Credentialing, Privileging, and Proctoring in the Era of Laparoscopic Surgery

History of Credentialing Problems Originating with Laparoscopic Surgery

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Laparoscopic surgery in the United States was revolutionized in 1989. Even though Semm had popularized laparoscopic surgery in the early 1980s in Germany,[1] it was the advent of laparoscopic cholecystectomy in 1989 that triggered the explosive training and credentialing issues in laparoscopic surgery.[2] In a letter to the editor of the *American Journal of Surgery*, in June 1990, the author had recommended the following for training courses: (1) the operators should have extensive hands-on experience in diagnostic laparoscopy prior to embarking on laparoscopic surgery; (2) hands-on training to develop hand-eye coordination using Berci-Sackier trainers; (3) extensive explanation on the use and abuse of videolaparoscope and accessory instrumentation; (4) a minimum experience as prime operator in at least 3 pigs, each weighing 90 to 100 lbs., with experience as an assistant operator and camera operator in 6 more pigs, making a total of 9 pigs per participant.[3] This letter was written with the intent that proper training of surgeons would take place. We advocated a surgeon/co-surgeon team approach[4] to avoid adverse outcomes. In those days, weekend courses proliferated and surgeons came back and started doing procedures with minimal experience. This explosive growth was driven by patient demands for this procedure. As anticipated, untoward outcomes were reported.[5]

Laparoscopic appendectomy and laparoscopic hernia repairs were the next procedures to come on the scene, and within two years every known general surgical procedure was performed through the laparoscope. This led to a plethora of credentialing and privileging problems. The hospitals' privileging committees were surprised by the rapid request for new additional privileges for new procedures.

DEFINITIONS

Credentials: These are certain documents provided following successful completion of a period of education or training.[6]

Certification: Certification may be defined as a final document attesting to a successful completion of a period of education and/or training.

Credentialing: Credentialing is a process to grant privileges regulated by the medical staff bylaws.

Economic Credentialing: It is impossible to define this term adequately. It may be defined as the use of certain economic factors (affecting the well being of the hospital/facility/HMO) to grant or deny privileges.

Clinical Privileges: A specific clinical privilege can be defined as the right of a medical staff member to provide specific medical care to a patient which is consistent with his/her medical training.[7]

Proctoring: Proctoring is an objective evaluation of a physicians' actual clinical performance by an appointed proctor/observer who is appointed by the medical staff. This report is usually presented to the specific department and/or the credentialing body as proscribed by the bylaws of the institution.

Peer Review: May be defined as an activity of the medical staff to monitor performance of colleagues.

Competency: Competence may be defined as a safe and acceptable level of skill and can refer to a physician's general ability within a specialty to care for patients.[7]

DISCUSSION

There are three ways of granting privileges for procedures.

1. Categorical privileging. A practitioner in a specialty is granted privileges common to the specialty as defined by the specialty board. This simplifies granting of these privileges and of re-examining these every two years. However, a specialist may not be competent to perform every procedure for which he has been granted privileges. For instance, a general surgeon may be granted categorical privileges for general surgery which includes the Whipple procedure. It may be discovered during the credentialing process that this general surgeon may have performed only one or two such procedures during his residency. Obviously, this would not be acceptable. There is another problem also with this form of privileging. It does not take into account new procedures developed after the completion of the surgeon's residency training program.

2. Privilege list privileging. This is a common form of privileging. A list is prepared which has all the known procedures for the specialty. The problem with this laundry list approach is that it is time-consuming to develop and maintain. It creates unnecessary medicolegal difficulties if the list is not updated and checked every two years. At the Chicago Medical School and the Good Samaritan Hospital, this method has been used successfully.

The third approach is a combination of the first two methods.[8]

3. Economic credentialing. As defined earlier, this form of credentialing and privileging is emerging as a matter of necessity. In other words, it may be any process that measures efficiency of medical care which affects the credentialing process. Over-utilization, underutilization, and inappropriate utilization may result in denial of credentials and re-appointment.[9,10] In the era of DRG's payments to hospitals, hospitals may resort to this form of credentialing. Thus, denial of privileges may be for "business reasons" as process efficiency, and cost of care become of paramount importance in the delivery of care. Hospitals may resort in the future to a controlled form of economic credentialing with the full knowledge of the medical staff.

LAPAROSCOPIC SURGERY

SAGES developed the first comprehensive Guidelines for granting privileges in laparoscopic surgery.[11] It addressed the issues of (1) the principles of privileging and (2) the training and determination of competence.[8] At Good Samaritan Hospital and Mount Sinai Hospital Medical Center, it was decided that only surgeons privileged to perform biliary tract surgery would be permitted to seek privileges in laparoscopic surgery. SAGES-approved hands-on laparoscopic cholecystectomy courses or equivalent laparoscopic cholecystectomy courses were considered by the credentials subcommittee on laparoscopic surgery to be acceptable for granting of privileges. Ten proctored laparoscopic cholecystectomy cases were initially required and eventually modified to five proctored cases. A surgeon and co-surgeon model for each procedure was used for a period of two years.[13] This was then modified so that a single surgeon with a qualified assistant could perform the procedure of laparoscopic cholecystectomy.

The requirement of a proctor brought forth the following problems:

1. Who should proctor? There were very few qualified surgeons who knew how to perform laparoscopic cholecystectomy at that time.
2. Could surgeons in group practices proctor each other (Sweetheart deal)?
3. Could surgeons in an institution who were economic competitors proctor each other without bias (conflict of interest)?
4. What were the liabilities of the proctor?
5. Whose liability insurance company provided the coverage?
6. Was a proctor's role defined in the medical staff bylaws?
7. Was a proctor reimbursed for his time and effort? If so, who reimbursed him?

It is the author's opinion that the *proctor* should be perceived to be free of conflict of interest, an impartial observer–not involved in the care of the patient. The duties of the proctor should be clearly defined in the medical staff bylaws and he or she should be allowed to intervene in direct patient care if the observed physician is grossly incompetent, dangerous, or may cause harm to the patient. The reactive action of the proctor should be reported to the medical staff immediately. The proctor should be provided liability insurance in case he or she intervenes in the care of the patient and this results in an adverse outcome. Since proctoring is part and parcel of the peer review process, protection

from liability is provided by existing state and federal laws. However, he or she is not immune from medical malpractice. There should be a clearly defined policy regarding proctors intervening in patient care. A confirmatory letter from the malpractice insurance carrier of the hospital, to indemnify the proctored physician for any damages that might occur due to the intervention of the proctor, should be on board and available.

EVALUATION OF COMPETENCY

Board certification, re-certification, and other related classroom written examinations do not completely assess competency. To assess competency properly, didactic cognitive skills can be evaluated by written examination; however, these examinations never fully evaluate the proper application of these skills to patient care. To evaluate actual clinical performance, such as in the case of practitioners of invasive procedures, only careful on-site evaluation would judge the competency of the practitioner. In other words, a practitioner's actual performance in his office and operating room should be taken into account. To perform these functions satisfactorily, hospital credentialing bodies are faced with "political" and "turf" problems. For example, who should be performing endoscopic evaluation of colon–family practitioner, gastroenterologist, general surgeon, colorectal surgeon, etc.? What numbers of colonoscopies should be performed prior to granting of privileges? How do you determine competency? Does time to reach the cecum matter? Do numbers of procedures performed matter in judging competency? SAGES and ASGE have had problems addressing these issues.[8] A proctor with proper qualifications may be able to provide credentialing bodies with sufficient information to evaluate a candidate properly.

MONITORING OF QUALITY

The quality, cost, and efficiency of care should be monitored as part of the Continuous Quality Improvement (CQI) programs. Concurrent review of all newly approved procedures should be maintained. All adverse outcomes should be analyzed and, if necessary, additional proctoring, additional training, or even restriction of privileges may be necessary. A clearly defined, well-structured process to identify, monitor, and remedy problems should be incorporated into medical staff bylaws to avoid unnecessary litigation.

The physician who is the peer reviewer today may be the physician under review tomorrow. It is in all physicians' interest, therefore, to seek fairness and balance in the peer review process.

NEW PROCEDURES IN LAPAROSCOPIC SURGERY

Newer techniques such as TEM (transanal endoscopic microsurgery), laparoscopic hernia repair, etc., are being developed rapidly. Surgeons who are already proficient in basic laparoscopic techniques should be allowed to progress onto advanced techniques if appropriate training is obtained, either by lecture or videotape or by preceptorship. The training would be scrutinized by the credentials committee, service chief, or both. Standards should be upgraded periodically when new variations of technique are introduced. Above all, constant concurrent review and analysis of adverse outcomes should be vigorously pursued.

In the era of cost containment, newer technology and new or revised minimally invasive procedures call for intensive evaluation of the benefits of the new procedures. It was proven beyond doubt that laparoscopic cholecystectomy was a cost-effective procedure. Not only did it reduce the length of stay, but it significantly reduced the postoperative care. The added cost was for technology used in the operating room. However, because of the widespread use of laparoscopic cholecystectomy, the cost of this technology was reduced significantly due to market competition for the newer products. The laparoscopic appendectomy, colon resection, laparoscopic assisted vaginal hysterectomy, and hernia operations may not be cost-effective. Due to this, hospitals, HMOs, and managed care organizations will in the future use economic credentialing to restrict the development of these newer techniques. The author perceives that the cost benefits of these procedures will have to be analyzed prior to the surgeon's being reimbursed for these procedures by these organizations.

Logical advancement of current standard operative techniques to minimally invasive surgery should be the cornerstone of rational granting of privileges. Completely new and unproven methods not evolving from standard operative techniques should be referred to the Institutional Review Board Committee so that uncontrolled human experimentation is not a byproduct of technology.

A MODEL FOR CREDENTIALING FOR NEW PROCEDURES

In 1989, at the onset of the current laparoscopic revolution, the authors were asked to set up a rational approach to credentialing, proctoring, and outcomes measurement for laparoscopic cholecystectomy in a community hospital.

An outcomes measurement model was proposed and accepted by the credentialing committee of the hospital.

Essentials

Credentialing. A laparoscopic subcommittee of the main credentialing body was formed. (The first author of the paper was the chairperson of the subcommittee.) At this time, the surgeons on the staff had not been privileged to perform laparoscopic cholecystectomy; the other members of the subcommittee consisted of three senior politically active surgeons.

The following standards were approved:

1. Training: SAGES-approved courses or equivalent training.
2. Proctoring of 10 cases in the operating room.
3. Two Surgeons requirement: surgeon/co-surgeon team to operate on every laparoscopic cholecystectomy patient.
4. Nursing team dedicated to LC.
5. Concurrent 100% review of all laparoscopic cholecystectomy operations.

Outcomes Measurement. All cases of laparoscopic cholecystectomy were monitored for the following:

1. Operating times.
2. Intraoperative complications.
3. Forced or elective conversions.
4. Re-operations.
5. E.R.C.P. referrals and concomitant survey of endoscopic suite procedures.
6. Requests from outside hospitals for records on our laparoscopic cholecystectomy patients to determine whether delayed complications were treated at other facilities other than our hospital.

Results of this specific, surgeon-friendly, cooperative effort were spectacular. There were no common bile duct injuries.[13]

Relaxation of Strict Criteria and Monitoring

In November 1993, the parent credentialing body changed the Two Surgeons requirement for LCs. One hundred consecutive laparoscopic cholecystectomies were monitored to see whether there would be any changes in the morbidity and mortality. None was observed. (Presented in Luxembourg, Third International Congress: June 17, 1995.)

The authors are of the opinion that strict credentialing, 100% outcomes measurement, proctoring, and gradual relaxation of criteria are in the best interest of the patient.

The authors submit that whenever a radically new procedure is introduced, the above model would prevent untoward patient outcomes. The patient is protected by this joint cooperative effort of the surgeons involved in providing high-caliber professional care.

CONCLUSION

The Joint Commission on Accreditation of Health Care Organizations has charged the hospitals in the United States to evaluate the credentials of applicants to the medical staff.[12] Based on a careful evaluation, specific clinical privileges should be granted to the practitioners. Prior to granting of privileges, careful evaluation of the training methods used to upgrade the skills of practitioners should be scrutinized. Only proper training should be acceptable.[11]

Each hospital has to develop its own criteria to determine (1) if a new procedure is safe, (2) whether a new procedure is sufficiently different from the current procedure to require additional privileges, (3) what should be the privileging criteria for this new procedure, and (4) how the quality and efficiency of performance of these procedures should be monitored.

It is the author's opinion that minimally invasive surgical technique may be applied to proven open surgical techniques with known outcomes. The results of this application should meet or exceed the expectations of outcomes based on open surgery. To achieve this, concurrent review of all new procedures should be maintained until surgeons develop sufficient proficiency with the given technique.

Institutional Review Boards should be active in evaluating new and unproven techniques that are not evolving directly from standard operative techniques.

It should be the responsibility of the department of surgery, through its chief, to recommend individual surgeons for privileges in laparoscopic general surgery and whenever newer techniques are introduced. A subcommittee of specialists in the particular discipline should evaluate each new procedure and recommend them to the chief of the department of surgery. The motto should be "Do No Harm."

Comments by David McConkey

"EHS Good Samaritan Hospital is committed to quality and is frequently interviewed by local and national news media regarding its quality services. When laparoscopic procedures were introduced, the author was one of the first in the metro Chicago area to perform the procedure. Due to his commitment to quality, he insisted on proper training and surgeon/co-surgeon teams and began to gather data regarding quality. Some hospitals quickly credentailed surgeons to perform the procedure without concern for appropriate credentialing criteria to be sure the procedures were done in their institutions. However, EHS Good Samaritan continued to support the two surgeon rule and appropriateness of skill.[13] As a result, we were picked by Prime-Time Live to illustrate how quality can be assured for patients."

Comments by J. Knipmeyer, M.D.

"In reviewing the article by Mohan Airan on credentialing, privileging, and proctoring in the era of laparoscopic surgery, it is certainly pertinent and important to the changes that are occurring in the healthcare field. As more and more surgery moves from the hospital to an outpatient setting, credentialing and proctoring of laparoscopy procedures become even more important and critical and the technology will continue to grow in this field.

The article is applicable to pelviscopy for the gynecological surgeon as the techniques become more refined in doing myomectomies, cystectomies, and reconstructive surgery.

The economic credentialing is an extremely important aspect that will need to be considered in more detail in the future. As Managed Care continues to grow, capitation is an entity that will dictate economic credentialing more and more for the physician in the hospital as well.

As system-wide hospital systems are developed, minimal standards for credentialing and proctoring in the field of laparoscopic surgery becomes important. Individual hospitals can then scrutinize for higher standards for specialized techniques as pointed out by the author. The cost of the procedure and time in the operating room must also be taken into consideration. This has been shown in studies from a gynecological point of view and the increased time that laparoscopy-assisted vaginal hysterectomies (LAVH) vs. vaginal hysterectomy has been shown not to be cost-effective as the LAVH becomes more expensive due to intraoperative charges.

In summary, an excellent article that is extremely pertinent to us at this time in the changing healthcare field where economic factors, credentialing, and new technology become important." STI

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