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SPECIAL ARTICLE

Risk management in Obstetrics and Gynecology

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Advances in technology and clinical practice increase the chance of medical errors. The combination of increased expectations and increased potential for error can be disastrous for obstetricians and gynecologists. In many countries, pregnancy and birth related claims top the list in compensatory expense. It is not surprising that malpractice losses have driven many physicians from the practice of obstetrics and gynecology. Therefore, risk management has become an integral part of the practice of obstetrics and gynecology. The identification and management of risk contributes to evidence-based clinical practice and produces the best outcome for the patient. A risk may affect the patient, the staff or the corporate organization resulting in harm to the health of the patients or staff, damage to the reputations of staff or the organization, and may have financial consequences. This article outlines the principles of risk management together with some examples from high risk areas of obstetric and gynecological practice.

Risks[1]

A risk may lead to an event which has the potential to damage the patient, the staff or a corporate organization. The damage may be to the health of patients or staff, to the professional standing of staff or to finances. Risk may occur in a variety of areas:

Facilities: lighting, stairs etc.

Equipment: steady wear and tear is more likely than sudden failure; failure to test critical equipment regularly; failure to perform regular maintenance and follow up all faults; maintenance and calibration of instruments.

Procedures: including disposal of hazardous waste and unsafe practices.

Organization: including training, level of experience and communication.

Risk management[2]

All human activities carry a degree of risk and their success or failure depends on their management. Good risk management techniques improve the quality of patient care and reduce the probability of an adverse medical malpractice claim or outcome.

Risk management is the systematic process of identifying, evaluating and addressing potential and actual risk, through a well designed program that prevents, controls and minimizes risk exposure. This includes the timely identification and management of existing risk to protect all parties, patients, staff and the public, including visitors. Risk management is concerned with the minimum level of legally and professionally acceptable care, and covers awareness of all risks to the continued survival and integrity of an organization, such as recruiting and retaining suitable staff, and financial loss. To be most effective in the hospital setting, risk management involves a multidisciplinary and proactive approach

Beneficial outcomes of risk management include:

Reduced patient harm and dissatisfaction.

Preventing poor use of staff, time and money.

Protection from liability and litigation.

Protection from bad publicity.

Making staff aware that there is a spectrum of outcome.

Improves morale by making organization more safety conscious.

Ranking of risks.

More explicit and justifiable decision making.

Risk managers

Risk managers have become increasingly important in hospitals. Their duties were identifying and evaluating risks; preventing/reducing loss; managing the insurance program; administering safety and security; managing litigation and handling claims; assisting in adjusting losses and serving as a risk management consultant.[3]

Risk management process[2]

Risk management consists of three distinct interrelated areas[1,2,4] : 1) risk identification, risk analysis and risk control; 2) loss reduction; and 3) risk financing.

Risk identification, risk analysis and risk control (Fig. 1.)

The first component involves those activities related to risk identification, risk analysis and risk control. Generally, these activities include the identification, analysis and correction of situations or problems which may give rise to events or incidents of potential liability for the hospital, its employees, physicians and other health care providers. These activities are vital to successful risk management since in most cases, the cost of preventing a liability claim is far less than the cost of resolving the claim after it occurs. Risk control activities also consist of the planning and presentation of regular educational programs to clinical and administrative departments which includes: orientation of new employees including medical staff, residents and nurses; continuing education in the form of in-service programs regarding medico-legal and risk management related subjects; and special seminars or conferences for target audiences in response to particular risk management problems.

Risk identification

Risk identification have been done by means of claims audit and untoward incident reporting. Incident reporting plays a crucial role in the risk identification. By analyzing a number of claims and incident reports, it is possible to build up a profile of common risks.

Risk analysis

Risk analysis consists of the evaluation of the probability of adverse effects from the risk situation and the estimation of the impact of the adverse effects. Evaluating risk means reviewing and categorizing information about problems over time, which allows managers to concentrate efforts where problems are greatest. Risk managers can use evaluative techniques such as cost-benefit and cost-effectiveness analyses to select the best course of action to deal with future, past, and present risks. Evaluative efforts also aid in identifying strategies to eliminate, reduce, or transfer risk. Risks are analyzed according to likelihood and severity and the cost-benefit in time and resources to eliminate or minimize the risk.

Risk control

The risk control relates to the prevention of accidents by the provision of adequate resources and improvements in clinical practice. Risk control can be achieved in many ways. Examples include sponsoring education and awareness programs for staff; enhancing the staff recruitment process and review of clinical staff activities; improving processes and procedures; initiating material management systems; improving patient and staff relations; and hiring qualified personnel in appropriate categories. It is preferable to eliminate risk, but that may be impossible for many types of risk; if so, the emphases must be on minimizing risk. The areas that frequently

merit attention are discussed in detail below.

Training

Understanding of the lessons to be learned from analysis of claims and the reporting of untoward incidents will not reduce accidents unless practice is improved by relevant training. Training is the natural conclusion of the audit cycle[5] and it is the consultant's responsibility to ensure that junior staff are adequately trained. It is a responsibility that easily neglected.

Supervision

Clear guidelines should be introduced for risk circumstances in which personal involvement by a consultant is essential.

Consultant availability

A related issue is the amount of time that consultants spend on the clinical work, such as, labor ward and operating room.

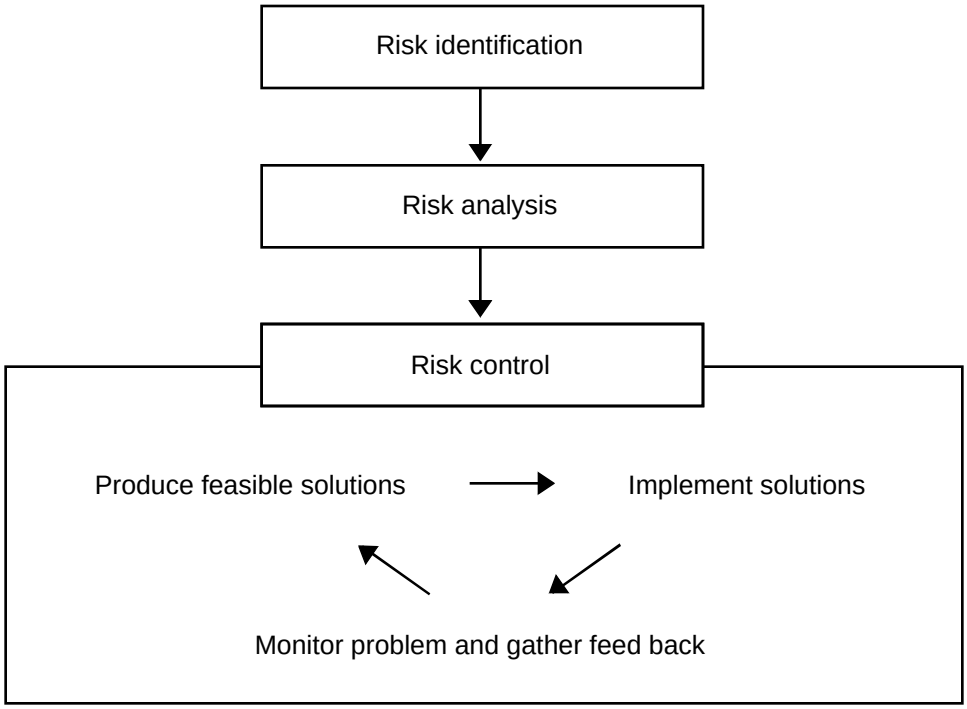

Fig. 1. Stages in clinical risk management. Clinical risk management involves identifying a risk. Further analysis will enable steps to be taken to avoid such risks. Incident reporting, including nearmisses as well as harmful events, plays a crucial role in the identification of risk. Complaints and claims are also studied. When an event leads to damage, then it is necessary to deal with the problem and undertake a damage limitation exercise. The loop is then completed by learning from the event and incorporating the findings into the risk management strategy.

Loss reduction

The second component involves loss reduction activities. Loss reduction includes those steps which are taken after an event or incident occurs that are aimed at minimizing the adverse impact, financial or otherwise, of such an event or incident on the patient, the hospital and its staff. These loss reduction activities are multifaceted and, depending on the facts and circumstances of the particular occurrence, include involvement and input from a number of the medical and administrative staff throughout the hospital. The foundation of an effective loss reduction program includes procedures that identify and respond as soon as reasonably possible to incidents which occur. In this way any adverse impact potentially resulting from the incident can be best minimized.

Many cases are difficult or impossible to defend because the requisite evidence is missing, not because the obstetric management was at fault. A risk management program should therefore identify potential cases of litigation and ensure that evidence relevant to the defense is gathered or at least, not lost. An elementary but often omitted precaution is that the original medical records should be secured and a copy made for clinical use if necessary. The records should be checked for completeness.

The risk manager can minimize loss after an injury to a patient has occurred by immediately taking four steps: First, if the patient has been discharged, the medical record (including radiographs) should be obtained and kept by the risk manager. Second, if the patient continues under treatment and the record is active, it should be photocopied (new entries are photocopied on a regular basis) and the copies retained by the risk manager. This standard operating procedure should be known throughout the hospital. Third, meetings should be held with the patient and/or family to determine their interest in settling any potential claim. Once the injured party retains legal counsel, the case is almost certain to become more complex and costly. Fourth, the hospital should do whatever it can to keep the patient's good will; above all, insult should not be added to injury. There is evidence that an apology is important in keeping the patient's good will. Further, an injured patient who needs additional treatment should not be charged for the extra services. Angry patients are much more likely to sue than are those who believe the hospital acted responsibly and did the best it could under the circumstances.

Risk financing

The third component is risk financing, which involves the mechanisms utilized to ensure that there are adequate financial resources available to cover any potential liability situations, and includes the procurement of adequate liability insurance coverage at reasonable premiums to cover such losses.

Incident reports[1,6]

A system of adverse incident reporting is the heart of most risk management programs, which aims to identify serious incidents shortly after they occur so that a comprehensive report may be made and statements by the staff involved taken as soon as possible. This enables a risk manager to review the management of the case to assess the likelihood of litigation, and to consider how future similar incidents might be prevented. If routine reporting of a specified list of incidents is introduced, the data from such a system can help uncover patterns, trends and underlying problems that, if uncorrected, can affect the quality of patient care. Although the reporting and analysis of adverse incidents seems a worthwhile undertaking, little or nothing is known about the effectiveness of the systems in detecting cases that may lead to complaints or claims, or about their broader use in enhancing the quality and safety of care provided. Examination of trends in a database that records untoward incidents will be unreliable unless all incidents are reported. Certain types of events might be reported more often than others and so give a misleading impression of their true nature and frequency.

The following types of incident should be reported:

* Personal accident
* Violence, abuse or harassment
* Ill health
* Clinical incident
* Fire incident
* Security incident
* Vehicle incident
* Complaint
* Other

The following are some examples of reportable incidents in gynecology[7] :

1. Missed diagnosis including: ectopic pregnancy, missed abortion, pregnancy, tumor.
2. Delayed diagnosis including: late appointment, inexperienced staff, lost or missed laboratory report.
3. Lack of resources including: staff, bed, emergency surgery time, surgical equipment, cancelled operation.
4. Failed operations including: termination, laparoscopy, laparoscopic sterilization.
5. Omission of planned operative procedures including: removal of IUCD, polyp, ovaries, sterilization.
6. Performance of planned or unconsented surgery including: ovaries, uterus.
7. Unexpected damage to structures including: perforated uterus, bladder, bowel, ureter, major blood vessel.
8. Retained foreign body including: swab, needle.
9. Incorrect drug therapy including: omission, incorrect dose or regimen, transfusion problems.
10. Serious post-operative complications including: major infection, collapse, death, return to the operating room, hemorrhage, dehiscence and fistula formation.
11. Readmission.

The incident report form is an administrative document, not part of the medical record. The fact that an incident report form has been completed should not be reflected in the medical record, nor should the report be placed in the medical record. In addition, no copies of the incident report form may be made. An objective description of the incident should be recorded in the medical record by both the medical and nursing staff along with any follow-up observations, diagnostic studies and results, and/or related treatment. Because these occurrences may form a basis for litigation even when there has been no negligence, the best defense is a record which contains timely, accurate and properly charted information.

Each section of the form must be completed according to the directions on the form. Assign a member of the treatment team with first-hand knowledge of the event to record the event. The report must then be immediately presented to the reporter's supervisor who must then investigate and recommend corrective action. The description of the incident should be a brief narrative which should consist of an objective description of the facts. It should not include the writer's judgment as to the cause of the event. Entries regarding an incident should include the date and time of the incident, a brief factual and objective description of what was seen and heard, using exact quotes when possible of the patient's description of the event, along with the findings of any physical examination and follow-up care. Quotes should be used where applicable with unwitnessed incidents, e.g., "Patient states..." The name of any witnesses should be included on this report. The name of the employee directly involved in the incident can be recorded in the witness space as well, if the employee is not the reporter. The patient must be examined by an appropriate physician, who should complete the appropriate section on the form regarding his or her findings. The incident report form should be completed no later than the end of the shift during which the incident occurred or was discovered to have occurred and must be forwarded to the supervisor within 24 hours.

When there is no apparent injury as a result of the incident, this should be clearly documented in the record. Avoid writing information unrelated to the medical care of the patient. When unanticipated

patient outcomes occur, documentation of the complication(s) should also be accurately recorded. Entries should include information regarding the complication in an objective fashion without judgment as to whether the complication is acceptable, unacceptable or anyone is to blame. The entry should indicate that the patient was informed of the complication and its consequences, as well as any change in his or her treatment plan, should it be necessary.

Investigation process of incident reports[8]

All investigations consist of a series of steps that should be followed, as a matter of routine, when an incident is investigated:

1. Ascertain that a serious clinical incident has occurred and ensure it is reported formally. Alternatively identify an incident as being fruitful in terms of organizational learning.
2. Trigger the investigation procedure. Notify senior members of staff who have been trained to carry out investigations.
3. Establish the circumstances as they initially appear and complete an initial summary, decide which part of the process of care requires investigation, prepare an outline chronology of events, and identify any obvious care management problems.
4. Structured interview of staff:

   Establish chronology of events

   Revisit sequence of events and ask questions about each care management problem identified at the initial stage

   Use framework to ask supplementary questions about reasons for each care management problem
5. If new care management problems have emerged during interviews add them to initial list. Interview again if necessary
6. Collate interviews and assemble composite analysis under each care management problem identified. Identify both specific and, where appropriate, general contributory factors
7. Compile report of events, listing causes of care management problems and recommendations to prevent recurrence
8. Submit report to senior clinicians and management according to local arrangements
9. Implement actions arising from report and monitor progress

Practical problems in gynecology[6]

Obstetrics and Gynecology is associated with a high risk of medico-legal activity. The principal problems in gynecology are:

* Female sterilization
* Gynecological surgery
* Minimal access surgery
* Smears and colposcopy

Female sterilization[6]

Female sterilization is a commonly performed, high risk procedure which attracts a disproportionate amount of medical legal activity. The operation is usually performed for social reasons and the patient is not suffering from any disease. It therefore seems that patients are more likely to pursue legal action when the outcome is unexpected. It is necessary to explain that sterilization is the intent of the procedure and then to describe the actual technique to be used (e.g. application of clips to the fallopian tubes). These following information should be informed to the patients:

1. The actual operative technique is described and the form is countersigned by the operating surgeon.
2. An operation involving a bigger scar (laparotomy) may be necessary.
3. The patient is to be informed post-operatively of any change in the technique during the procedure
4. The patient should continue using contraception until the next period.
5. The risk of failure is about 1 in 200 in the lifetime of a woman
6. There are three reasons for failure.
   1. Pregnant at the time of the procedure.
   2. The Fallopian tube is not blocked at the time of the operation because of technical problems.
   3. The tubes may rejoin at a later date
7. Subsequent pregnancy may occur in the fallopian tube (ectopic pregnancy).

8. If the patient thinks she may be pregnant after the procedure, she should see a doctor immediately.

The operation can be performed at any time in the menstrual cycle. It was thought impractical to limit the operation to the first half before ovulation occurs. A full menstrual history, sexual history and contraceptive history must be taken on the day of the procedure. If the woman has had unprotected intercourse at the fertile time, then the surgeon should postpone the procedure. If the patient still wishes to proceed, then her wish and the details must be written in the notes. Some hospitals routinely perform pregnancy tests prior to surgery on all women of reproductive age and the test must always be performed if a woman has a late or missed period. In the latter case, the patient must be warned of the occurrence of false negatives. Surgeons must perform adequate amount of sterilizations under direct supervision by an experienced consultant before independent practice.

Gynecological surgery

There are many risks associated with general gynecological surgery. Some common problems are retained swabs following surgery, removal of an ovary without consent and the damaged ureter at hysterectomy.

Retained swabs following gynecological surgery [6,9]

After operations in the peritoneal cavity, such as a cesarean section or a hysterectomy, there is usually a swab count performed by nursing staff before and after the operation. Commonly, the scrub nurses report to the surgeons that all swabs have been removed before he closes the peritoneum and again as they finish suturing the abdominal wall. However, the responsibility for seeing that all swabs have been removed from the abdomen rests with the surgeons, who should inspect the operative area visually and remaining peritoneal cavity manually. Other foreign bodies such as safety pins and the ends of suction drainage tubes are occasionally misplaced. These spread a wider responsibility between the surgeons, the operating room nurses and the staff in the post-operative wards.

Removing the ovaries

A risk management program must take special steps to ensure that ovaries are not removed without valid preoperative consent. Surgeons should never assume that they are acting in the best interests of their patients in this situation. It is important that the surgeon carries out the correct operation as listed and agreed to by the patient.

Damage to the ureter

Damaged ureter claims can be difficult to defend even if the surgeon thinks there has been no substandard care. Risk management analysis shows the need for adequate training and comprehensive knowledge of the anatomy of the ureters. It is important that difficult cases, e.g. hysterectomy in the presence of severe endometriosis or post-hysterectomy oophorectomy, are not delegated to inexperienced staff. There is still no consensus on the need to check the position of the ureters and to record this observation in the operation notes of a straightforward hysterectomy. Ureteric stents may be of use but would require proper training for their use. Damage limitation would require that any injury is repaired by a consultant urologist.

Minimal access surgery [6]

There have been many problems with minimal access surgery in recent years. The safety of laparoscopy has been extensively studied. Risk managers should be aware of these recommendations and ensure that surgeons are appropriately trained and experienced. The main reason for complaints about laparoscopic surgery is the patient's apparent lack of knowledge about what is to be done and can be done endoscopically and the unexpected occurrence of a laparotomy. Consent forms should state that there may be a need for laparotomy. Patients should be:

1. Made aware of possible complications prior to surgery.
2. Provided with written information.

3. Warned that a diagnostic procedure may have to be converted to an operative procedure.
4. Warned that open surgery may be necessary due to technical difficulties.
5. Made aware that a short hospital stay does not exclude the risk of late complications.

Colposcopy and cervical screening [6]

Risk management is particularly important in the field of colposcopy and cervical screening. Patients have a high expectation that problems are not missed.

Practical problems in obstetrics [10]

Most obstetric cases arise in relation to the management of labor, but claims may arise because of problems with antenatal diagnoses and the failure to diagnose congenital abnormality. Furthermore, the failure to act on abnormal antenatal screening tests may result in legal action, where the outcome of the pregnancy is unsatisfactory.

The principal problems in obstetrics are:

* Antenatal care
  - o Prenatal diagnosis
  - o Antenatal fetal monitoring : Non-stress test (NST)
* Intrapartum care
  - o Intrapartum fetal monitoring
  - o Operative delivery
  - o Shoulder dystocia
  - o Breech delivery
  - o Management of twin pregnancies
  - o Retained swabs in vagina following repair of an episiotomy wound.

Antenatal care

Prenatal diagnosis *[11]*

Sources of litigation in prenatal diagnosis are :

* Failure to give advice
* Giving wrong advice
* Errors in diagnosis
* Inability to make a diagnosis
* Safety of procedure

Amniocentesis carries a small but well recognized risk of abortion, although this risk is minimized by using a fine bore needle and by performing procedure under ultrasound guidance. It is therefore essential to advise mothers of the following facts that amniocentesis carry a small risk of abortion, cell culture may fail and that diagnosis may therefore be delayed or be impossible, the purpose of prenatal diagnosis and the consequence of an abnormal finding could be to have the pregnancy terminated. A written record of the advise given should always be recorded, and it may be advisable, although not necessary, to have signed consent forms for all these procedures.

There is need for increased awareness among all health professionals dealing with pregnant (and potentially pregnant) women of the range, availability, benefits and risks of prenatal screening procedures for women in both high-risk and low-risk groups. Written information about the tests available, emphasizing their purpose risks and voluntary nature, should be supplied to patients. Access to detailed scanning should be available when an abnormal screening test occurs, and invasive procedures to make a definitive diagnosis should be concentrated in centers where sufficient numbers of such cases are seen to allow the development of special expertise. Written consent should be obtained for invasive procedures after full consultation.

Antenatal fetal monitoring

Antenatal fetal monitoring including non-stress test (NST) should be checked and signed by an member of the medical staff. Although the recordings can be performed reasonably by the nursing staff, the interpretation and decision relating to these tests is the responsibility of the medical staff. Unsatisfactory recordings should be repeated and a clearly defined decision made about subsequent action following an abnormal recording. If this is not possible, then from a medico-legal point of view, it is perhaps better not to perform the tests.

Intrapartum care

Most of the claims made in relation to obstetric care occur from events occurring in labor. Intrapartum obstetric care is likely to be the target of litigation if the outcome for the fetus is unsatisfactory.

Intrapartum fetal monitoring

The quality of intrapartum fetal monitoring is important as difficulties often arise because the recording is inadequate and unsatisfactory for interpretation. If the recording is technically unsatisfactory because of a faulty machine, a faulty electrode or from the misconnection or misplacement of an electrode or transducer, then the fault should be corrected or the recording discontinued and labor managed by fetal heart rate auscultation. Interpretation of the fetal heart rate must be made in relation to uterine activity. However, it is occasionally ignored or even missing. Therefore, intrapartum fetal monitoring must be checked by properly trained medical staff and appropriate action must be initialed.

Labor ward procedures should defined the chain of command. It must be realized that the responsibility for outcome will be attributed to the individual observer. Thus, if the guidelines are ignored, then legal liability will rest with the individual who failed to comply with those instructions.

Many problems occur at the changeover of staff. Vital information concerning the progress in labor and abnormalities of the fetal heart rate is often overlooked and not passed to on-coming staff; it is essential that such important observations are made available to the new staff.

Delays in progress of labor are best shown to the staff by the use of either Friedman's curve or partogram.

Operative delivery [12]

The circumstances most commonly leading to litigation in relation to operative delivery are listed below:

1. Attempting vaginal delivery when:
   a. Mechanical warning signs are ignored or misinterpreted.
   b. Basic rules are disregarded.
   c. Fetal compromise is already present.
   d. Head position or head level are wrongly assessed or nor assessed at all.
2. The delivery being undertaken by doctors who are too junior or inexperienced.
3. Repeated attempts at delivery by junior doctors.
4. Delay in the decision to delivery interval.

Shoulder dystocia [12]

Shoulder dystocia is the most frightening and threatening obstetric emergency because of the desperate need to act quickly to prevent morbidity and mortality. With shoulder dystocia the common difficulties arise because:

1. warning signs are ignored
2. the doctor in charge of the delivery is too junior/ inexperienced
3. there is no predetermined plan or protocol to deal with the emergency

Breech delivery [12]

Babies born by the breech have a much higher morbidity and mortality than those presenting by the vertex. Important associates are prematurity and congenital malformation. In breech delivery, the common problems are

1. failure to detect unfavorable presentations such as footling
2. prolapse of the umbilical cord
3. artificial rupture of the membranes when the breech is high or in an unfavorable presentation
4. failure to appreciate the significance of delay
5. incorrect diagnosis of full dilatation
6. difficult delivery of the aftercoming head.

Management of twin pregnancies [10]

An increasing number of legal actions now arise in relation to the management of twins in labor. The delivery of the second twin often presents an acute problem for the attendants and should be supervised by medical staff with appropriate experience and with adequate anesthetic and pediatric services available

on site. Perinatal mortality and morbidity have always been higher with the second twin; these difficulties are related to placental separation, cord prolapse and difficult deliveries.

Retained swabs in vagina following repair of an episiotomy wound

Small swabs are often left in the vagina during repair of an episiotomy or perineal tear. The swab count in this case is often entirely the responsibility of the obstetrician; a swab left in the vagina may lead to serious pelvic infection. Obstetrician must check the vagina for swabs after repair of an episiotomy wound, check the rectum for swabs and remove them if the sutures have penetrated the rectum.

In conclusion, most problems have two clear elements. First, something has gone wrong whether because natural causes or because of poor practice. That in itself may not be enough to generate the complaint. The second factor is poor communication and often a lack of humanity. On the first issue the standards must be set and audit conducted. The importance of the involvement of consultants on the clinical works has been recognized. There should be protocols and guidelines of good practice. Finally, full and frank discussion is required at every level.

In conclusion, the key element in the success of the risk management program in preventing and reducing these particular claims and associated financial losses, is the participation of physicians, nurses, other health care providers and hospital employees in implementing effective risk management strategies. Each individual must be committed to reducing risks.

The identification and management of risk contributes to evidence-based clinical practice and produces the best outcome for the patient. A risk may affect the patient, the staff or the corporate organization resulting in harm to the health of the patients or staff, damage to the reputations of staff or the organization, and may have financial consequences.

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