.3)
All	2847	44 (1.5)	------

Classen *et al.*, NEJM 326:281, 1992.

Nosocomial Bloodstream Infection

Primary Bloodstream Infection

- Laboratory-confirmed (positive blood culture)
- Clinical sepsis (negative or no blood culture)
- Bloodstream infection related to a intravascular catheter

Secondary Bloodstream Infection

- Infection at another site (pneumonia) with secondary seeding of the bloodstream

Nosocomial Bloodstream Infection

Frequency and Significance

- Not common: ~5% of all infections
  Frequent use of central venous catheters or high-risk patients will increase incidence
- Attributable mortality: related to etiology, may be significant for gram negative bacteremia, enterococcal bacteremia, and candidemia
- Cost: >US$ 3000/case

Nosocomial Bloodstream Infection

Risk Factors

- Intravascular catheters
  - Percutaneous central venous catheters >
    - catheters inserted by cut-down >
    - arterial catheters >>
    - peripheral venous catheters
  - Implanted or tunneled, cuffed central venous catheters are low risk
- Parenteral nutrition (lipid emulsion)
- Heavy colonization with *Staph. aureus*
- Chemotherapy or immunosuppression

Nosocomial Bloodstream Infection

Clinical Signs

- Fever
- Chills, rigors
- Tachypnea, tachycardia, hypotension
- Apnea/bradycardia in neonates
- Nausea, vomiting, diarrhea
- Organ dysfunction
  (pulmonary, cardiac, renal, hepatic, neurologic)

Nosocomial Bloodstream Infection

Microbiology

- Blood culture
  - # of cultures
  - Bacteremia vs. colonization of the catheter
  - Pathogen vs. contaminant
- Culture of catheter tip
- Catheter hub
- Culture of infusate

Nosocomial Bloodstream Infection

Common Microorganisms

- Coagulase-negative staphylococci
- *Staphylococcus aureus*
- *Enterococcus* sp.
- *Escherichia coli*
- *Pseudomonas aeruginosa*
- *Enterobacter* sp.
- *Klebsiella* sp.
- *Candida* sp. and other fungi

Nosocomial Bloodstream Infection

Procedures & Practices to Reduce Risk

- Minimize use and duration of intravascular catheters, particularly percutaneous central venous catheters
- Wash hands before and after inserting an intravascular catheter
- Cleanse the skin with an effective antiseptic before insertion
- Wear sterile gloves and gowns and use sterile drapes when inserting percutaneous central venous catheters
- Use aseptic technique during catheter insertion

Nosocomial Bloodstream Infection

Procedures & Practices to Reduce Risk

- Procedures to minimize contamination of intravenous fluids and medications
- Minimize manipulation of catheter or infusion set tubing; use aseptic technique when manipulation is necessary
- Adequately disinfect pressure transducers used for CVP or arterial pressure monitoring
- Establish and follow protocols for catheter removal when clinical signs and/or culture information indicate bloodstream infection or catheter exit site infection
- Reduce or eliminate colonization by *Staph. aureus* in high-risk patients

Nosocomial Lower Respiratory Tract Infection

Frequency and Significance

- 10-20% of all nosocomial infections
- Many outbreaks of gram negative pneumonia in mechanically ventilated patients
- High attributable mortality: ~10-20% overall, may be > 50% in ventilated ICU patients
  - Gram negative pneumonia
  - Immmunocompromised patients
- Most expensive: > US$ 5000/case

Nosocomial Lower Respiratory Tract Infection

Risk Factors

- Mechanical ventilation
- Tracheostomy
- Abdominal or thoracic surgery
- Advanced age
- Chronic cardiac or pulmonary disease
- Immunosuppression
- Depressed level of consciousness
- Prior viral respiratory tract infection

Nosocomial Lower Respiratory Tract Infection

Clinical Signs

- Fever
- Cough
- Tachypnea
- Chest pain
- Increase in O2 or ventilatory requirement
- Change in character of sputum
- Rales, dullness to percussion, wheezing

Nosocomial Lower Respiratory Tract Infection

Radiography

- Chest X-ray
  - Infiltrate or consolidation
  - Cavitation
  - Pleural effusion
- CT scan (complicated cases or suspected fungal pneumonia in immunocompromised patient)

Nosocomial Lower Respiratory Tract Infection

Microbiology

- Sputum or tracheal aspirate
  - Gram stain
    - Quality of specimen
    - Semi-quantification of inflammatory cells (granulocytes)
    - Semi-quantification of predominant organism(s)
  - Culture
  - Viral culture or rapid viral diagnostic test (NP aspirate)
- Blood culture
- Bronchoscopy
  - Quantitative culture and intracellular organisms

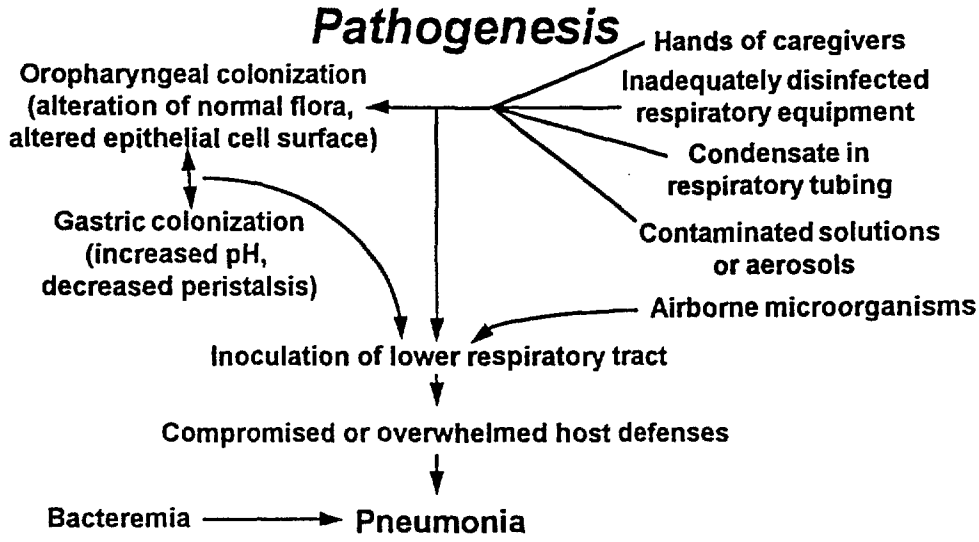
Nosocomial Lower Respiratory Tract Infection

Microorganisms

- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*
- *Enterobacter* sp.
- *Klebsiella* sp.
- *Hemophilus influenzae*
- *Moraxella catarrhalis*
- *Legionella pneumophila*
- *Streptococcus pneumonia*
- Influenza virus
- Respiratory syntytial virus
- Parainfluenza virus
- Adenovirus
- Cytomegalovirus
- Aspergillus sp.
- Rhizopus sp.

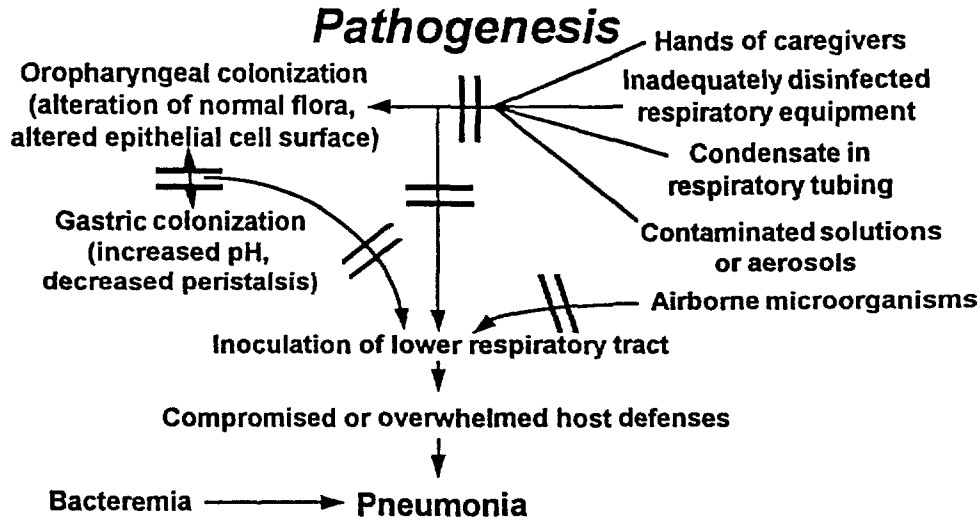
Nosocomial
Lower Respiratory Tract Infection

Pathogenesis



Nosocomial
Lower Respiratory Tract Infection

Pathogenesis



Nosocomial
Lower Respiratory Tract Infection

Procedures & Practices to Reduce Risk

- Minimize the use and duration of mechanical ventilation
- Use of spirometry and chest physiotherapy for post-op patients
- Minimize use of medications that elevate gastric pH
- Minimize use of nasogastric tubes
- Elevate the head of the bed
- Use jejunal feeding tubes instead of gastric feeding tubes
- Use continuous instead of bolus enteral feedings

Nosocomial
Lower Respiratory Tract Infection

Procedures & Practices to Reduce Risk

- Minimize potential for contamination of solutions used in suctioning and aerosolized medications
- Prevent condensate collecting in respiratory tubing from draining into patient
- Adequately disinfect respiratory equipment
- Wash hands before and after suctioning or touching the endotracheal tube or respiratory tubing
- Identify and isolate patients with active pulmonary tuberculosis

Assessing & Improving Quality of Care

Continuous Quality Improvement / Total Quality Management ⟷ *Epidemiology / Biostatistics*

- Mobilize and organize problem-solving teams
- Define and measure relevant processes and outcomes
- Improve processes
- Monitor effects on outcomes

- Describe and analyze patterns of disease in populations
  - Type
  - Frequency
  - Consequences
  - Transmission
  - Exposure
  - Risk
  - Effect of interventions

Nosocomial (Hospital) Infection

General Definition

Infection acquired during hospitalization

or as a consequence of hospital care

? Nosocomial (Hospital) Infections ?

1. Child admitted with chicken pox with some lesions secondarily infected with *Staph. aureus*
2. Child hospitalized for 3 weeks with pneumonia with empyema who develops chicken pox 2 days after discharge
3. Elderly woman admitted with a stroke and an *E. coli* urinary tract infection
4. Elderly woman admitted with a stroke who has a urinary catheter placed and develops an *E. coli* urinary tract infection on the 5th day of hospitalization
5. Man who develops a *Staph. aureus* infection at the site where a mole was excised in an outpatient clinic
6. Man who develops osteomyelitis caused by methicillin-resistant *Staph. aureus* after surgery for a broken hip

Nosocomial (Hospital) Infections

2. Child *hospitalized for 3 weeks* with pneumonia with empyema who develops chicken pox 2 days after discharge

4. Elderly woman admitted with a stroke who has *a urinary catheter placed* and develops an *E. coli* urinary tract infection on the 5th day of hospitalization
5. Man who develops a *Staph. aureus* infection at the site where *a mole was excised* in an outpatient clinic 5 days ago
6. Man who develops osteomyelitis caused by methicillin-resistant *Staph. aureus* after *surgery for a broken hip*

Exposures and Risks in Hospitals

- Communicable infections
  - Increased likelihood of exposure
  - Susceptible patients and workers
- Invasive devices, procedures, and treatments
  - Enable colonizing microorganisms to invade
  - Compromise host defenses
- "Hospital" microorganisms
  - Gram negative bacteria
  - Antimicrobial resistant bacteria
  - Opportunists

Minimize Exposure and Risk

- Communicable infections
  - Isolation precautions
  - Vaccinate hospital personnel
- Invasive devices, procedures, and treatments
  - Reduce unnecessary use
  - Procedures to reduce risk of skin and mucosal colonization
  - Procedures to reduce risk of contaminated devices
- "Hospital" microorganisms
  - Handwashing
  - Isolation of patients infected or colonized with antimicrobial resistant organisms

Nosocomial (Hospital) Infections

- Lower respiratory tract infection
- Urinary tract infection
- Surgical wound infection
- Bloodstream infection
- Gastrointestinal infection
- Transfusion-related or blood-borne infection
- Reproductive tract infection
- Bone or joint infection
- Cardiovascular infection
- Central nervous system infection
- Skin and soft tissue infection
- Upper respiratory tract infection
- Ocular infection

NNIS = National Nosocomial Infection Surveillance

Nosocomial Urinary Tract Infection

- Symptomatic urinary tract infection
- Asymptomatic bacteriuria

Nosocomial Urinary Tract Infection

Frequency and Significance

- Most common infection:
  ~1/3 to 1/2 of all nosocomial infections
- ~80% related to urinary catheters
- Relatively small but important contributor to mortality
- Cost: >$US 600/case

Nosocomial Urinary Tract Infection

Risk Factors

- Urinary catheterization or instrumentation
  - Indwelling >> intermittent
  - Long term catheterization>>short term
- Advanced age
- Female
- Urinary retention or incomplete emptying
  - Postoperative or postpartum patients
  - Neurologic or pharmacologic inhibition of voiding
  - Prostatic hypertrophy

Nosocomial Urinary Tract Infection

Clinical Signs

- Fever
- Dysuria
- Frequency
- Urgency
- Suprapubic tenderness
- Cloudy or foul smelling urine

Nosocomial Urinary Tract Infection

Laboratory

- Pyuria
  - Dipstick (leukocyte esterase, nitrate)
  - Microscopic examination
- Gram stain of unspun urine (any organisms)
- Urine culture
  - Method of collection
  - # of colonies (cfu/ml)
  - Single vs.. multiple microorganisms

Nosocomial Urinary Tract Infection

Microorganisms

- *Escherichia coli*
- *Enterococcus* sp.
- *Pseudomonas aeruginosa*
- *Klebsiella* sp.
- *Candida* sp.
- *Proteus* sp.
- *Enterobacter* sp.

Nosocomial Urinary Tract Infection

Procedures & Practices to Reduce Risk

- Minimize use and duration of urinary catheters
- Wash hands before and after inserting a urinary catheter
- Cleanse the meatus and surrounding area with an effective antiseptic before insertion of a urinary catheter
- Use aseptic technique during catheter insertion
- Minimize disruption of the catheter-drainage system junction
- Keep the drainage reservoir below the level of the bladder
- Use individual containers to empty drainage reservoirs
- Wash hands before and after touching the catheter or the drainage system

Simple statistical methods

can be used to make valid conclusions

from well designed studies.

Even sophisticated statistical methods

will not enable valid conclusions to be made

from poorly designed studies.

Types of Studies

	Design	Example of Study Question	Comments
Observational Studies			
Descriptive	Study exposures and outcomes	What is the frequency of UTI? How frequently are urinary catheters used?	Generates hypotheses about cause and effect Sample of the population usually sufficient
Case-Control	Define outcome, study exposure Case--outcome + Control--outcome -	Have patients with a UTI more frequently had a urinary catheter?	Investigate hypotheses of cause and effect Small sample size Short time frame
Cohort	Define exposure, study outcome Group 1--exposure + Group 2--exposure -	How frequently do patients with a urinary catheter develop a UTI?	Further investigation of cause and effect Larger sample size Longer time frame
Experimental Studies			
Clinical Trial	Study effect of treatment on outcome Group 1--treatment + Group 2--treatment -	Does prophylactic TMP/SMZ prevent UTI in patients with urinary catheters?	Large sample size Long time frame

Descriptive Study

Do patients receive "appropriate" perioperative antimicrobial prophylaxis?

Was antimicrobial prophylaxis given to patients for whom it is recommended?
Was an appropriate antimicrobial given?
Was an appropriate dose given?
Was the antimicrobial given at the appropriate time (first dose, subsequent intraoperative doses)?
Was prophylaxis extended beyond the appropriate time frame (were too many doses given)?

Study Population

Inclusion Criteria
All patients undergoing a surgical procedure in the Operating Room during the past 2 months for whom perioperative antimicrobial prophylaxis is recommended by a published guideline

Exclusion Criteria
Patients receiving antimicrobial treatment for any reason more than 24 hours prior to surgery
Patients undergoing procedures that do not involve an incision
Patients less than 18 years of age

Definitions

Published guideline for perioperative antimicrobial prophylaxis
Procedures for which antimicrobial prophylaxis is recommended
Appropriate agent(s) for specific procedures
Appropriate dose
Time for subsequent intraoperative dose(s)
Total number of doses (duration of prophylaxis)

Variables

Prophylaxis given (Yes or No)
Antimicrobial
Dose
Time of incision
Time of incision closure
Time of administration of the first antimicrobial dose
Time of subsequent intraoperative antimicrobial dose(s)
Total number of antimicrobial doses administered

Outcomes

Antimicrobial prophylaxis given when recommended
Antimicrobial agent corresponds to guideline
Dose corresponds to guideline
First antimicrobial dose within 2 hours before the incision
Additional intraoperative antimicrobial dose(s) if length of surgery >4 hours

Data Collection

Identify patients
Collect data regarding variables

Data Analysis

Percentages
- % receiving antimicrobial prophylaxis when recommended
  - % receiving an agent corresponding to guideline
    - % receiving an dose corresponding to guideline
    - % receiving the first dose within the 2 hours before the incision
    - % of surgeries lasting longer than 4 hours
      - % receiving a subsequent intraoperative dose after 4 hours of surgery
    - % receiving doses 24 hours after the surgery is complete

Sample Size

Sufficient size (at least 100 patients), exact size not critical

Case-Control Study

What factors are important in determining whether patients receive antimicrobial prophylaxis at the appropriate time?

Type of surgery (type of procedure, elective vs. emergency)?
Service?
Location where antimicrobial prophylaxis was administered (Operating Room vs. ward)?
Time (day of week, time of day)?

Study Population

Cases

All patients undergoing a surgical procedure involving an incision in the Operating Room who received perioperative antimicrobial prophylaxis with an appropriate agent, and

who received the first antimicrobial dose <u>within 2 hours before the incision</u>

Controls

Patients undergoing a surgical procedure involving an incision in the Operating Room who received perioperative antimicrobial prophylaxis with an appropriate agent, and

who received the first antimicrobial dose <u>more than 2 hours before the incision or after the incision</u>

No matching

Definitions

As described previously

Variables

Type of procedure
Elective or emergency
Service
Location where first dose administered
Day of week
Time of day

Data Collection

Identify patients
Collect data regarding variables

Data Analysis

Odds Ratios
- One type of procedure vs. all other types of procedures
- Elective vs. emergency
- One service vs. all other services
- Operating Room vs. ward
- Weekday vs. weekend
- Daytime (8:00-17:00) vs. nighttime (17:00-8:00)

Stratified Analysis (by elective/emergency)
- One service vs. all other services
- Operating Room vs. ward
- Weekday vs. weekend
- Daytime vs. nighttime

Logistic Regression

Sample Size

Sufficient number of cases (at least 30, preferably 50)
Controls (at least 2 controls/case, preferably 3)

Measures of Risk

Relative Risk

Probability of disease among exposed persons divided by the probability of disease among non-exposed persons

RR = (a/a +b)/(c/c+d)

	Disease		
Exposure	Yes	No	Total
Yes	a	b	a + b
No	c	d	c + d
Total	a + c	b + d	

Odds Ratio

Odds of exposure among persons with the disease divided by the odds of exposure among persons without the disease

OR = [(a/a +b)/(b/a +b)]/[(c/c + d)/(d/c + d)] = ad/bc

	Disease		
Exposure	Yes	No	Total
Yes	a	b	a + b
No	c	d	c + d
Total	a + c	b + d	

Confounding

Variable that partially or totally accounts for the observed association between another variable and disease

Effect Modulation

Variable for which different values affect the strength of the observed association between another variable and disease

Attributable Risk

Incidence of disease in exposed persons minus the incidence of disease in non-exposed persons

Diagnostic Tests

	Disease		
Test	Yes	No	Total
Positive	a	b	a + b
Negative	c	d	c + d
Total	a + c	b + d	

Sensitivity

Probability that the test is positive if the person has the disease

Sensitivity = a/a +c

Specificity

Probability that the test is negative if the person does not have the disease

Specificity = d/b +d

Positive Predictive Value

Probability that the person has the disease if the test is positive

PPV = a/a +b

Negative Predictive Value

Probability that the person does not have the disease if the test is negative

NPV = d/c +d

Cohort Study

Does the location where the first dose of perioperative antimicrobial prophylaxis is administered have an effect on whether the dose is administered at the appropriate time?

If the first antimicrobial dose is administered in the Operating Room, is it more likely to be given within the 2 hours before the incision instead of the ward?

Study Population

Group 1

Patients undergoing a surgical procedure involving an incision in the Operating Room who received perioperative antimicrobial prophylaxis with an appropriate agent, and

who received the first antimicrobial dose <u>in the Operating Room</u>

Group 2

Patients undergoing a surgical procedure involving an incision in the Operating Room who received perioperative antimicrobial prophylaxis with an appropriate agent, and

who received the first antimicrobial dose <u>on the ward</u>

Definitions

As described previously

Outcome

Patients receiving first antimicrobial dose within 2 hours before the incision

Data Collection

As described previously

Data Analysis

Relative Risk
Operating Room vs. ward

Sample Size

Sample size calculation is critical

Determine sample size using estimates of frequency of administration of first antimicrobial dose within 2 hours before surgery in:

Operating Room	Ward	Total # in both groups
50%	25%	130
80%	40%	54
80%	60%	180

Descriptive Statistics

Describe the character of a population

Measures of Central Tendency

Mean (average)--arithmetic sum of values divided by the # of observations
Median--middle value (equal # larger and smaller)
Mode--most frequent value

Measures of Variability or Dispersion

Range--lowest to highest values
Variance--sum of squared deviations of all values from the mean divided by the number of degrees of freedom (sample size minus 1)
Standard Deviation--square root of the variance

Inferential Statistics

Make valid conclusions about population(s) based on a study of samples

Types of Error

Type I (alpha)
Probability of detecting a difference when no difference truly exists

Type II (beta)
Probability of failing to detect a difference when a difference truly exists

Test Procedures for Qualitative or Discrete Quantitative Variables

Example: chi square

Test Procedures for Continuous Variables

Normal Distribution
Example: t-test, ANOVA

Non-Normal Distribution (non-parametric tests)
Example: Wilcoxon rank sum test, Kruskal Wallis test

HISTORICAL PERSPECTIVE

Semmelweis used both retrospective and prospective surveillance methods in demonstrating the efficacy of handwashing in preventing puerperal sepsis

SURVEILLANCE

definitions of events to be observed

systematic, observation of the occurrence and distribution of events/disease

record of events or conditions, that increase of decrease the risk of disease

appropriate analysis

communicated to appropriate persons

ELEMENTS OF SURVEILLANCE

definitions of events to be observed or surveyed

systematic data collection and analysis

GOAL

Reduce nosocomial infections

provide baseline infection rates

identify outbreaks/epidemics (sentinel function)

verify efficacy of control measures

compare nosocomial rates with other hospitals

use in problem solving or research

HOSPITAL SURVEILLANCE

provide baseline infection rates by:

type of infection (e.g., SWI, UTI, LRI)

pathogen

service or hospital unit

SYSTEMATIC COLLECTION OF DATA

define events to be surveyed

use agreed upon definitions

apply criteria systematically

POSSIBLE DATA ITEMS ON NOSOCOMIAL INFECTION REPORT

patient's name or identification number;

age, sex, service , nursing unit;

site of infection e.g., SWI, UTI, LRI etc.,;

organisms, antibiotic susceptibility pattern;

presence of invasive devices, surgical procedures, wound class;

surgeon (by name or code number)

SURVEILLANCE STRATEGIES

ongoing hospital wide surveillance

ongoing focused surveillance by high risk patient, high risk unit, surgery, procedure, and/or microorganism;

periodic surveillance by surgery, procedure, nursing unit(e.g., every 6 months for 1 month)

prevalence surveys for surveillance of specific site infections such as UTIs, or validation of incidence data

combination of any of the above.

HOSPITAL-WIDE SURVEILLANCE

Indications:

Consider when:

developing surveillance system

developing baseline information

testing definitions, denominators

Methods:

Perform surveillance on all patients, all sites {when establishing baseline information do for 6 to 12 months}

Compare with published data of hospital with comparable populations

Outcomes:

Keeps clinicians informed of possible strengths and weaknesses of IC program

Identifies areas, services, procedures for further study

Provides information about surveillance system requirements[e.g. areas requiring intensive surveillance due to the complex patient factors, minimal surveillance activities may suffice for low risk areas.]

Identifies areas for improvement projects

Limitations:

Uses resources

Provides general information that may be difficult to interpret

Identifying specific risk factors may be difficult

Excludes information about risk factors and/or severity of illness data

FOCUSED SURVEILLANCE

Indications:

Response to problems identified through reports in the literature or through surveillance data

Methods:

Develop a plan that specifies event to be monitored such as surgical procedure, invasive device,[include denominator that will be used to establish rates]

Reassess periodically (example of all orthopedic infections)

Outcomes

Provides specific feedback to clinicians

Identifies problem areas

May provide information about efficacy of specific interventions

Limitations:

Problems in other areas of the hospital may be missed

TYPICAL SURVEILLANCE COURSE OF HOSPITAL SURVEILLANCE ACTIVITY

Period of hospital-wide surveillance

Priorities established for focused surveillance by services, units, microorganisms, or procedures

Surveillance plan reassessed annually

EXAMPLE OF SURVEILLANCE PLAN

ICU surveillance, including a project directed towards reducing ventilator associated pneumonia

all primary bacteremia (lab)

all multi-drug resistant microorganisms e.g. MRSA(lab)

total hip replacements for 3 month period (twice a year)

all open heart surgeries, including 30 day post-discharge surveillance

occupational infections in hospital staff

DATA COLLECTION METHODS

Design

Retrospective

Looks "backward" and uses data available from patient charts, laboratory reports, and other hospital or clinic records. Often used to verify that the occurrence of a disease [infection]exceeds the expected rate.

Prospective

Looks "forward" from the exposure of a risk factor ,then measures the rate of disease present in those exposed.

Populations

Total hospital vs. selected units or selected patient populations

Examples:

ICU

surgical patients

patients on ventilators

Frequency

will depend upon:

patient length of stay,

number of beds on service

adequacy of data on patient charts

Sources of data:

patient charts,

interviews with physicians, nurses,

nursing records (shift report books/kardex),

microbiology reports

laboratory log books

post-discharge surveillance

DATA ANALYSIS

consider calculating infection rates for:

service

unit

surgeon

hospital

invasive devices

other: surgical wound classification, ASA score, duration of operative procedure,

host factors: extremes in age, diabetes, immunosuppression

INFECTION RATE

rate == numerator x constant =
denominator

The denominator represents the population at risk for the event.

INCIDENCE RATE is the number of NEW cases of a disease in a specified time period
divided by the population at risk for the event. Example, the number of surgical wound infections
in hospital A in January, divided by the number of surgeries performed in hospital A in January.

Number of NEW cases of a specified time period x constant = _____
Population at risk for same time period

PREVALENCE RATE is the number of EXISTING cases of a disease present at a specified point in time divided by the number of persons at risk for the disease at the same point in time. Example, the number of persons with a surgical wound infection in the hospital on January 15, divided by the number of patients with a surgical wound also present in the hospital on January 15.

Prevalence rate number of EXISTING CASES from a specified interval or point in time
Population at risk for same time period x constant =____

DENOMINATOR DATA
(can be presented by month or year)

-total number of hospital admissions or discharges

-patient days
(Patient days provide a more sensitive reflection of the patient population and the exposure to the device).

.
-number of total surgical procedures
Total number of surgical procedures performed at hospital A in the month of January or for the entire year of 1994

-number of specific surgical procedures

-number of procedures performed by specific surgeons. The number of infected surgical wound infections in patients operated upon by Surgeon B is divided by the total number of surgeries of Surgeon B

COMMUNICATION OF SURVEILLANCE RESULTS

Results of surveillance should be regularly communicated to hospital administration, including the Medical and Nursing Directors, chiefs of services, and head nurses.

Surveillance also provides an opportunity for the infection control practitioner to observe patient-care practices on the nursing units, provide consultation to the nursing staff about infection prevention and/or control issues; and provide a visible reminder of the infection control program within the hospital.

EXAMPLES OF COMMON SURVEILLANCE DEFICIENCIES

Lack of planning as to desired outcome of surveillance activity
Lack of communication of physicians and nurses
Inconsistent application of surveillance methodology
Lack of agreement with key clinicians on infection definitions
Lack of careful analysis

EXAMPLES OF APPLIED SURVEILLANCE STRATEGIES

Passive surveillance systems frequently underestimate the infection rate. For example in a hospital in Brazil, the reported infection rate in ICU patients in 1987 {using a passive surveillance system in which physicians filled out a nosocomial infection from at the time of discharge was 11.6%. After an active surveillance system was implemented the reported rate was 24.8%. The Centers for Disease Control definitions for nosocomial infections were used for this study.

In response to a shortage of nurses and in an effort to increase the efficiency of the infection control program, some hospitals in the US, Canada and Thailand have used a surveillance system in which a general duty nurse on each nursing unit is designated as an "assistant" [or "ward"] infection control nurse.

Routine surveillance data indicate a higher than expect rate of surgical wound infections in abdominal hysterectomy patients at Hospital C.
-Verify the existence of the problem ,review changes in laboratory methods, changes in personnel or surveillance methodologies;
-Compare infection rate to other reported rates with a comparable patient population
Present information to the ICC, design plan for presenting information to the surgical service [ob/gyn], hospital administration, nursing
Obtain agreement on prospective surveillance and control strategies from key members of the obstetric and gynecologic service
Institute control measures
Perform surveillance on all abdominal hysterectomy patients, consider:

post-discharge surveillance by establishing a reporting system with the outpatient clinic and obtaining surgeon specific wound infection rates--(code surgeons by number or letter--maintain code in confidential manner)
Evaluate surveillance findings
Evaluate control measures.

Routine surveillance shows a higher than expected number of ventilator associated pneumonia in ICU patients.

HISTORICAL PERSPECTIVES INFECTION CONTROL IN THE US

1950s-stringent disinfection of the environment, identification and treatment of Staphylococcal carriers among hospital staff

1960s-rise in the number of immunosuppressed patients and in the number of infections caused by opportunistic infections

1970s-voluntary reporting of infections by physician and nurses found to be unsatisfactory. 1st International Conference on Nosocomial Infections at CDC. debates pros and cons of surveillance ICN concerns regarding the cost and feasibility of staffing IC programs--result-strong recommendations for surveillance. ICNs, cessation of environmental culturing
CDC performs a Study of the Efficacy of Nosocomial Infections (SENIC
infection control programs in the US are described and effective infection program components are identified

1980s-financial incentives for hospitals to reduce nosocomial infections. Infection Control programs become more involved in employee health and AIDS issues.

1990s-focused surveillance programs using systems which stratify patients by risk factors and using an outcome oriented approach.

ACTIVITIES OF THE INFECTION CONTROL NURSE

(SENIC data)

50% of time spent on surveillance

25% on policy and procedure development

25% on investigating clusters of infection, serving as a resource to hospital staff (regarding questions related to patient placement, isolation techniques and employee health issue)

INFECTION CONTROL COMMITTEE/PROGRAM ACTIVITIES

Plan program goals and objectives

Review and approve methods to accomplish goals

Approve surveillance plans

Review findings of surveillance activities(including the findings from other infection prevention or control activities such as results of antimicrobial usage studies

Review and approve prevention strategies (all epidemiologic cultures of patients and/or environment should be under the control of the ICC or program).

Direct activities of the program

Evaluate processes(e.g., 80% of ICNs time spent on surveillance so inadequate time remaining for prevention and control activities)

Evaluate outcomes(e.g., hospital with a consistent report of ventilator associated pneumonia at the 75th percentile when compared to similar ICUs reported in the US NNIS study.

Return to #1-plan program goals and objectives