Implementation of an Evidence-based Protocol for Surgical Infection Prophylaxis

John A. Savino, Jane Smeland, Ellen L. Flink, Angelo Ruperto, Amanda Hines, Thomas Sullivan, Kerri Galvin, Donald A. Risucci

Abstract

Objective: An evidence-based surgical antimicrobial prophylaxis (AMP) protocol was implemented in multiple facilities to determine if compliance led to a decrease in New York State reportable surgical site infections (SSIs). Implementation focused on changing practitioner behavior. **Methods:** An evidence-based protocol was developed and approved by participating clinical divisions in the five hospitals involved in the project. Quality assurance (QA) processes were established at each facility to promote compliance. One facility included repeated noncompliance with the protocol in physicians' QA profiles. Randomly selected clean and clean-contaminated procedures were retrospectively reviewed for patients discharged in 2001 (prior to AMP implementation) and 2003 (the implementation period). Trained nurses collected data on compliance with selection of the appropriate antibiotic, timing of administration, redosing, dose adjustment, and postoperative duration. **Results:** Compliance indicators improved at all facilities. Compliance with the combination of all five indicators improved from 11 percent to 34 percent ($P < 0.001$), and there was a nonsignificant decrease (3.0 percent vs. 2.5 percent; $P = 0.22$) in SSI rates. **Conclusion:** Compliance with an AMP protocol can be increased by implementing a multifaceted QA and educational process focused on changing physician behavior. Medical board oversight of noncompliance and inclusion in the physician QA profile seemed to be the most efficacious step in assuring physician compliance.

Introduction

Nosocomial infections are, by far, the most common complications affecting hospitalized patients.[1] Among these, surgical site infections (SSIs) constitute the second most common category of adverse events—approximately 20 percent of all nosocomial infections—and rank third with respect to cost.[2] Prevention of SSI requires aggressive efforts to modify physician behavior and implement system-based changes aimed at eliminating indiscriminate and/or inappropriate use of antibiotics. The New York State Department of Health and the Agency for Healthcare Research and Quality (AHRQ) funded a multi-institutional project to implement and test an evidence-based antimicrobial prophylaxis protocol (AMP). This project is one of three demonstration projects involving hospital networks that were funded under the New York State Safety Improvement Demonstration Project. These demonstration projects aim to improve the completeness of

reporting into the New York Patient Occurrence Reporting and Tracking System (NYPORTS), develop systems improvements, test the effectiveness of interventions designed to reduce the occurrence of adverse events, and disseminate and share successful intervention strategies.

The project involved a partnership between one tertiary-care teaching hospital (approximately 600 beds, regional center); two nonteaching hospitals (approximately 200 beds, acute care); and one small, rural hospital (approximately 50 beds). Approximately 6 months following initiation of the project, one of the nonteaching hospitals closed; a second, comparable hospital was recruited, and the project was initiated at that time at the replacement hospital. The AMP was aimed at preventing SSI among surgical patients undergoing clean and clean-contaminated surgical procedures, decreasing the incidence of resistant organisms associated with prolonged antibiotic use, and decreasing costs. The project was designed to evaluate the change in the incidence of protocol compliance observed pre- vs. postimplementation of the AMP project.

This paper describes the theoretical background underlying our approach to the promotion of behavior change, the development and implementation of the AMP, the methods used to promote and monitor compliance, the data collection methods and computerized database, and changes observed during the period of implementation with respect to physician compliance and the incidence of SSI. The purpose of this paper is to share lessons learned during implementation that may assist others engaged in similar future endeavors.

Theoretical background

This project applied elements of the Commitment to Change Model and the Trans-theoretical Model[3–4] of Behavior Change in an effort to improve physician compliance with the AMP. Our approach also incorporated elements that have proved successful in efforts by pharmaceutical companies to change physician behavior (e.g., forming personal one-to-one relationships with physicians, providing on-demand education and support).

The Commitment to Change Model includes three stages through which a physician theoretically progresses in the course of behavior change: (1) the physician perceives dissonance between current and desired practice, (2) the physician commits to implement a specific change, and (3) observable change is made. Application of this model requires three basic elements: (1) asking the physician to make a change; (2) following up with the physician to assess the level of commitment; and (3) determining at a later date whether or not the change has been made, and if not, assessing what prevented the physician from making the change.[5] This model emphasizes the importance of information-sharing activities between the learner and the facilitator/evaluator of change. Previous studies applying this model with physicians have used written contracts as a means of identifying intent to change.[5–8] Generally, these studies have shown that those who commit to change, in writing, have higher rates of success than those who do not.[5] These contracts theoretically encourage physicians to reflect on practice parameters and how they will utilize guidelines in their own practices.

It is believed that the act of reflection may be the impetus that is needed to ensure the adoption of the desired new behavior.[5–9]

The Trans-theoretical Model is one of the most commonly cited behavior change models, according to AHRQ.[10] This model focuses on the readiness of an individual to change or attempt to change behavior. The Trans-theoretical Model assesses behavior change on a more individual level, looking particularly at what causes an individual to initiate a behavior change. Most applications of this model have addressed health-related behaviors (e.g., smoking cessation). According to the Trans-theoretical Model, an individual progresses through five stages as behavior change is accomplished:

- **Precontemplation.** The individual does not believe there is any need for behavior change and is somewhat resistant to change.
- **Contemplation.** The individual has acknowledged a need for change and has begun to deliberately increase awareness and knowledge about the behavior.
- **Preparation.** Before initiating behavior change, the individual self-evaluates with respect to the behavior, develops a commitment to change, and constructs a detailed plan for change. By the time she or he reaches this stage, the individual begins to perceive greater benefits than barriers to change.
- **Action.** Behavior change is initiated. Others are likely to recognize a person's progress toward change. After a period of time, the person may move into the fifth stage.
- **Confirmation.** Though change is maintained more easily now, some vigilance is still required to avoid slips or setbacks. If and when the change becomes so automatic that there is no possibility of reverting to a former method of practice, the goal is reached.[4]

These models of behavior change provided the theoretical basis for the educational approaches and methods of outcome assessment.

Methods

Protocol development

Perioperative antibiotic prophylaxis can decrease the incidence of SSI.[11] For most procedures where prophylaxis is indicated, an agent with activity against community-acquired organisms is most appropriate. The administration of antibiotics prior to surgery is commonplace and of proven benefit in many circumstances to minimize postoperative SSIs. However, if not administered properly, antibiotic prophylaxis will not be effective and may be harmful. Antibiotic prophylaxis is indicated clearly for most clean and clean-contaminated operations. Antibiotics for dirty operations represent treatment and not prophylaxis.

A thorough review of published evidence concerning antimicrobial prophylaxis resulted in development of a procedure-specific AMP and alternative antimicrobial agents considered acceptable when allergic reaction was a specific concern. Guidelines promulgated by the American Society of Health-system Pharmacists (ASHP)[12] formed the basis of the protocols. The guidelines are published by ASHP but are a compilation of guidelines from many sources, such as the Medical Letter and the Infectious Diseases Society of America.

The AMP required (a) administration of a specific antibiotic within 30 minutes of incision time; (b) readministration intraoperatively, as needed; (c) adjustment of dosage for weight categories; and (d) discontinuation of antimicrobial prophylaxis after 24 or 48 hours, depending upon the procedure.

Educational program

The investigators systematically reviewed the literature related to SSI; the pre-, intra- and postoperative factors that can precipitate SSI; and antimicrobial prophylaxis. Review of the continuing medical education (CME) literature revealed that efforts to modify physician behavior through education have had moderate success, at best.[13] Many previous efforts have employed traditional CME approaches, based on sound educational principles, but rarely have they integrated these approaches with methodologies derived from well-developed theories or models of behavioral change.

The principal investigator of the project—professor and chairman of surgery at the tertiary-care hospital and primary study site—in collaboration with representatives from the New York State Department of Health, developed and presented an educational lecture primarily aimed at surgeons and anesthesiologists at all participating hospitals. The lecture described the protocol and summarized Level-1A evidence from previously published studies that have identified a wide variety of approaches to reducing the incidence of SSI, as mentioned above. These lectures were presented at each of the participating hospitals in the month prior to implementation.[*] The target audience of these lectures included approximately 530 surgeons representing the following specialties: plastic/reconstructive, cardio-thoracic, otolaryngology, orthopedics, orthodontics, general surgery, neurosurgery, obstetrics/gynecology, trauma/critical care, vascular, transplant, and urologic surgery. A videotape of the presentation and copies of the slides that accompanied the lecture were made available for those that were unable to attend the lecture. Participants received 1.5 Category I CME credits for attendance.

A total of 185 surgeons and 129 anesthesiologists operated on at least one patient included in the study. Of these, a total of 51 physicians (~16 percent) attended the educational sessions. The majority of attendees were high-volume physicians at the participating hospitals responsible for the care of the majority of study patients. Many of the physicians who did not attend these sessions did view

[*] The protocol was launched at each of the four original hospitals in February 2003; the protocol was implemented in July 2003 at the hospital that was subsequently recruited to substitute for the facility that had closed.

the videotapes of the sessions and/or review the slides from the presentation; however, the exact number that did so was not recorded. Evaluations of the educational sessions by participants were uniformly very positive.

Other educational efforts focused on nurses and ancillary personnel (i.e., operating room technicians, respiratory therapists, etc.). In-service sessions were held for the nursing staff at each institution, focusing on identification of NYPORTS reportable events with the appropriate mechanism to report them, the importance of the nurse's role in the reporting and quality improvement process, and understanding of the AMP.

Coders at all sites were educated about surgical wound classification, criteria for SSI (i.e., superficial, deep incisional, and organ/space), likely SSI pathogens, signs and symptoms of wound infection, treatment, most commonly administered prophylactic antibiotics, principal diagnoses, secondary diagnoses, external cause-of-injury codes (E-codes) associated with SSI, coding guidelines for SSI, and physician query. A professional medical record reviewer performed chart reviews, which were then checked for coding efficiency, completeness, and accuracy at all sites. Corrective action and further in-service training sessions were held based on the needs and findings from the reviews. These coding audits were conducted prior to the educational in-services and then again at the end of the project.

The focus of all educational efforts was to increase the "buy-in" of participants. The highly interactive nature of all educational sessions promoted discussion of concerns and questions. Participants were challenged to identify potential obstacles to implementation and identify possible solutions. They were also informed of the various benefits to both patients and health care providers that may accrue as a result of the implementation of the AMP.

Protocol implementation

Adult (>18 years of age) patients, undergoing specific clean and clean-contaminated surgical procedures, were eligible for inclusion in the study.

Each operating room (OR) at the participating hospitals was equipped with a bound series of laminated reminder cards that contained the AMP protocol (Appendix A)† for each eligible category of surgery. Surgeons, anesthesiologists, and OR nurses at all hospitals were instructed to refer to the reminder cards as needed for each case. In addition, certain facilities added the AMP administration to the OR "time-out" prior to the start of the case as an opportunity to remind the OR team to administer the antibiotic in accordance with the protocol.

Promoting compliance

The following methods of intervention were implemented on an individual, as-needed basis in efforts to move the physician into the later stages of behavior change:

† Appendixes cited in this report are available from the corresponding author.

- Presentation of information that relates to the individual questions that the physician may have about the protocol (including individualized educational information packets—research literature, evidence-based reviews, hospital-specific data, national guidelines, etc.)
- Competitive feedback comparing the physician's compliance data,[8] infection rates, etc., to that of colleagues[9]
- Frequent reminders using various types of media (e.g., e-mail, letters, phone calls) about specific aspects of the protocol and other practices that may promote compliance and/or reduce incidence of SSI
- Monthly report cards from the Department of Quality Clinical Resource Management (QCRM) that incorporated data on SSI and other morbidities
- Communications from opinion leaders (i.e., department chairman, division chiefs, the QCRM director, other colleagues who have successfully implemented the protocol, outside experts)

Improvements in compliance were acknowledged during meetings with departmental staff. In rare cases of noncompliance, departmental peer review was conducted by QCRM staff. Failure to respond and/or continued deviations were either included in quality assurance (QA) profiles/report cards or addressed on a one-to-one basis.

Representatives from the following hospital departments were recruited to help enhance compliance: Infectious Disease, Surgery, Anesthesia, Nursing, Quality Management, Pharmacy, and Risk Management. Contact persons were identified at each facility, including the medical director, the vice president of patient care services, medical records supervisors, NYPORTS coordinators, and infection control staff. Project managers from the New York State Department of Health also maintained regular contact with onsite coordinators and data collection staff.

Monitoring compliance

The project enabled us to establish a procedure for collecting a wide range of data on patients with clean and clean-contaminated wounds. Personnel were trained on how to collect the data, review charts, and analyze data. Monitoring of compliance was a twofold process. First, the QCRM department reviewed cases for compliance on a weekly basis as part of the concurrent review. In addition, retrospective chart reviews were conducted after patients were discharged. Their charts were completed, coded, and available for data abstraction. The study design utilized full data collection from a 40 percent random subsample of all eligible surgical cases.

Surveillance

SSI is defined, in accordance with NYPORTS criteria, as an infection that requires incision and drainage during the initial hospitalization or hospital

readmission within 30 days of the original procedure for treatment of infection. Infection control nurses reviewed the following sources of information to identify SSIs: microbiology laboratory reports, Admitting Face Sheets for admitting diagnoses that may precipitate an SSI occurrence, Statewide Planning and Research Cooperative System (SPARCS) reports for discharge codes that could be related to SSI, and OR procedure logs that categorize all surgical procedures by surgical wound classification. The infection control nurses also made rounds on nursing units where other health care workers may report SSI to the nurses. All records reviewed by the nurses were checked for SSI. Nurses working in QCRM performed concurrent reviews of medical records and reported SSI to Infection Control, where SPARCS reports were cross-checked for SSI to validate all occurrences that had been identified. When Infection Control determined that an SSI existed and fulfilled requirements for reporting to NYPORTS, a NYPORTS Surgical Wounds Form was forwarded to Risk Management for entry into the New York State database.

It is noteworthy that more than 70 percent of surgical procedures in the United States are now performed on an outpatient basis, which presents a major problem for the surveillance of SSI. Since most infections will occur after discharge from the hospital, voluntary reporting by surgeons will be necessary to accumulate accurate data. Clearly, a patient diary would be ideal; however, the likelihood of surgeons participating in such a study in the United States is probably very small. Methodologies for capturing these data for critical appraisal are needed.

Description of database

An extensive database was developed for this project. The elements in the database were derived from the literature review that identified a variety of pre-, intra-, and postoperative factors related to risk and prevention of SSI. The data dictionary for the database is provided in Appendix B. This data collection enabled analysis of risk-adjusted outcomes and assessment of the role of factors other than the AMP in the occurrence of SSI.

Results of the intervention

Data were collected on a total of 2,526 patients that met the study selection/ exclusion criteria. There were 1,302 patients in 2001 (baseline sample) and 1,224 in 2003 (postintervention sample). The sample size for this study was based on a range of estimated effect sizes corresponding to changes in percent compliance between the pre- and postintervention periods. In particular, nQuery Advisor® software was used to estimate the number of subjects needed to detect pre- vs. postimplementation rates as small as 10 percent (i.e., 10 percent vs. 20 percent) and as great as 25 percent (i.e., 25 percent vs. 50 percent). Assuming the use of the chi-square statistic with alpha set at $P < 0.05$ (two-tailed) and power of 80 percent, it was estimated that we would need a minimum of 199 cases per year for each pre- vs. postimplementation comparison. A 40 percent random sampling of

eligible cases was used to ensure a minimum sample size of 1,200 cases per study period.

Data were analyzed to compare AMP protocol compliance across time periods with respect to each of five criteria and all five criteria combined:

1. Administration of the AMP drug specified by the protocol (see Appendix A)
2. Preoperative AMP administration of the correct drug within 45 minutes of the procedure (or the correct protocol-specified alternate drug within 90 minutes of the start time of the operation)
3. Intraoperative repeat dosing after 3 hours (if applicable)
4. Weight-adjusted dosing of protocol-specified AMP
5. Protocol-specified postoperative duration of AMP

Figure 1 depicts the breakdown of the types of procedures performed on study patients during both 2001 and 2003. There was a statistically significant ($P < 0.05$) increase in the relative proportion of vascular and liver transplant procedures from 2001 to 2003.

Figure 2 presents the percentage of patients for whom compliance with each of the AMP protocol criteria was met during both the baseline and implementation periods. Statistically significant ($P < 0.001$) improvements in

Figure 1. Distribution of types of procedures across time periods

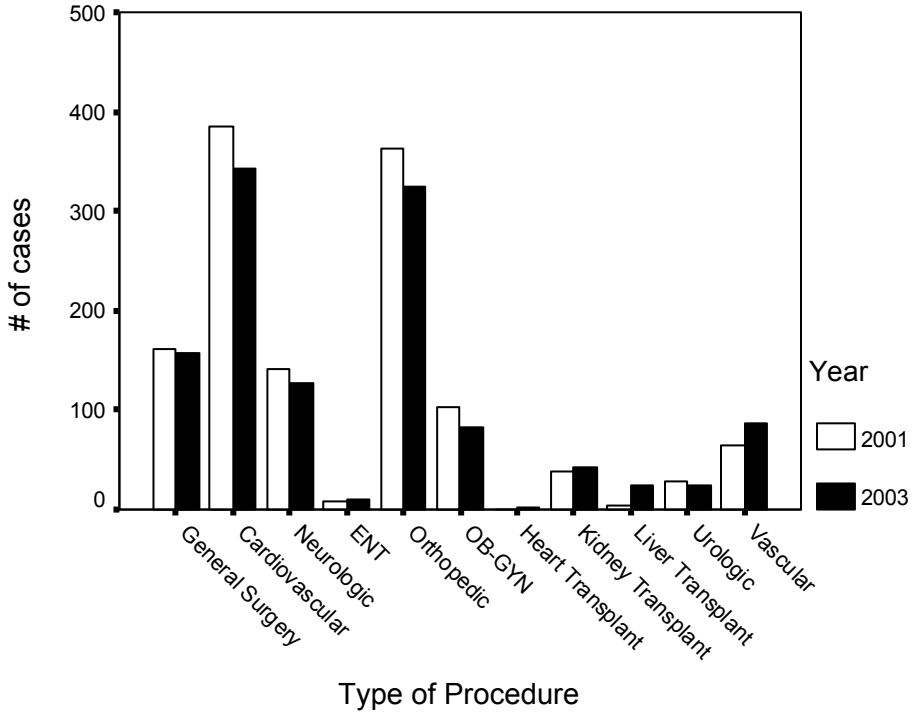
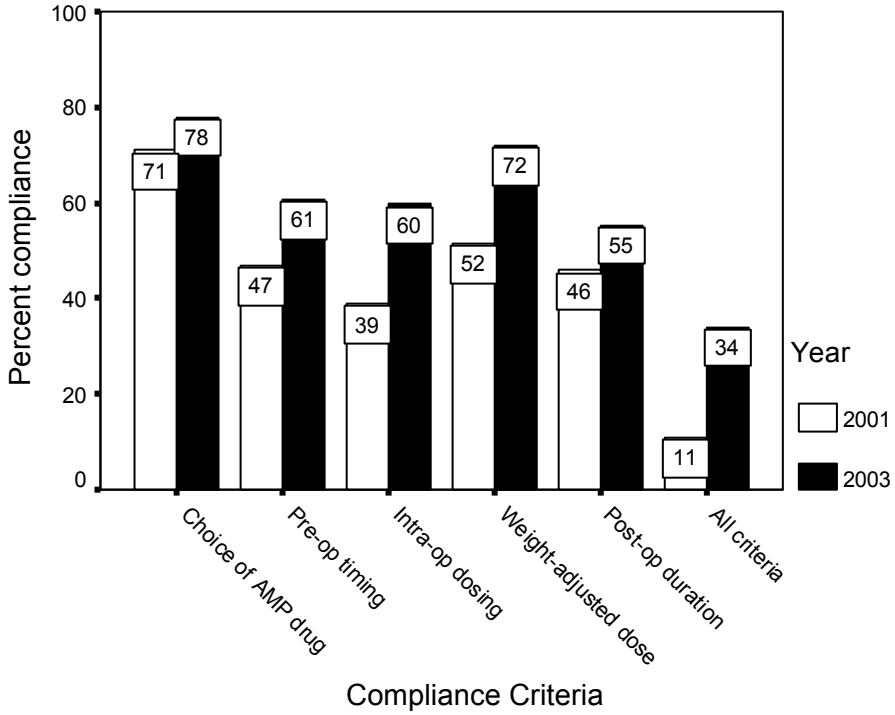


Figure 2. Percent of patients for whom each compliance criterion was met during baseline and implementation periods



compliance were observed with respect to each criterion, as well as all criteria combined. During the baseline period, compliance with all five criteria combined was observed in 11 percent of patients. This overall compliance rate increased to 34 percent during the implementation period.

A second database was analyzed, which included information from reviews of all SSIs that were reportable under the NYPORTS system. The number of reported SSIs among patients in this database who were eligible for inclusion in the AMP protocol was tabulated. In order to estimate SSI rates for each type of procedure, the number of cases of each type appearing in the 40 percent random sample database for each year was multiplied by 2.5. This provided an estimate of the volume of cases of each type for each year (i.e., the denominator).

A statistically nonsignificant ($P = 0.22$) decrease from 3 percent to 2.5 percent was observed in the overall SSI rate comparing the baseline and implementation periods. Among procedures with estimated volumes of 30 or more per year, the SSI rates ranged from 0.6 percent (knee arthroplasty) to 6.8 percent (biliary tract surgery) during the baseline period, and from 0.8 percent (knee arthroplasty) to 4.6 percent (colon surgery) during the implementation period.

Conclusions

Factors promoting compliance

Previous studies have demonstrated the utility of continuous quality improvement and evidence-based clinical management guidelines in reducing provider variability and error.[14, 15] In particular, successful interventions have included the following components: identifying a local opinion leader to serve as a champion of change, frequent in-service training sessions, reminder systems, checklists, and physician-specific benchmarking. Long-term success requires ongoing surveillance. The ultimate goal of these approaches is to optimize care while minimizing costs. The interventions utilized in the current project incorporated each of these components.

Initial efforts to implement the protocol were, as expected, met with some resistance from a number of surgeons, since the protocol imposed substantial constraints on the selection of specific antimicrobial agents and the timing and duration of their use. In some instances, the AMP required surgeons to deviate significantly from apparently tried-and-true practices that physicians had been employing for many years. Nevertheless, we were successful in gaining acceptance and substantial compliance from the majority of surgeons involved in the project.

It appears that certain components of the intervention were particularly valuable. The laminated cards delineating the specific antibiotics, duration, weight adjustment, and dosing parameters were well accepted and utilized at all sites.

Anesthesiologists, by and large, took the initiative during operations to ensure that the AMP was followed. Each hospital developed a consensus statement (Appendix C) that was signed by their respective medical boards, which indicated their acceptance of the protocol as a standard of care and reflected an institutional commitment to change. The Risk Management Department at the primary site reviewed the consensus statement to address concerns about liability that had been expressed by some of the physicians.

Institutional cultural differences played an important part in the successful implementation of the AMP at each site. The culture of academic institutions tends to be more open to experimentation, which may have facilitated adoption of the AMP protocol. In contrast, acute-care hospitals seemed to need more time to discuss changes within informal networks and committees to gain their physicians' buy-in. Once buy-in was achieved, however, they appeared to embrace the protocol, and informal networks supported the implementation.

Barriers and challenges

Numerous barriers and challenges were confronted in the course of implementing the protocol, many of which would be likely to emerge in other contexts where a change in physician behavior is required.

Geographic considerations can help and/or hinder efforts to implement a new protocol. For example, some physicians in our study operated at more than one hospital. In one case, two hospitals shared their medical staffs. Initially, this created some confusion, because only one of the institutions was involved in the project. Subsequently, the second hospital joined the project, and the existence of a shared medical staff went a long way toward facilitating a smooth acceptance and implementation of the protocol. In a separate case, proximity of the academic institution to one of the acute-care hospitals, utilizing a rotating medical staff from the academic institution, led to a rapid increase in compliance.

Some problems emerged that were unsolvable. During the course of the study, one of the hospitals closed, requiring the addition of another institution after the study had been underway. In other instances, the volume and type of specific surgical services changed.

Summary and recommendations

With implementation of the AMP at multiple sites, clear lessons were learned:

1. The laminated AMP cards in the OR were extremely important reminders to ensure that OR teams remembered to apply the protocol.
2. The collaborative development and acceptance of a consensus statement at each institution solidified the commitment to change.
3. The implementation of a concurrent review mechanism is key to early identification of noncompliance.
4. Clear definition of eligible ICD-9 codes for procedures of interest needs to be established prior to initiation of the protocol.
5. The implementation of preoperative standing orders that included prophylaxis, coupled with postoperative automatic stop orders, forced compliance in many instances.
6. The educational component is most effective when supported by ongoing reinforcement via informal networks and meetings.

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Author affiliations

New York Medical College (JAS, KG, DAR). Westchester Medical Center (JAS, JS, AH, TS). New York State Department of Health (ELF, AR).

Address correspondence to: Donald A. Risucci, Ph.D., New York Medical College, Department of Surgery, Munger Pavilion, Valhalla, NY 10595; phone: 914-594-3246; fax: 914-594-4359; e-mail: Donald_risucci@nymc.edu.

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