

The introduction of laparoscopic cholecystectomy to Australia and New Zealand: an illustration of establishing training and standards for new clinical privileges

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The introduction of new technology or procedures raises the issues: who should do it and use it? what training should they have? where should it be performed? what cases are appropriate? and how is outcome evaluated and who does the evaluation? The problem is well illustrated by laparoscopic cholecystectomy, which in Australia and New Zealand unlike other countries, was introduced within the College of Surgeons. The College's responsibility was to assess and then disseminate the new procedure to the community by training surgeons, yet at the same time minimize the risk to the community. The College defined criteria for performing laparoscopic cholecystectomy, facilitated workshops and defined how they should be organized, carried out a national audit of laparoscopic cholecystectomy and has subsequently set criteria for the introduction of advanced and other minimal access techniques. With the College delineating guidelines, individual institutions then had the responsibility of credentialling their surgeons. As it is impractical to credential for each individual procedure, the solution is to credential groups' procedures. Equivalent procedures are those in which what is achieved laparoscopically is the same as open, e.g. cholecystectomy (provided intraoperative cholangiography is still used). Alternate procedures are those in which the laparoscopic procedure is changed from the open procedure or the outcome is uncertain, e.g. bowel resection. These procedures should be limited to those undertaking them within an institutional trial or audit. Indifferent procedures are those in which existing surgical principles are not followed, e.g. laparoscopic inguinal hernia repair. These procedures should only be performed in a controlled clinical trial. New techniques and procedures can be introduced safely provided guidelines are established by the Colleges for institutions to act on. Audit by both is essential.

Key words: Laparoscopic cholecystectomy; credentialling

Professor Alfred Cuschieri at the 1993 Annual Scientific Conference of the Royal Australasian College of Surgeons described the development of laparoscopic general surgery as the 'greatest unaudited free-for-all in the history of surgery'. This is a lamentable truth but perhaps has not been so severe in Australia and New Zealand. This is perhaps due to the involvement of the Royal Australasian College of Surgeons from the begin-

ning of the general surgical laparoscopic revolution. This is unlike many other countries where the procedures started outside academia and the surgical mainstream, encouraged by commercial interests as well as media publicity and were indeed actively resisted by the surgical establishment.

The introduction of laparoscopic surgery, like the introduction of any new technology or procedure raises the issues: who should use it or do it? what training should they have? where should it be performed? what cases are appropriate? and how is outcome evaluated and who does the evaluation? Before the first laparoscopic cholecystectomy was performed in Australia at the Austin Hospital in February 1990, the President of the Australasian College of Surgeons was notified regarding the Professorial Unit's preparation. Appropriately, as the

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custodian of surgical standards in Australia and New Zealand, the College has been involved ever since.

Who should perform laparoscopic cholecystectomy and what training they should have was established by the College and published in the November 1990 College Bulletin; i.e. the person should have biliary surgical experience, laparoscopic experience and laparoscopic cholecystectomy experience, the latter in workshops plus clinical assisting experience as opportunities developed¹. The dilemma then was how to provide that experience for established biliary surgeons who were currently doing 30 000 cholecystectomies per year in Australia and New Zealand, as well as how to train the next generation of surgeons, the advanced trainees. Workshops were run throughout the country with outstanding cooperation and contribution from the country's experienced surgeons. These workshops were generally run under the auspices of the continuing Medical Education (CME) of the Royal Australasian College of Surgeons. The workshops' success was also dependent upon support from the instrument/equipment manufacturers. These workshops were not designed to be profit-making and the CME Committee carefully defined, in the College Bulletin, guidelines to ensure that the scientific content of the programmes was totally independent and that the financial aspects (i.e. profits if any) were appropriately dispersed for further education².

What cases should be selected for laparoscopic treatment resulted from discussion at such workshops and by the Upper Gastrointestinal Section of the College, a subgroup of the Division of General Surgery. Where the surgery should be performed was an issue initiated by those responsible for providing the funding, i.e. Government. It is a process in which the College is participating by laying down principles. It is clear that a surgeon and an institution should perform sufficient cases, first to maintain expertise and second to ensure efficient economic utilization of capital outlay for the equipment.

The College, in laying down guidelines regarding laparoscopic cholecystectomy and participating in the training process, then had a duty to evaluate the performance of that training. As a result, a national audit was coordinated and reported at the 1991 Annual Scientific Conference of the College in Sydney. Although questions remain as to whether adverse outcome was missed in this semi-voluntary audit, the result suggested minimal morbidity, with a bile duct injury rate of 0.2%, equivalent to the open procedure. Even though laparoscopic cholecystectomy was performed in selected (uncomplicated) cases, this appeared to be an acceptable outcome³. Subsequent audits and reviews, however, have suggested this injury rate may not be accurate^{4,5}. The rate of referral of major bile duct injury to specialist hepatobiliary surgical units has increased, for example to Professor Miles Little, Westmead Hospital, Sydney, it has increased 2.4-fold⁴. A study in New Zealand incorporating a voluntary audit as well as an audit of endoscopic retrograde cholangiopancreatography (ERCP) referrals, suggested that, overall, bile duct injuries actually occurred in almost 1%⁵. This suggests that either the original audit was incorrect or

that as the procedure became more widespread less experienced surgeons were causing more injuries. Both are perhaps true as injury rates are high early in a surgeon's experience⁶. However, quality of training does influence outcome in that in a US centre where surgeons had to be assisted by an experienced surgeon in their first 10 cases, in 511 laparoscopic cholecystectomies there were no duct injuries as compared to a 0.6% rate for the rest of the country⁷. Untrained surgeons learning as they go and thereby producing an epidemic of complications has led to governments and private institutions becoming involved in regulation and credentialling. In New York, the Department of Health banned laparoscopic surgery for a period as a result of the 7–15-fold increase in duct injuries. They rightly demanded that guidelines for training and credentialling be set by professional associations⁸. In London, a private hospital introduced its own credentialling for laparoscopic surgery after it found itself in court as co-defendant following a laparoscopic surgical death⁹. The latter, hospital credentialling is not only appropriate but essential. The former, government involvement in any aspect of surgical decision-making or practice, although necessary in this case, is a dangerous precedent. The initiative for standards of practice must be set by the custodian of standards, i.e. the College of Surgeons, with government and hospitals then using those guidelines for regulation and credentialling. Guidelines for credentialling are therefore essential and it is not sufficient to say that a Fellowship alone qualifies a surgeon to perform any procedure they wish. Unlike most other major developments in surgery, the laparoscopic revolution has required the learning of completely new skills^{10–12}.

The problem of training and credentialling becomes even more complex as the use of the laparoscopic is extended in both number of cases and types of procedures performed. At the Austin Hospital, Melbourne, for example, comparing two 12-month periods before and since laparoscopic cholecystectomy started, the number of cholecystectomies performed has more than doubled, which with an initial increased operating time per patient, resulted in a reduction of 12% of total cases performed. This increase in cholecystectomy reflects increased referral, not altered indications for cholecystectomy. By the end of 1992, the role of the laparoscope had expanded such that 14% of all non-day case surgical procedures were being performed laparoscopically. Note, interventional laparoscopic procedures are not yet being performed on a day case basis in Australia. This change in practice clearly has implications for theatre and ward design, hospital budget allocation, as well as surgeon, nurse and technician training and possibly type of surgical discipline. A suggestion however that a speciality of laparoscopic surgery develop should be resisted at all costs to prevent surgeons being reduced to mere technicians.

Should credentialling apply to each and every one of these new procedures? To attempt to do so might create the following problems. First, restrictive credentialling guidelines by those who assume themselves to be in a position to create them might result in accusations of turf

protection. Such an example is the flexible endoscopy guidelines laid down unilaterally by the Gastroenterology Society of Australia. This newly formed Society was rightly concerned about the growth of gastro-intestinal (GI) endoscopic procedures, the training of those who were performing it and thus the safety and productivity of these procedures. Naïvely, they set a rigid criteria for endoscopic procedures, including specific and arbitrary numbers, without consultation with the custodians of standards, the Royal Colleges. The College of Surgeons was rightly concerned that the guidelines would mean even fewer surgeons practising GI endoscopy. First, this was because some hospitals concerned about the legal implications acted immediately on these guidelines and removed privileges from surgeons for whom endoscopy had been part of their practice for years but who were not in a position to document their original training. Second, because some medical gastroenterology units refused to train surgeons, ultimately this would have meant even fewer surgeons trained to the arbitrary standards and therefore credentialled to perform the procedures. The belated establishment of a tripartite endoscopy recognition (not credentialling) committee of the Colleges of Surgeons, Physicians and the Gastroenterology Society has partially resolved the issue. The second problem of restrictive credentialling guidelines is that they may be inappropriately used as a legal precedent in a malpractice suit. Fulfilling numbers of cases is a measure of experience, not necessarily competence, some surgeons learning laparoscopic cholecystectomy in five cases whilst there are others who will never learn. It is necessary for Hospital Credentialling Committees using College guidelines to identify the latter.

The opposite end of the credentialling spectrum is to have loose or no guidelines at all. The problem then is that the public at large may be put at risk as each surgeon learns from the experience of their own complications. It is preferable, as new procedures develop, that the numbers of patients exposed to possible risks be minimized by investigating the procedure in controlled trials in a limited number of appropriate institutions. If found to be safe and effective, the most appropriate technique can be disseminated to the rest of the profession. An example of the implications of this approach, laparoscopic hernia, is given below.

Irrespective of the guidelines established, the development of new procedures raises the question of informed consent. Every patient should be told the presumed benefits of a new procedure, the known or predicted complications and their possible incidence, the alternative therapies available and their risks and benefits, as well as the individual surgeons' experience.

A compromise between these two extremes of guideline establishment for credentialling may be to group procedures together as suggested by Cuschieri at the 1993 Annual Scientific Congress of the Royal Australasian College of Surgeons. The first group of procedures might be defined as equivalent procedures, i.e. those in which what is achieved laparoscopically is exactly the same as was achieved in the open era. Individual surgeons should

be responsible for auditing their own experience. An example is laparoscopic cholecystectomy, provided intraoperative cholangiography is performed. This was the standard of care in Australia and New Zealand in the open cholecystectomy era, 87% of cholecystectomies having an intraoperative cholangiogram¹³. It is no longer the standard, only 23% of cholecystectomies now have an intraoperative cholangiogram, instead ERCP usage has increased 43% whilst endoscopic sphincterotomy has increased 242%¹³. The abandonment of the surgical principles that all stones, gallbladder and bile duct, be diagnosed and dealt with at the same procedure cannot be justified on the basis of the additional risk of these alternative procedures¹³. The second group of procedures are alternative procedures i.e. those in which the laparoscopic procedure is new or changed or in which there is some uncertainty of outcome or place. Such procedures should only be carried out in an audited environment or clinical trial. An example is colon resection. Guidelines laid down by the Colorectal Section of the Australasian College clearly define principles of, indications and contraindications for laparoscopic treatment as well as the role of audit of outcome.

A third group of procedures might be defined as indifferent procedures. These are procedures in which existing surgical principles are not followed or there is no attempt to reproduce that which was achieved in the open era. An example is laparoscopic inguinal hernia repair. If the two criteria for performing a procedure laparoscopically are accepted i.e. that the pathology be safely and effectively managed with laparoscopic instrumentation and that the major morbidity of the procedure replaced was the wound of access, then laparoscopic inguinal hernia repair simply defies logic. Although controlled clinical trials of the procedure are in process, there has to date been no published data of outcome confirming benefit. Despite this, laparoscopic hernia repair was widely practised. This practice was based on published or presented clinical reports of personal series, all self-assessed. Scientifically, these reports are valueless. In the interim, the next best source of data is prospective clinical series, independently assessed.

Such a series was presented at an Australia update of endosurgery at Hamilton Island, Queensland, July 1993, sponsored by Monash University Melbourne. Of 232 consecutive patients, at follow-up, recurrence for indirect hernia use was 4% whilst for direct hernias it was 40%¹⁴. This is 3–30 times worse than could be expected from open hernia repair¹⁵. Further, a potentially local-anaesthetic day-case procedure was converted to an inpatient general anaesthetic case with its associated cost and risk. Of more major concern were the reports of complications such as ruptured bladder (1.3%), hernia through the cannula sites (1.7%) and nerve injury (2.3%). Even more disturbing still, as a result of the peritoneal cavity being entered, was the predictable occurrence of adhesional small intestinal obstruction at 0.5% in the short follow-up period of 12 months. This is likely to be four times greater in the patient's remaining lifetime. Adhesions account for 75% of all small bowel obstructions with a 10–15% mortality¹⁶. In Australia, 40 000 inguinal

hernia repairs are performed every year. The estimate was that 5% were being performed laparoscopically in an uncontrolled manner by individual surgeons. Currently, there are three clinical trials being undertaken of open vs. laparoscopic hernia repair in which it is calculated that 110 patients are required in each arm to determine whether there are differences in immediate morbidity, hospital day stay and return to work. Table 1 demonstrates the reduction in exposure to the risk of complication, reduction in recurrence and reduction in long term small bowel obstruction between the three Australian clinical trials vs. 5%¹⁴ of the population being experimented on in an uncontrolled manner. With a six-fold greater number of recurrences and bowel obstructions as well as the still-unanswered question as to the value of the procedure, it is clear that indifferent procedures should not be performed at all in the wider community. Those who believe that such procedures do have a role have a duty to prove it in a controlled clinical trial. Fortunately, as a result of such meetings in Hamil-

Table 1. Laparoscopic hernia: the effect of clinical trials on risk reduction

	At 2 years	
	Recurrence	Bowel obstruction
Open access, 40 000/year 5% done laparoscopically	400	10-40
Controlled trials (3) 330 cases	66	1.6-6.4

The figures are based upon an independently assessed Australian audit of laparoscopic hernia¹⁴, i.e. 4-40% recurrence rate, 0.5% initial bowel obstruction rate which might increase four-fold in the patients' lifetime. Numbers in the controlled trials are based on three Australian trials with requirement in each that 110 be in the laparoscopic hernia arm.

ton Island, the number of hernias being performed laparoscopically in Australia has declined sharply.

To conclude, the introduction of new technology such

Table 2. The Royal Australasian College of Surgeons¹⁷ policy on credentialling for and training in new technology or procedures

Credentialling

Delineation of privilege should be determined by a credentialling committee set up by the governing body of the hospital. Credentialling committees should consist of medical practitioners only, and they should include a representative of the College, who is not a member of the hospital staff.

Surgical privileges should be individual-specific, and based upon criteria which include:

1. The individual's curriculum vitae
2. Fellowship of the Royal Australasian College of Surgeons or an equivalent diploma with approved training (the FRACS diploma in a surgical discipline should not necessarily imply competence in every procedure of that discipline; a Credentials Committee might reasonably require additional evidence for privileges to practise in certain areas of the discipline).

Guidelines for Fellows

Fellows wishing to utilize new technology and/or to undertake new or as yet unproved procedures should:

1. Obtain appropriate training and experience in the particular field of surgical practice under consideration.
2. Become knowledgeable in the technology and obtain appropriate experience in the use of the new surgical techniques or technology to be employed.
3. Participate in training courses relating to the new technology and/or procedure(s) when these are available.
4. Demonstrate a satisfactory acquisition of relevant technical skills by assistance at procedures undertaken by a surgeon experienced in the field of practice, and subsequently seek the assistance of such a surgeon during the initial operations of that type, performed by him/her.
5. Follow specific guidelines of a College Division or Section relevant to the procedure(s).
6. Undertake an on-going audit of indications and outcomes of procedures personally performed and to participate in hospital/region/College-based audits of aggregated data.
7. Participate in peer review.

College

To assist Fellow gain appropriate knowledge and experience, the College will:

1. Ensure that the training programmes and examinations for Fellowships include due consideration of the requirements of new technology.
2. Encourage the development of special centres suitable for training in new technology and related procedures. The essential requirement is that such centres are established under the guidance of reputable Fellows, knowledgeable in the field and with experience and acknowledged skill in the procedures. They should be supported with adequate facilities and sufficient staff to enable them to teach surgical colleagues, to assess the technology and to evaluate the procedures.
3. Encourage courses in new technology and related surgical practice to be conducted by appropriate centres.
4. Encourage new procedures to be evaluated initially in specialized units prior to their wide adoption throughout the surgical community.
5. Facilitate the performance of the required audits and peer review.
6. Be advised by the Surgical Boards, the Endosurgery Group, and other specialized groups which may be established by Council on progress and problems associated with the introduction of new technology into surgical practice.

as laparoscopic cholecystectomy illustrates the problem of bringing a new technique to the community yet at the same time minimizing the risk to individuals in that community. It raises the issues of how to evaluate and confirm the benefits of the technology, how to train existing surgeons if the procedure is confirmed to be of value and how to train the next generation of surgeons. The custodians of standards of practice have a duty to prevent an unaudited free-for-all. In Australia and New Zealand, the Australasian College of Surgeons has attempted to lay down guidelines and introduce training for laparoscopic cholecystectomy. As potential laparoscopic applications have been developed, it has laid down broad principles applicable to new technology which furthers science and safeguards the public (Table 2). Within this framework more specific guidelines for individual procedures are being produced. Under these guidelines, individual hospitals are in a position to credential surgeons to practise their art safely and governments are in a position to provide appropriate and adequate facilities and regulate a cost-effective health service. With economic pressures demanding even greater economies, combined with the development of anaesthetic/analgesic techniques and minimal access surgical technology, shorter stay surgery will expand even more in the future. It is hoped that the lessons learnt from the introduction of laparoscopic general surgery will better prepare us for the introduction of the next revolution, whatever and whenever it might be.

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