THE JOURNAL OF OBSTETRICS AND GYNECOLOGY OF INDIA

The Journal of Obstetrics and Gynecology of India (January–February 2013) 63(1):7–13
DOI 10.1007/s13224-013-0405-3

REVIEW ARTICLE

Standards for Gynecologic Surgery

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Received: 7 February 2013 / Accepted: 12 March 2013 / Published online: 26 April 2013

Abstract There are significant problems to consider when we reflect on "Standards for Gynecologic Surgery." Surely most professional standards are already in place, or are they? Are standards already available, locally, nationally, or internationally? Where those standards are not already available will it be possible set new standards for the multiplicity of operative interventions, performed by an array of trainees, specialists, and colleagues many of whom are outside of our remit and spread over the continents? If we do set standards how do we audit outcomes to gynecologic surgery and insure that the standards are being complied with? How do we tutor our trainees effectively and also insure that established specialists retain their skill base, are up-to-date, and compliant with continuing medical education? It is important to realize that the success or failure of a modern surgical investigation or procedure will now be judged not on the pure surgical outcome alone, but will also need to reflect patient focus through excellence in the areas of communication, patient information, informed consent and confidentiality. The accessibility to services, appropriate environment, and processes being offered by trained and competent staff members—who are supervised when required—should all be included in audits of outcomes set against agreed auditable standards.

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Introduction

Gynecologic surgical procedures and instrumentation were perfected by world-acclaimed colleagues from previous centuries. James Marion Sims, the Father of American Gynecology, Sir Kedarnath Das of Calcutta foundation—a member of the Royal College of Obstetricians and Gynaecologists, London, along with the great surgeons, Victor Bonney of London and Munro Kerr of Glasgow, shaped the future of gynecologic surgery for many decades. However, the advent of endoscopic investigations and procedures pioneered by Kurt Semm of Kiel in Germany in the mid-1980s was to challenge the old order.

The scope of modern gynecologic surgery, encompassing the older conventional or open surgery and the newer endoscopic approach, is complex. Setting standards is therefore intricate and no easy task. Before launching into the topic it is well to remember that surgery is inherently a risky procedure. The long term benefits and side-effects of surgery are often not evaluated. In addition, we must acknowledge that medical errors do also occur.

Based on the information gathered from the Royal College of Surgeons in London, general surgical procedures are very common, equating to one operation for every 12 persons per year, and account for roughly one tenth of the HealthCare budget [1]. Although English

figures are not directly comparable, one wonders what the statistics for India could be with its population of 1.21 billion.

The Scope of Gynecologic Surgery

The speciality has gone through major changes over recent decades and now gynecologic surgery is performed and shared by many colleagues. There are Obstetrics and Gynecology generalists who perform a wide range of surgical interventions and sub-specialists whose expertise lies in specific areas although such professionals may also serve on a generalist obstetrical roster while "on call." In addition there are our trainees, from the novice to those now awaiting specialist certification.

Other disciplines, such as general surgeons, urological and rectal surgeons, general practitioners, family planning experts, and others operate on the reproductive tract or structures close by. It is also well to remember that obstetrical surgery encompasses a rising 27–30 % Cesarean Section rate and operative vaginal deliveries and their unwanted side-effects are common.

The rapid growth of endoscopic surgery since the mid-1980s has changed the modern operating list which now reflects expertise gained in new techniques, but reflects a loss of skill in what was once considered the pantheon of general gynecology surgical investigations and procedures.

Added to this is a combination of various other factors that have shaped the current gynecologic surgery procedures, such as effective newer medications like the Mirena IUCD and their impact on reproductive functions, as well as the reduction in family size; loss of generalist gynecologists, while sub-specialisms flourished; the difficulty in retaining inpatient gynecology surgical beds; the increased use of outpatient surgery and the increased public awareness and medical litigation; and changes in training curricula and actual time spent in training with the consequent loss of hands-on operative experience.

Therefore, there are significant problems to consider when we reflect on "Standards for Gynecologic Surgery." What are those standards and how may they apply to the diverse interest groups, operative scenarios and the multiple operative procedures involved?

What are Standards?

By definition, a standard is an agreed level of quality or attainment that is required to develop safety, repeatability, or quality in a process [2]. Medical standards of care are investigations and/or treatment guidelines based on scientific evidence and collaboration between the professionals involved. It is well to remember that in legal terms, a medical standard is the level at which another prudent professional—with the same level of training and experience, in good standing, and working in a similar community—would conduct his/her practice in a similar set of circumstances.

A physician also has a duty to properly inform the patient of the benefits and of any material risks that might cause the patient to reconsider a procedure. The Code of Ethics Medical Council of India clearly states "The physician should neither exaggerate nor minimize the gravity of a patient's condition. He should insure himself that the patient, his relatives or his responsible friends have such knowledge of the patient's condition as will serve the best interests of the patient and the family" [3]. A recipient of pro bono (free) services is entitled to expect the same standard of care as a person who pays.

Why are Standards Necessary?

Why in 2013 is standard setting even necessary; surely, after all the advances in our profession, we know what standards apply, and on a routine basis which we comply with, and attain those standards? The international news media organisations pay close attention to surgical outcomes, and some recent news stories from the UK might dent our confidence in relation to standards in the profession.

NCRI Cancer Research UK

The National Cancer Research Institute (NCRI) in the UK made headline news in November 2012, in an item on cancer carried and debated widely in the national media. A press release from the 8th National Cancer Research Institute Cancer Conference pointed out that until late 2012 there were no national figures on complication rates in Gynecologic Oncology surgery in the UK. The news media reported that the first UK multicenter figures available revealed that one in five women having major gynecologic cancer surgery have some sort of complication.

The initial findings of the UK Gynaecological Oncology Surgical Outcomes and Complications (UKGOSOC) audit also revealed that one in 30 women experiences a serious complication which may need another operation or procedure.

According to the authors of the audit "there have been no multicenter figures on complication rates following surgery for gynecologic cancers. This has meant that we have been unable to properly counsel our patients in preparation for surgery". In a further statement they said

"we hope to see this electronic data collection process brought into routine practice to help us to continue to improve surgical outcomes in the UK". The Director of the NCRI commented that "all surgery carries risks and its important that patients know that there may be complications during and after their operations. Setting nationwide benchmarks… will give better outcomes for the patients of the future" [4].

Bonuses, General Health News

Hot on the heels of the above announcement on cancer services came the news on financing the Health Service in the UK. In an item carried in General Health News (November 09, 2012), Krishna reported in a paper by Matt Sutton of Manchester University and colleagues that "financial incentives may improve hospital mortality rates. Economists and health experts from the four UK universities examined how the introduction of a scheme that paid bonuses to hospitals based on measures of quality affected the delivery of care" [5, 6].

A "significant" fall in mortality rates for certain conditions emerged in the study of financial incentives at hospitals in the North West of England. Paying bonuses for improving quality of care resulted in 890 lives being saved during the 18 month scheme. The findings could have major policy implications in healthcare.

Another key conclusion of the paper was that despite the competitive nature of the incentives program, staff met regularly within the region to share problems and ideas of best practice. This in turn led to higher standards of care and better outcome for patients.

The Bristol Inquiry

From an historical perspective it was the Bristol Inquiry that brought international attention to standards of medical care. The Bristol Case involved heart surgery on babies in Britain's world-renowned Bristol Royal Infirmary. A whistleblower raised concerns about the high mortality rate of babies undergoing heart surgery there. This eventually led to the biggest public inquiry ever undertaken into the workings of the NHS. The inquiry determined that between 30 and 35 babies died over a 5-year cycle and that over a whole decade, up to 170 might have been saved had they been operated upon elsewhere.

The whistleblower, a cardiac surgery anesthetist at Bristol, repeatedly raised his concerns with the surgeons, colleagues and the chief executive apparently to no avail. He also contacted the President of the Royal College of Surgeons and the Department of Health was also informed. Two surgeons and the chief executive faced charges of serious misconduct. Sir Ian Kennedy who chaired the Bristol Inquiry found that there were staff shortages, a lack of leadership and the unit was "simply not up to the task." The inquiry found "an old boy's culture" among doctors, a lax approach to safety, secrecy about doctors' performance and a lack of monitoring by management [7, 8].

King Edward Memorial Hospital Inquiry

More recently, the so-called Douglas Inquiry investigated the Obstetrics and Gynaecological services at King Edward Memorial Hospital (KEMH), Perth. The inquiry found that there was inadequate clinical governance and failed delivery of safe, quality care. Management failed to respond effectively to complaints. Quality systems were absent or ineffective. Links between complaints and quality improvement were non-existent or ineffective, as were training, credentialing, and performance management systems.

In a paper reporting on the findings, McLean and Walsh wrote: "The Douglas Inquiry is a wake-up call for governments, Boards, chief executives, managers and clinicians to understand and meet the responsibilities and challenges of safety and quality in health care. No longer is it acceptable for Boards and managers to treat the safety and quality of clinical services as the exclusive prerogative and responsibility of the clinician. No longer is it acceptable for boards and managers to ignore or override safety and quality concerns in the name of rigid adherence to externally imposed financial constraints.

At KEMH, inadequate clinical governance, poor or non-existent systems and ineffective responses to important issues resulted in serious adverse events and poor clinical outcomes for women, babies and families. The system-wide implications are significant and clear—to enable safe, quality care the industry needs:

- strong, effective clinical governance and leadership supporting a culture of open disclosure;
- commitment to and accountability for effectively addressing performance problems;
- a rigorous third party accreditation system that assures acceptable practice and performance standards; practical and useful data collection systems for inter-hospital comparisons;
- standardised credentialling systems to ensure clinicians have appropriate skills and training;
- reliable and consistent incident and adverse event reporting systems and follow-up processes;
- clear and practical statutory requirements and systems for mortality reporting and investigation.

Governments, health service boards, health care leaders, managers and clinicians have the opportunity to learn from the Douglas Inquiry's lessons and lead the way to improved hospital systems and better, safer patient care" [9].

Elective Conventional (Open) Gynecology Surgery

There are many reports on the safety, or otherwise, of conventional gynecologic surgery. Papers published in the American Journals during the last decade carry a flavor of the outcomes for older women undergoing conventional (open) surgery for utero-vaginal prolapse and urinary disorders. Toglia and Nolan [10] reported a 27 % complication rate in their study, including a number of deaths. While in another study from New Orleans, Mains, Magnus, and Finan reported a 44.6 % complication rate including a mortality rate of 3.6 % in older women [11]. However, what about laparoscopic procedures and their complication rates?

Gynecology Laparoscopic Complications

In a French study of almost 30,000 cases Chapron and colleagues reported a low complication rate of only 4.9 per 1000 laparoscopies but commented that "the methods of postoperative monitoring must be adapted to take into account the shorter hospital stay" and worryingly stated that a considerable number of complications go unnoticed intra-operatively [12]. The authors also stressed that the part played by the surgeon's experience in their study highlighted the importance of the methods and training assessment in endoscopy.

MacCordick and co-workers recorded a complication rate for operative laparoscopy of 2.9 % from a tertiary care center where only senior surgeons operated. About half of the complications occurred during the installation of the laparoscopic procedure. The authors extolled the virtues of adherence to safety rules to reduce the incidence of unwanted side-effects [13].

Audit of Standards

The first gynecologic audit came from the research of Thomas Addis Emmet of the Woman's Hospital New York. He wrote a definitive account of 202 vesico-vaginal fistula cases, their outcome and means to improve those outcomes in 1879 [14]. However, Ernest Codman of Boston, Massachusetts became known as the first true medical auditor following his research on monitoring of surgical outcomes in 1918 [15]. Codman's "end result idea" was to follow every patient's case history after surgery to identify individual surgeon's errors on specific patients. Eventually, clinical audit as part of professional healthcare was formally incorporated into the healthcare systems of a number of countries only 20 years ago, for instance in 1993 into the United Kingdom's National Health Service.

Clinical Audit

The general definition of an audit is an evaluation of a person, organization, system, process, enterprise, project or product. The key component of clinical audit is that performance is reviewed or evaluated, i.e., audited to insure that what should be done is being done, and if not it provides a framework to enable improvements to be made [16].

The commonest type we deal with is standards-based audit, a cycle which involves defining standards, collecting data to measure current practice against those standards, and implementing any changes deemed necessary. Adverse occurrence screening (critical incident monitoring), peer review, and patient surveys are other types of audit that may be necessary.

The Cycle of Audit

The cycle of audit involves identification of the problem or the practice to be audited and setting criteria or standards. The relevant practice is observed and data collected. At this stage, the data can be compared with the criteria already agreed. Finally, changes can be implemented, if required.

Standards for Gynecology

There are some excellent examples for standard setting in the literature. In general surgery the Royal College of Surgeons of England produced the excellent "Good Surgical Practice in 2008 [17]. In gynaecology, the ICOG/FOGSI recommendations for "Good Clinical Practice, Female Sterilization" were at the forefront of the recent evolution of standard setting in medical practice and offer a vision for future standard setting in both obstetrics and gynecology [18].

In Europe, the Royal College of Obstetricians and Gynaecologists stated objective is to set standards to improve women's health with the ultimate objective to provide an equitable and safe service with best possible outcomes for women seeking gynecologic care. The Standards for Gynaecology [19] and Standards for

Maternity Care [20] produced by the RCOG provide very clear objectives and methodology and are models in standard setting, worth aspiring to.

Within the Standards for Gynaecology document, the standards for laparoscopy are expertly laid out and are of particular relevance to this review. It is important that we apply these or similar national standards for endoscopy and also to apply them to conventional open surgery where possible.

We are aware that lack of patient focus has led to inappropriate surgery and litigation in many cases, and the Medical Council deals with many complaints about poor professional performance in this area. To avoid poor practice, the RCOG recommends that verbal and written information of high quality be provided so that women can make properly informed choices about their care. A full declaration of risks and complication rates associated with laparoscopic surgery, as well as the benefits and also the alternatives to laparoscopy should be made.

While the risks associated with laparoscopy have been well documented, they need to be balanced against the undoubted clinical benefits compared with laparotomy. The focus is toward safe and effective practice, and women need to be supported in making informed choices.

The operating environment, facilities, and staff should be compatible with high-quality equipment for image acquisition and recording. The procedure should be performed to a standard that is recognized nationally and recorded as such in the patient's notes. Protocols should be in place such as "see-and-treat" standards, as well as guidelines for unexpected complications and a referral system, if advanced laparoscopy interventions are required and not available locally.

Data on the outcome to surgery should be collected, and complications evaluated on an ongoing basis. The operator's workload must be appropriate to retain skill-base, and attendance at regular up-dates and recognized scientific meeting should be made mandatory.

When we look to other institutions worldwide, a similar ethos is common to all. Clinical governance structures should be implemented; all health professionals must have a clear understanding of the concept of risk assessment and management to improve the quality of care and safety while reducing preventable adverse clinical incidents. Then, where an adverse incident has occurred, every unit should follow a clear mechanism for managing the situation including investigation, learning, and communication and where necessary, implementing changes to existing systems, training, or staffing levels.

Safety and Surgery

Surgery is intrinsically a risky procedure; yet there are simple safety rules to follow which lead to quality care. In a paper on Safety and Surgery, Haynes et al. [21] wrote that surgical complications of up to 17 % are common and often preventable. The introduction of the simple "WHO Surgical Safety Checklist (SSC)" into operating rooms in eight diverse hospitals internationally by the co-workers was associated with marked improvements in surgical outcomes.

Postoperative complication rates fell by 36 % on average, and death rates fell by a similar amount. Use of the WHO checklist involved both changes in systems and changes in the behaviors of the individual surgical teams. Another mechanism that helped achieve better results was the so-called Hawthorne effect, i.e., an improvement in performance due to subjects' knowledge of being observed.

The WHO SSC does not mention surgical technique at all but identifies three distinct phases of an operation, each corresponding to a specific period in the normal flow of work. There is the "sign in" before the induction of anesthesia; "time out" before the incision of the skin, and "sign out" before the patient leaves the operating facility. In each phase, a "checklist coordinator" must confirm that the surgical team has completed the listed tasks before it proceeds with the procedure.

Confirmation of the patient's identity, the site of operation, the procedure to be carried out, the consent for the procedure, the presence or the absence of allergies are expected at "sign in." At the "time out" prior to the surgery, any anticipated critical events, administration of perioperative antibiotics, and/or anti-thrombotic agents are among the matters to be clarified. The "sign out" procedure involves a nursing staff's check on instruments, sponge, and needle counts and equipment, and insuring that specimens are appropriately labeled. The surgeon, anesthetist, and nursing staff must use the opportunity to discuss any key concerns for recovery management of the patient [22].

However, Sivathasan and colleagues found that, in a study of 238 hospitals, both private and government-run in the UK, there was cause for alarm. Almost all the relevant staff who were interviewed had heard of the SSC, but in only two-thirds of hospitals was its use mandatory. Where the SSC was not compulsory, 80 % were using it informally or sporadically. One-quarter of senior theater personnel in hospitals without compulsory use indicated that they did not know or that their department did not plan on using the checklist in the next 6 months, despite a deadline for implementation [23].

Training

Expressing their unease in 2005, Rogers and Julian of the USA wrote "educators in obstetrics and gynecology are

concerned that the surgical training of residents is not sufficient to meet the needs of new graduates" while remarking that the specialty has greatly increased its body of knowledge, expanded the number, and the variety of procedures performed, and become more business oriented. They concluded "with the current emphasis on evidence-based decision making, shouldn't this same philosophy guide the education of future gynecologic physicians and surgeons?" [24].

The old dictum held by many of "see one, do one, teach one" also known as the "apprentice–tutor model" was useful for training surgeons for many years, but the complexity of surgical technology in the twenty-first century, especially endoscopic surgery, has dramatically increased the demands for surgical education.

As mentioned on the FOGSI website, training methods should ideally follow simulation techniques that evolved in the airline industry [25]. Writing from Perth in Western Australia, Hammond and Karthigasu [26] examined overall training, assessment, and competency in gynecologic surgery noting that the trainee gynecologist requires specific teaching to achieve competency in gynecologic endoscopic surgery.

Basic skills should be acquired outside the operating theater and may be learned on simulations, including bench models, using synthetic materials, life-like models, and animal tissues. They underscored the belief that video training equipment is useful for the development of basic laparoscopic hand–eye coordination. Intermediate and advanced skills require simulations using more sophisticated bench models, live animals, and virtual reality computerized systems.

At a later stage in training, they proposed supervised operating experience on patients which is of course crucial and which should be assessed regularly using a global rating form with constructive feedback to facilitate improvement. The trainee should be assessed in respect of tissue, time, and motion, instrument handling, knowledge of instruments, flow of operation, use of assistants, and knowledge of the specific procedure. The trainee may then be found competent, or not competent, to perform the procedure independently. The paper included a model for training from the novice to the specialist who in turn should be engaged in life-long learning.

LASTT

Molinos and colleagues developed a laparoscopic skills testing and training (LASTT) model and evaluated its use. They concluded that the LASTT model seems a cost-effective tool for providing an in-house program for continuous training and evaluation of LPS in all surgical disciplines in which laparoscopic procedures are, or might be, performed [27]. Simulation training does translate into improved operative performance but must be combined with structured teaching and assessment methods.

FOGSI and ICOG Gynaecology Surgical Training Courses

The FOGSI website notifies excellent Endoscopy training courses, a Basic course of 7 days and an Advanced one of 14 days. Meanwhile, available since 2006 and carried on the ICOG website is the "Principles of Conventional & Minimal Access Surgery" EthiSkills course. In the Slide Share section under Recent Advances is the superb PowerPoint presentation on Hysteroscopy. The FOGSI website also contains a model "consent form" for adoption by the obstetrician gynecologist [28, 29].

Time in Training

Reflecting changes in Europe and the USA, the Calman System of training began in 1996 in the UK and embraced a focused system of training with defined competencies and a shorter training period. This replaced the previous system which was based on the experience gained in an apprentice-type setting with no defined duration of training. Another recent reform that impacted on surgical training in gynecology in Europe was the European Working Time Directive (EWTD) which regulates the number of working hours for junior doctors and aims for a 48-h working week.

The concern among trainees and their trainers is that surgical exposure has been reduced, and therefore trainees acquire limited surgical experience by the time they complete training; in addition, the number of trainees has increased. Results of an audit revealed that the average number of procedures performed by each trainee was reduced by up to 73 % [30]. With those challenges, it is clear that innovative approaches to surgical training in gynecology are required to produce a competent surgeon in a shorter time, or the risk of future consultants having limited surgical experience will increase.

Revalidation

Another impact on doctors is that those who wish to keep their license to practice in the future will need to revalidate. The purpose of revalidation is to assure patients and the public, employers, and other healthcare professionals that licensed doctors are up to date and fit to practice. Doctors will need to demonstrate to the General Medical Council

periodically that, normally every 5 years, they are up-to-date and fit to practice, and complying with the relevant professional standards. The process of revalidation began in the UK in December 2012 [31].

Conflict of interest There are no conflicts of interest to declare.

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