

Quality improvement processes for patient safety in operating room

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Background : *Due to the fact that many risk factors causing complications in surgical patients are related to the processes of patient care. Most surgeons are afraid of any form of complication in their patients and do their best to prevent any risk that may be related either to surgical diseases or surgical treatments. Nevertheless, complications do occur; most of them are specifically related to surgical diseases, It is also important to analyze the processes of care in an effort to decrease complications related to the treatment of the diseases. It is these processes of care that are being increasingly recognized as the etiology for medical errors.*

Methods : *From January 2002 – December 2007, all surgical patients were operated by the operating room services of the Department of Surgery, Bangkok Metropolitan Administration Medical College and Vajira Hospital. The following data were the time intervals to the start of emergency operations, rate of cancellation of operations, rate of repeated operations in single admissions cases, rate of death among operated patients, foreign bodies or instruments retained either in the wound or body of*

the patients, surgical site infections, operations on the wrong patients/ wrong sites/using of wrong procedure, incidence of surgical fire as well as the number of patient operations where accidents were recorded, The data were analyzed and the processes of quality management were improved for patient safety.

Results : *The time interval to the start of an emergency operation was significantly within The target range from 2002 – 2005 ($p < 0.05$). The death rate for operated patients was not significant during the initial process. After the root causes were analyzed and quality improvement processes were completed the death rate significantly decreased after 2004 ($p = 0.01$). Also the rate of operation cancelations has decreased and the result has been significantly within the target range since 2003 ($p < 0.05$). The rate of repeated operations was well correlated with preoperative preparations and the death rate of operated patients. The results of prevention of any foreign body being retained either in the wound or body of the patient were not significantly controlled but incidences of any surgical fire, operations on the wrong patient and incidences of the patients having accidents never occurred. The surgical site infections were significantly within the target range ($p < 0.05$)*

Conclusions : *Improvements in the processes of care in the operating room can decrease complications related to treatments and improve patient safety.*

Keywords : *Patient safety, Quality improvement processes, Operating room.*

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ทวิวงษ์ จุลกมนตรี, ประยุทธ์ ศิริวงษ์, กนก สุวรรณกิจ, ศุภกานต์ เตชะพงศธร, เกษมณี นากสุข, ศิริวรรณ ตันกิตติวัฒน์, ปฎิมา ดีประเสริฐวงษ์, สุธีรัตน์ วงศ์อ่อม. กระบวนการพัฒนาคุณภาพเพื่อความปลอดภัยของผู้ป่วยในห้องผ่าตัดศัลยกรรม. จุฬาลงกรณ์เวชสาร 2553 มี.ค. - เม.ย.; 54(2): 163 - 76

- เหตุผลของการทำวิจัย** : จากความจริงที่ว่าความเสี่ยงที่ทำให้เกิดภาวะแทรกซ้อนในผู้ป่วยศัลยกรรมส่วนหนึ่งเกิดจากกระบวนการดูแลผู้ป่วย, ไม่ได้เกิดจากโรคหรือการผ่าตัดรักษาเพียงอย่างเดียว
- วัตถุประสงค์** : เพื่อวิเคราะห์ข้อมูลของกระบวนการดูแลผู้ป่วย ซึ่งพบว่าเป็นสาเหตุสำคัญส่วนหนึ่งที่ทำให้เกิดภาวะแทรกซ้อนในผู้ป่วยที่รับการผ่าตัดทางศัลยกรรม เพื่อลดภาวะแทรกซ้อนดังกล่าว
- ประเภทโรงพยาบาล** : วิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาล ซึ่งเป็นคณะแพทยศาสตร์ และเป็นศูนย์การแพทย์ระดับตติยภูมิและตติยภูมิขั้นสูงแห่งหนึ่งในประเทศไทย
- รูปแบบการวิจัย** : การวิจัยแบบเก็บข้อมูลไปข้างหน้า ในรูปแบบของการทำวิจัยจากงานประจำ
- สิ่งตรวจและวิธีการทำวิจัย** : เก็บข้อมูลของผู้ป่วยที่รับการผ่าตัดที่ห้องผ่าตัดศัลยกรรมภาควิชาศัลยศาสตร์ วิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาลทุกราย, ทำการวิเคราะห์ข้อมูลที่มีผลต่อความปลอดภัยของผู้ป่วย รวมทั้งกระบวนการพัฒนาคุณภาพการดูแลผู้ป่วย เพื่อความปลอดภัยของผู้ป่วยที่ได้รับการผ่าตัดดังกล่าว
- ผลการศึกษา** : ระยะเวลาที่ผู้ป่วยได้รับการผ่าตัดฉุกเฉินอยู่ในเป้าหมายที่ทำให้เกิด ความปลอดภัยต่อผู้ป่วยอย่างมีนัยสำคัญ ($p < 0.05$) อัตราการตายของผู้ป่วยที่ได้รับการผ่าตัด ($p = 0.01$) และอัตราการยกเลิกการผ่าตัดลดลง อย่างมีนัยสำคัญ ($p < 0.05$) อัตราการทำผ่าตัดซ้ำสัมพันธ์กับการเตรียมผู้ป่วยก่อนการผ่าตัด และอัตราการตายของผู้ป่วยด้วย การพบสิ่งแปลกปลอมในร่างกาย หรือแผลผ่าตัดของผู้ป่วยยังไม่สามารถควบคุมให้อยู่ในเป้าหมายได้ แต่การควบคุมการติดเชื้อแผลผ่าตัดอยู่ในเป้าหมายอย่างมีนัยสำคัญ ($p < 0.05$) การผ่าตัดผิดคน, ผิดตำแหน่ง, ผิดประเภท และอุบัติการณ์การเกิดอวัยวะในห้องผ่าตัดไม่เคยเกิดขึ้น

สรุป : การพัฒนาคุณภาพของกระบวนการดูแลผู้ป่วย สามารถลดภาวะแทรกซ้อน และเพิ่มความปลอดภัยของผู้ป่วยที่ทำผ่าตัดที่ตีกล้ามเนื้อคัลยกรรม

คำสำคัญ : ความปลอดภัยของผู้ป่วย, การพัฒนาคุณภาพกระบวนการดูแลผู้ป่วย, ห้องผ่าตัด

The term “medical errors” has become commonly used as an industrial term that is now prevalent in quality improvement (QI). Complications in surgery have been issues for centuries and are not new concepts. Surgeons are afraid of any form of complication that happens to their patients and they do their best to prevent any adverse event that may be related to surgical diseases or to surgical treatments. It has been well recognized for decades that the onset of a complication usually prolongs the course of an illness and lengthens a hospital stay, as well as increases the morbidity and mortality rates. Therefore the prevention of surgical complications is very importance for surgeons.

Traditionally surgical textbooks have focus more on complications and less on the processes that may have initially led to the complications. A dialogue that has arisen around medical errors now more reasonably provides the surgical community with an opportunity and an improved environment to focus on the processes of care that can lead to a decrease in complications.^(1,2) Although complications do occur that are related specifically related to a surgical disease do occur, it is also important to analyze the processes of care in an effort to decrease complications related to the treatment of the disease. It is these processes of care that are increasingly being recognized as the etiology for error—not the diseases or treatments themselves.

Many QI efforts have now begun to shift toward patient safety and medical errors. Previously, most efforts in surgical QI programs were orientated toward patients’ diseases and their complications (e.g. postoperative abscesses following a perforated

viscous repair), provider decisions (e.g., a delayed diagnosis or error in decision making), and to a lesser extent, the system related to patient care. Currently, the awareness of patient safety has moved beyond organized healthcare system enterprises and a few professional organizations, the focus on QI programs at many levels has also appropriately begun to shift toward patient safety, processes of care and a recognition of the inherent complexity that characterizes all health care processes is necessary before any alternative quality improvement solutions can be sought.⁽³⁻⁶⁾ Recently, groups such as the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), the Leap Frog Group, and the Institute for Healthcare Improvement (IHI) have begun offering alternative quality improvement solutions specific to the health care system.

The quality improvement processes are now an integral part of healthcare system. The majority of programs focus on the recognition of problems, errors, system inefficiency or patient safety concerns and ongoing improvements in care efficiencies in order to become an inherent goal for practitioners in the various health care systems and environments.^(2, 4-21)

This qualitative analysis is an integral part of The quality improvement processes for the hospital accreditation program.

Methods

From January 2002 to December 2007, the Bangkok Metropolitan Administration Medical College and Vajira Hospital (BMA), one of the medical schools in Thailand, is undergoing a quality improvement

process for Thailand’s institute of hospital quality and improvement accreditation program. The Department of Surgery, BMA, is a tertiary and supertertiary medical center and teaching hospital for nursing and medical students, and also for residents in surgical. In the quality improvement (QI) processes, the Department of Surgery has two responsibilities, the operating room service and the surgical patient care teams (PCT)

The operating room service is the service lead team (SLT). (Figure 1) it is comprised several specialties e.g. general surgery, cardiovascular thoracic surgery, neurosurgery, urologic surgery, plastic surgery, colorectal surgery, pediatric surgery including orthopedic surgery, otolaryngology and ophthalmology.

The operating room quality improvement committee (OR-QIC) comprises of surgeons from every specialty, i.e., anesthesiologists, anesthetists and operating room nurses. The quality of operating room service will be monitored by the OR-QIC. The data of quality improvement indicators will be recorded every month by an assigned operating room nurse. The outcomes, problems, errors or any untoward incidents are reported and discussed in the monthly meeting of the OR-QIC. The OR-QIC will communicates and discusses the problems with the hospital’s board of the administration committee and surgical PCT in the monthly meetings. Any information or pending issues after discussion are fed back to the operating room organization for management and communicated to all levels of the operating room organization (Figure 2)

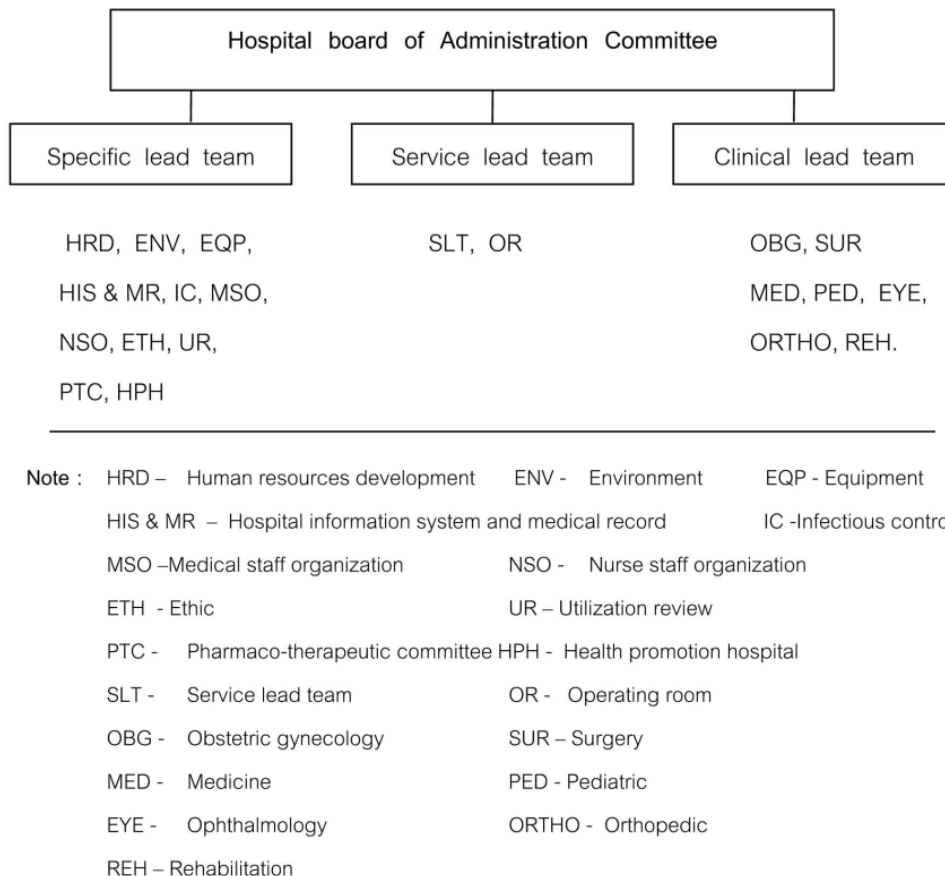


Figure 1. Quality improvement team.

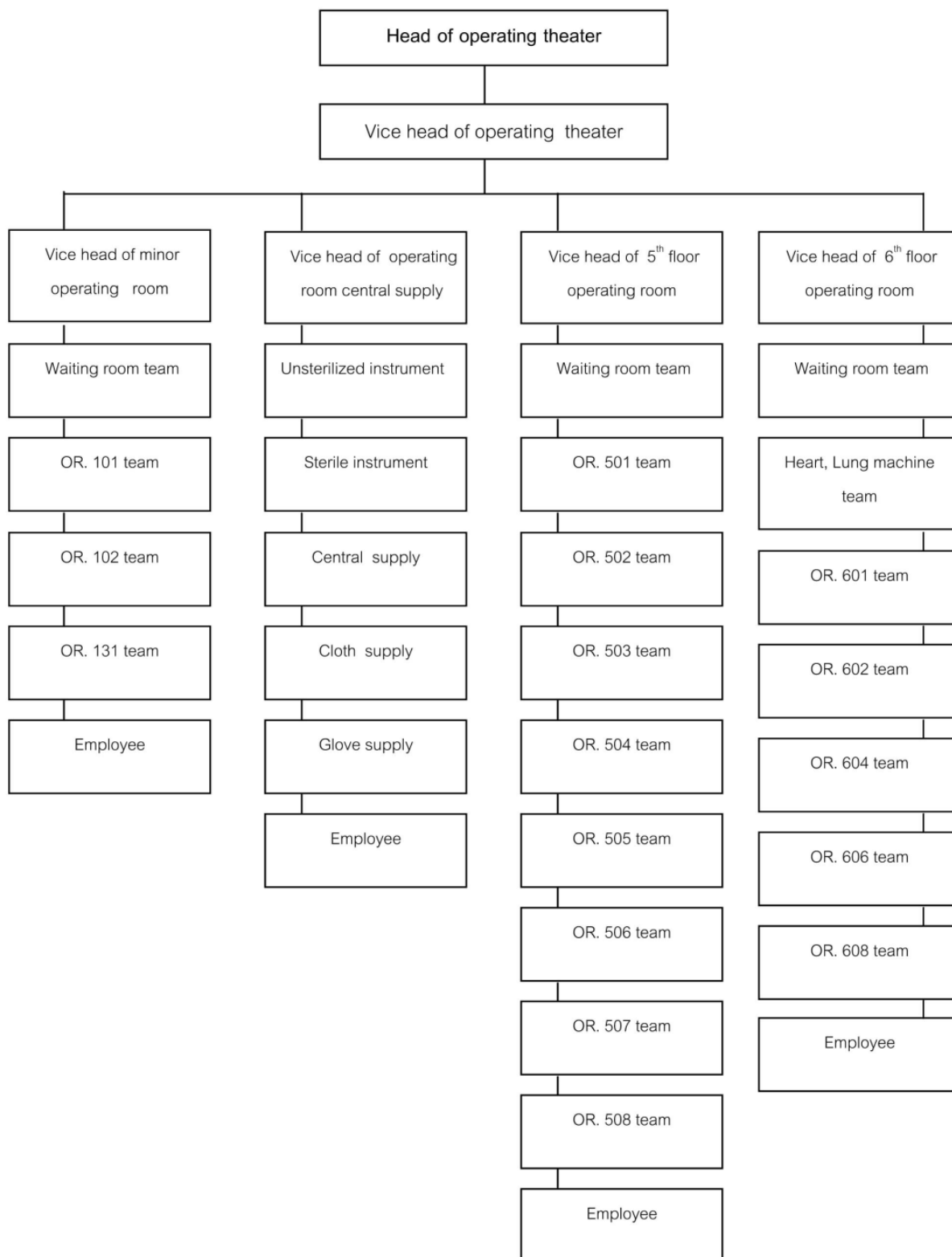


Figure 2. Operating room organization.

The services of each operating room team are divided into pre-operative, operative, and post-operative services (Figure 3). During The pre-operative service, the surgical PCT, anesthesiologists, and operating room nurse co-operate in taking

care of the patient. As for any medical problem of the patient the relevant physicians are consulted e.g. cardiologist, endocrinologist, etc. Then, an anesthesiologist will also be consulted.

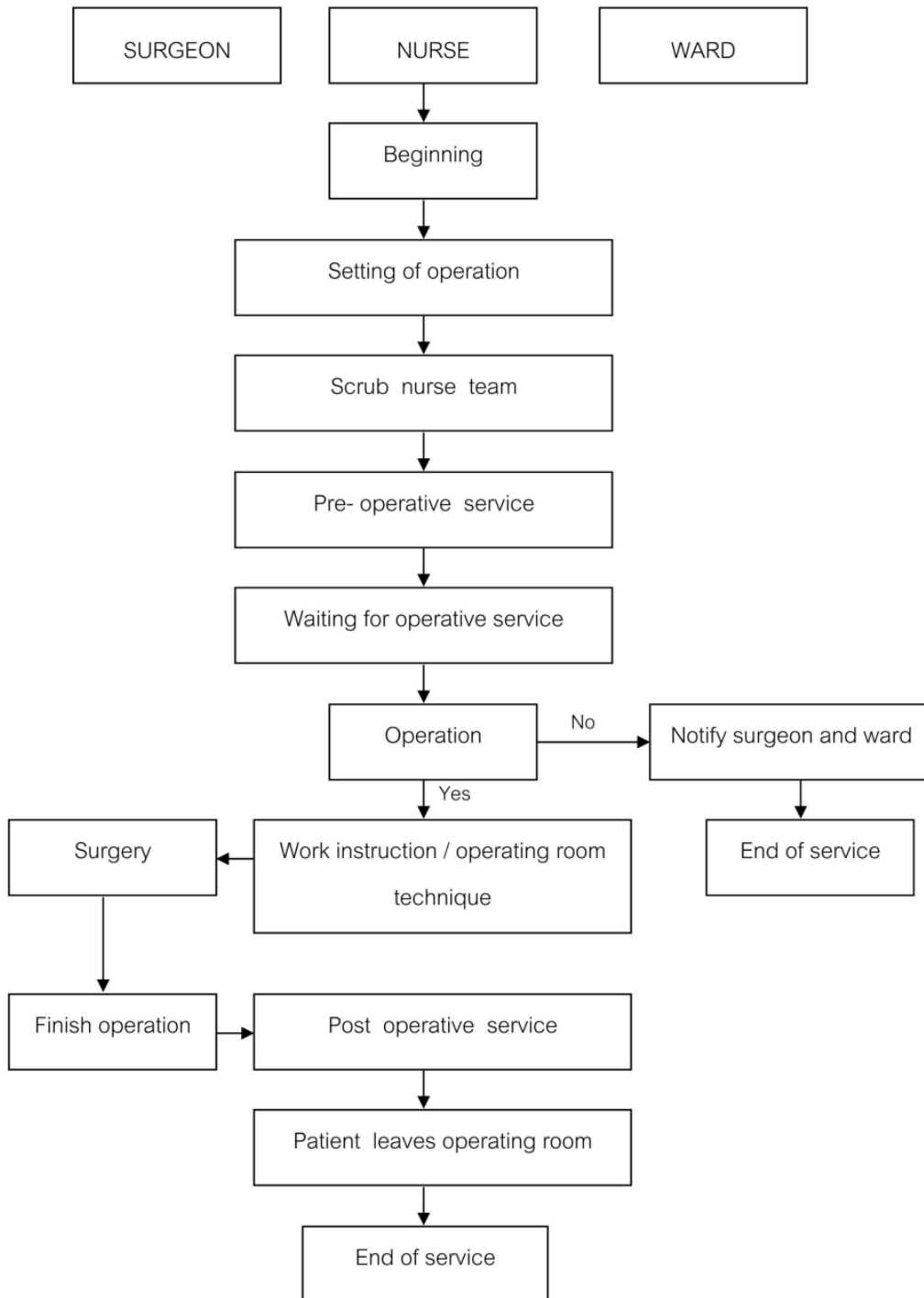


Figure 3. Top – down flow chart of operating room service.

An operating room nurse will visit the patient at the surgical ward during the pre-operative service process, especially patients those who are going to have major surgery. All relevant medical information of the patient will be noted by the surgeon, anesthesiologist and operating room nurse prior to the operation to ensure the maximum safety of the patient. The identification of the patient's procedure, and site of operation are also parts of the safety processes before an operation commences.

Statistical analysis

Data were expressed as mean \pm standard deviation ($\bar{X} \pm SD$) for all outcomes. The statistical analysis between the outcome data and target of quality improvement processes were performed by student t-test with a statistical significance of $p < 0.05$.

Results

The time interval to the start of an emergency operation was counted from the time that the surgeon sets for the operation either at the emergency room or surgical ward to the time of the actual start of the operation. The target is 30 minutes and the quality process is significantly within these limits from 2002 – 2005 ($p < 0.05$). After 2005 we closely monitored this process and the death rate of operated patients has decreased even though there was nothing significant undertaken during the initial process. However we analyzed the root cause of significant deaths arising in the pre-operative preparation of the patient, and the medical problems were diabetes mellitus, hypertension, ischemic heart disease etc. Inexperience of the surgeon and surgical teams were another significant cause of death. After improvement

in the process of preoperative preparation, any medical problems were solved by expert medical specialist consultations. Experienced surgeons attended the operations especially in complicated cases and the instruments were well prepared. After 2004 the death rate has significantly decreased ($p = 0.01$). Cancelled operations will reflected on the management of the operation processes and the harm to patients both psychologically and physically. The causes of cancelled operations may or may not be controlled. The controlled causes were the surgeon was busy, over scheduled, and the instruments were not available etc. The uncontrolled causes were the patient had a sudden fever, hypertension and hyperglycemia etc. We also analyzed the root causes and the outcome of the quality improvement process and found that the rate of cancelled operations decreased and the result has been significantly within the target range since 2003 ($p < 0.05$).

The rate of repeated operations without planning showed the quality of the process and it was well correlated well with the preoperative preparation of the patients, operative teams, instruments and correlated with the death rate of operated patients.

Just prior to the end of every operation we conduct a counting procedure to check for any instruments, needles, operative gauzes and swabs to prevent any foreign body being retained in the wound or body of the patient. The ideal target should be zero or there should be no incidence of this. Even though we followed the counting procedure and revised the counting procedure when such an incident occurred; the results were not significantly controlled. But the incidence of any surgical fire, operation on the wrong patient, the wrong site, using wrong

procedure and the incidence of the patients having an accidents in the operation room. None of have ever occurred. Surgical site infections were significantly found within the target range ($p < 0.05$).

Discussion

A strong QI program should have the following components (1) an expectation that all levels of employees can provide ongoing identification of any problems and issues, (2) that the reporting of problems can occur in an environment where employee job security is not threatened (3) there is a recognition and tabulation of identified problems with objective feedback to the reporting employee and those potentially affected by the reporting, (4) all problems are processed after they are evaluated for significance and prioritized, (5) objective clarification of the issues related to the identified problems are solicited, (6) clinical and administrative databases are maintained to provide comparative reference data for evaluating the identified problems, (7) organized discussion forums are maintained for refinement of the evaluation process and for the development of proposed solutions to identified problems, (8) a system for soliciting more detailed information when complex problems require further analysis prior to initiating change, (9) a respected reporting system within an organizational hierarchy that is recognized internally and externally as a valid QI program, (10) the reporting system is integrated with other QI programs and process improvement initiatives within the health care system, (11) there is an oversight committee for institutional QI programs and / or a reporting mechanism directly attached to the institution's board of governors, (12) an ability to

mobilize institutional resources when significant problems have been identified and the proposed solutions are beyond simple restructuring or behavior change, (13) monitoring and tracking of success or failure when solutions are initiated in response to completely processed problems, (14) documentation of the entire QI process in a record system that is easily obtained and reviewed at all times, (15) ongoing communication with the employees who are affected by the changes (or planned lack of change) instituted by the QI program, (16) reassessment of the changes after an appropriate length of time to ensure that long-term change has occurred, (17) forums for repeated discussions when difficult problems remain resistant to significant change or improvements, and (18) as needed, an incentive or reward system to facilitate change in human behavior. If needed. Our QI program is a part of the hospital accreditation program. We have a system of clinical risks which are closely monitored and detailed database records. The processes are a two-way communications; an incident will be reported from all levels of personnel to the OR-QIC. Any serious incidents or complicated problems will be discussed and studied by root cause analysis. The results are reported and integrated with the surgical PCT and hospital board of administration. Any issues from the board of administration will be communicated to the surgical PCT, OR – QIC and to all levels of personnel in the organization (Figure 1, 2).

The quality assessment conference will be integrated with the quality improvement outcome, the incidents and problems from all levels of the hospital. From the result of the initial quality improvement outcome (Table 1). The time interval of an emergency

operation could start early within the target range. The emergency cases could start early. The patient is safe and the death rates of operated patients have decreased.

The services of the operating room after changing the indicators for long-term quality improvement have changed (Table 1). The patient having a repeat operation in a single admission without preoperative planning might be as a result of the physical health of the patient, the surgical team or inexperience of the surgeon.^(2, 4, 8, 19, 22) In cases of a high rate of repeat operations, the quality improvement process will lead to improved preoperative preparation, consultation with an experienced surgeon attending during the operation, especially major complicated cases, will solve the problem. The problem of cancelled operations may result from controlled causes e.g. the surgeon is busy or unavailable during the operative schedule, Too many ongoing operative settings or unavailable instruments. The uncontrolled causes are, for example, the surgeon is sick; the patient has a sudden fever, uncontrolled hypertension, uncontrolled hyperglycemia, congestive heart failure etc. Moreover, the patient may have psychological problems, such as fear of operation, worry from preparation for the operation. The Instruments or foreign body's. being retained in the body, for example scissors, swab, gauze etc. These incidences of this should never happen at all in a high quality operating room service because of the work instructions for the prevention of any retained foreign body.^(20, 23, 24) When it occurs it is a high risk to both the psychological and physical well-being of the patient for any reoperation, the same applies to operating room

standards to prevent operations on the wrong patient, the wrong site and using wrong procedure. Identification of the patient either from the OPD card, patient chart, informed consent, patient operative form, ward nurse and patient interview with the aim of double checking or triple checking was our policy to prevent such serious incidences.^(4, 5, 9-19) The quality improvements process continues to control these incidences within the target range .

A surgical fire means a fire caused by any operating room material that is flammable. For example; gauze, alcohol disinfectant, surgical scrub, cloths, coagulation devices, lasers etc. It is a great fear because the majority of patients can not be moved and we might lose our patient and personnel.⁽⁵⁾

For surgical wound infections at the initial process we follow only clean wound infection, at the later processes we join with the infectious control committee of the hospital to follow the infection in four major operations which are namely mastectomy, cranio-craniectomy, cesarean section and herniorrhaphy. As for the quality improvement processes of the operating room services as a part of the hospital accreditation program, our hospital is qualified. However the great challenge still remains, i.e., to maintain high quality processes and to constantly improve, in order to attain a higher quality standard of care.

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