CRM (clinical risk management) is a systemic approach to ensure patient safety and improve standards of care to prevent medical error leading to adverse events and harm to the patient, distress to the family, friends and relatives, defaming the organization. It demands a complex system, wide range of actions in performance & improvement, environmental safety, risk management, infection control, safe use of medicine, safe and honest clinical practice & safe care environment.

Medical error not only result in additional cost for hospitalization, litigation, hospital acquired infection, lost income, disability but also causes erosion of trust, confidence and satisfaction among the public and health care providers, defamation of organization but also cause psychological trauma to treating doctor and team.

In obstetrics CRM is particularly important as it is high risk specialty and the cost of mistakes is high both financially and in human terms. As reported 1/3rd of obstetrical cases may end to moderate to severe morbidities and mortality both in maternal, fetal and neonatal term.

CRM program analyses the factors contributing to obstetric emergencies, analyses the feto-maternal outcome and importance of judicious use of obstetric drill to train the dealing medical professionals to deal with emergencies in a more effective way, is an initial and crucial step towards safe delivery outcome.

**CRM- Objectives**

The objectives of CRM are to establish standard approaches to risk management (RM), effective incident management, assist healthy services, and to have a consistent and coordinated approach to identify, notify, investigate and analyze the incident. Learning lesson from adverse event prevents recurrence, is of paramount importance. The aims are to promote a “just-culture” for learning from mistakes in a blame free atmosphere. The initial aim of CRM arose from the response to rising litigations in obstetrics. USA has long been the 1st runner up in this field, now it is accepted in Europe and elsewhere. India is now not in backseat. Although the initial aim was to reduce the payouts of litigation claims but now the Main drive of CRM is patient safety.
To have patient safety in every aspect several challenges are met with and are being fulfilled such as clean care, safe surgery, antimicrobial resistance.

In 2007 Jakarta declaration highlighted the role of patient involvement for patient safety.

Another important challenge is “human error”. To “Err is Human”.

Human error is inevitable, one cannot change human conditions but can change the conditions under which they work.

- The government, health care providers, industry and consumers can prevent medical errors.
- Reports published in USA highlighted that most commonly errors occurred from system failures rather than individual error.
- Strategy for improvement of human error include
  - Leadership & research to improve knowledge on patient safety
  - Identification & mandatory reporting of incidents
  - Raising performance standards
  - Implementation of safety systems to ensure safe practice at delivery level
- In UK a key publication by department of Health “An organization with MEMORY” in 2000 highlighted the need to “Learn from clinical errors”. Considering this UK recommended a new reporting and analysis system for health care errors bringing RM to the fore, it also has been the publication of documents specific to obstetric practice on standards for safe child birth explain the need for robust RM procedures to ensure quality care in obstetric field.
Patient safety is of paramount importance, every clinician should know "What “Patient safety” mean, it is prevention of harm to patients during hospital care:

- To eliminate preventable medical mistakes
- To guard human error
- To establish systems to safeguard patient’s health and well-being

Patients safety is everyone’s responsibility and so Clinicians should be aware of the role of risk management. The concept of patient safety is not new. Hippocratic oath refers to causing no harm to patients.

There is global awareness of patient safety, in India. The Director general of Health services ministry of Health and Family welfare, Government of India, has taken up patient safety issues on priority in the form of new initiatives “Hospital safety”. The aims are safe, error free, successful healthy outcome, to avail most expert & advanced medical care to patient with comfort & peace of mind to patient & providers.

**Obstetrics and RM**

Obstetrics is high risk specialty dealing with the living challenges - mother and baby. The responsibility starts from prenatal, antenatal period continuing through the intra partum course to post-partum period. Labour is the most critical and high-risk time where the clinical situation can change very quickly and without warning, so it is vital to have systems in place to ensure a healthy outcome. Hence it is vital that all clinicians are aware of the role of clinical risk management. CRM also plays an important role in ensuring safe practice in clinicians, financial gains, curtails expenditure for example extra hospital stay, cost of unexpected admission of baby in neonatal ICU. It also saves the cost of litigation claims.

**RISK MANAGEMENT** is an important part of clinical care; one of the cornerstones of clinical governance and encompasses many of the other pillars of clinical governance including

- Audit
- Education
- Training
- Resolution of complaints

RM is a useful tool in driving forward the quality of patient care as it focuses on evidence-based medicine.

Clinical Governance is the process of providing the best care for patients by regular monitoring of performance and constant strive to improve.

Challenges in Risk management: There should have an awareness regarding reporting of adverse incidence either maternal mortality, morbidity or a fetal/neonatal mortality or morbidity. Proper and accurate reporting helps in prevention and recurrence by improvement in system, medical skill by skill and drill training, advice from higher authorities. The lack of data is attributed to a lack of clear definition of what constitutes a risk event and in the reliability of reporting and investigating such events.

**Further information on risk events may be obtained from national audits.**

Unfortunately, accurate data of incidents is difficult to find out due to underreporting or non-reporting and there is also huge geographical variation that may be due to level of RM in place and amount of data collected.

Near misses, neonatal fetal morbidity such as, fetal congenital abnormalities diagnosed or undiagnosed, neonatal seizures, premature birth, still birth, fetal laceration during caesarean delivery. IUGR etc.

Maternal morbidity resulting from PIH, Hypertensive disorders, GDM, Anemia etc. are often non-reported.
**Principles of RM**

Patient safety is every one's responsibility hence it is vital that all clinicians are aware of the meaning of patient safety and the principles of RM. It considers patients’, social, cultural and environmental status and that of persons involved, creates target group-oriented transparency, helps in Organizational development. It is a part of decision-making process. It addresses clinical risk in connection with prevention, diagnosis, treatment and decision making, fosters inter professionals, and interdisciplinary communication, and reacts to development of medicine, nursing, health related economic and demographic changes.

Risk Strategy: it describes the implementation of principles of RM specified in risk policy, risk policy defines the arrangements and responsibilities of RM.

- Describes the implementation of principles specified in risk policy
- Looks at mother and baby safety
- Focusses on learning from mistakes
- It lays down specifications regarding:
  - Linkage of organizational goal
  - Provisions of resources
  - Risk related responsibilities
  - Setting up and running a system
  - Evaluation of way to determine the efficacy of CRM

Safety of mother and baby
Good evidence based practice
Risk Management Process

The Risk Management Process consists of a series of steps that, when undertaken in sequence, enable continual improvement in decision-making. Clinical risk management in obstetrics require a full team to have an effective obstetrical risk management, in obstetrics the risk management team is a multidisciplinary team having obstetricians, senior midwives, anesthetist and neonatologist, a member of the team with experience in RM process. Often hospitals have a clinical governance department to oversee obstetric risk management team. In turn the risk events are reported to the outside bodies either regionally or nationally.

RM process: To minimize the risk and harm to the patient RM process follow a series of steps.

There are various ways but the common one generally followed focuses on four basic principles, the KEY steps:

- Establishing the context & identification of risk even
- Risk analysis
- Risk evaluation
- Treatment & control measure

Clinicians in practice when face a risk should take a step back to look the process, structures and environment within which they provide care and then manage the risk in a stepwise manner after judging the risk and planning to either avoid an adverse outcome or to minimize the risk at best.

Risk events identification: Identification of risk events may come from local source (within the maternity service) or from external source such as national audit.

Risk identification considers notification from reporting and learning system, especially Critical Incident Reporting System (CIRS), events that has caused harm to patients, liability cases, occupational accidents and complaints.

There are two types of risk events categorized into

1. Proactive risk events i.e. in anticipation of risk events and
2. Reactive risk events, investigation of event after it has occurred.

Focus is on proactive one the, but CRM team must focus on both the areas.
Important activities in this phase:

- Document risks in “risk register”
- Categorize risks to help ensure comprehensive and non-overlapping set of risks. Risk identification is done Prospectively and Retrospectively

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Prospective risk identification

- Watches for outcome during study period; over a longer period
- Relates this to other factors (Ex. suspected risk or protection factors)
- Interest should be common
- Bias should be avoided

Risk assessment should be conducted in all clinical areas including delivery suite, theatres, clinics.

Findings collected & assembled in risk register, risk register helps to highlight the risk such as faulty CTG machine, cardiac arrest trolley etc., do prioritization of risk by giving them a score, the Risk score.

Risk score is made up of potential seriousness of potential risk combined with the Likelihood of its occurring, this further decides the action plan to deal with.

Risk score = L x S (Likelihood x Severity)

There are various guides to likelihood scoring, one of them is 1-5 scoring,

<table>
<thead>
<tr>
<th>Occurrence</th>
<th>Frequency</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rare or remote</td>
<td>every 5yrs.</td>
<td>1%</td>
</tr>
<tr>
<td>Unlikely</td>
<td>every 2-5 yrs.</td>
<td>10%</td>
</tr>
<tr>
<td>Possible</td>
<td>every 1-2 yrs.</td>
<td>50%</td>
</tr>
<tr>
<td>Likely</td>
<td>bimonthly</td>
<td>75%</td>
</tr>
<tr>
<td>Almost certain</td>
<td>at least monthly</td>
<td>99%</td>
</tr>
</tbody>
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Severity of impact (S), scoring 1-5 indicates impact of harm to service users, employees, service provision, environment or organization.

<table>
<thead>
<tr>
<th>Score</th>
<th>Impact</th>
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<tbody>
<tr>
<td>1.</td>
<td>Negligible</td>
</tr>
<tr>
<td>2.</td>
<td>Minor</td>
</tr>
<tr>
<td>3.</td>
<td>Moderate</td>
</tr>
<tr>
<td>4.</td>
<td>Major</td>
</tr>
<tr>
<td>5.</td>
<td>Extreme</td>
</tr>
</tbody>
</table>

Risk Matrix Score classification cut off value:

1 to 5 = Low risk.
6 to 12 = Medium risk.
15 to 25 = High risk

Example: Risk = L x S
4 x 3 = 12 = Medium risk.
Evaluation of risk decides which risk require treatment and mode of treatment. Evaluation: Accept the risk, too small risk, specified treatment not needed. Treat the risk either control, transfer or avoid the risk.

Risk treatment or mitigation looks at what can be done to minimize the chance of something occurring again, assist in decision making. Control the risk, potentiality of adverse effect reduced by redesigning the system and process.

Transferring the risk, some part of risk is bared by another party such as contracted team, insurance, outsourcing, joint ventures etc. Risk is transferred to solve the problem.

Staff consultation- organizing staff workshop is a useful way to pick up risk events, such as unreported near misses. Staff consultation allows staff to voice any concern they have regarding staffing, training, or equipment

**Retrospective risk identification come from**

Complaints

Trigger list

Incident reporting

Claims to legal departments

Clinical audit

**Retrospective risk identification**

Looks backwards and examines exposures to suspected risk or protection factors in relation to an outcome that is established at the start of the study. Confounding and bias error are common, often criticized

Emergency Drills and Simulation are training methods to expertise the trainees in RM. Drill take place where the actual events occur particularly useful in delivery suits for practicing frequently encountered emergencies such as post-partum haemorrhage, shoulder dystocia, edamemia are handled by multidisciplinary team and infrequently occurring emergencies like acute uterine inversion, amniotic fluid embolism.

**Challenges: lack of knowledge of staffs and lack of equipment.**

Helps to practice team culture and to have good communication among the team members. Simulation is a means for training to health providers to gain &maintain competence to manage obstetric emergencies, to identify common clinical error & allowing interventions to reduce them, it is practiced in simulation lab on mannequin. These methods are very useful for prospective RM, make health providers perfect to manage frequently infrequently occurring obstetric emergencies, improves skill, to work as a team and good communication culture, to recognize the deficiencies in skill and lack of knowledge.

**National confidential enquiries:**

Organizations are working throughout the world to highlight the outcome of pregnancy by national audits and are providing recommendations for the best outcome through reports published. UK has the longest running national audit on maternal death in 2012, MBRRAC (Maternal Babies Reducing the Risk Through Audits and Confidential enquiries) is now running the program, reports published recommends best outcome by lessons learnt from adverse incidents,

Improvement in standards of investigations and Reporting of serious incidents. UKOSS (UK obstetric Surveillance System) is working on near misses, recommendations are made for best and improved practice for best outcome to avoid maternal morbidities in cases such as Amniotic fluid embolism, septic shock. WHO in 2004 outlined methods for safer pregnancy by maternal death review. Facility Based Maternal Death Review (FBMDR) review maternal deaths including abortion.

Maternal Newborn Infant Clinical Outcome Review Program (MNI-CORP) do enquiries on maternal, fetal, newborn mortality and morbidity. January 28, 2018 reports from MBRRAC says that Cardiac disease as the indirect leading cause of maternal death, Thrombosis and Thromboembolism are direct causes of maternal death up to or during 6 weeks of pregnancy. Other causes of maternal death are sepsis, haemorrhage, Anesthetic complications, neurological conditions, other medical and surgical conditions, Amniotic fluid embolism.

The main causes of maternal morbidities are uncontrolled epilepsy in pregnancy, postpartum mental illness. UKOSS current studies are on Amniotic fluid embolism, Aortic dissection, Myeloproliferative disorders, Pituitary tumor in pregnancy, Placenta accrete, Pulmonary vascular disease, Obstetric Cholestasis, Non- Renal transplant recipient, Sickle cell disease.

UKOSS in planning studies are: HELLP syndrome, Epidural hematoma/abscess, Pregnancy in post laparoscopic gastric band surgery, Pregnancy in heart valve recipients, Septic shock, Pregnancy in women more than 48 years. National Centre for Biotechnology (NCBI) specifies the causes of maternal morbidity and mortality in India. Report says 50% maternal death are due to sepsis related to illegal abortion. Other causes of maternal death are Haemorrhage, infection, Hypertensive disorders, ruptured uterus, Hepatitis, Anaemia. But there is significant improvement in recent years. MMR has declined significantly. India has improved much in last 15 years, more concern on women’s health. Neonatal, fetal, maternal mortality and morbidity has reduced significantly.
Advice from patient safety organizations

- NPSA is a government organization (National Patient Safety Agency) in UK
- Aims to lead and contribute to improved, safe patient care by informing, supporting & influencing individuals, organizations working in health sectors
- Analyses report on patient safety nationally
- Identifies risk
- Recommends actions to reduce risk.
- NHSLA (National Health Service Litigation Authority) in UK work on litigation claims & focuses on work to improve risk practice
- CNST (Clinical Negligence Scheme for Trust) deals with litigation claims
- AHPI (Association of Health Providers, India) work as “non-profit” organization
- Collaborates with Government, Regularity bodies & other stakeholders bearing and delivering appropriate health services.
- Educates members by a comprehensive guideline on “patient safety protocols” initiating standard treatment guidelines on evidence based clinical pathways
- In USA, the Institute for Health Care improvement (IHCI) provides information and tools for improvement in quality and value in Healthcare.

Advice from National colleges

RCOG, UK provides guidelines on

- Parallel patient information on clinical practice
- Clinical Governance including risk management
- RCOG provides advice to have patient consent

Advice from RCOG acts as an aid to good clinical practice. It has “Green TOP Guidelines” which evaluates with reference to individual patient needs, resources, limitations

- National evidence based clinical guidelines provides systematically developed recommendations which assist clinicians and patients in making decisions about specific conditions. RCOG provides advice to have patient consent to ensure that all patients are given a consistent and adequate information for consent.
- National evidence based clinical guidelines provide systematically developed recommendations which assist clinicians and patients making decisions about specific condition.
- ACOG, American college of obstetricians and gynecologists
  - guides & publishes documents on importance of patient safety, as a key part of CRM, one important objective is regarding women’s health care, it says women’s health care should be delivered in a learning environment that provides encouragement for disclosure and discussion of adverse events and exchange of information in the event of error and near misses.
  - Promote the concept of “just culture”, and explains and acknowledges that even competent professionals can make mistakes

ACOG on April 23, 2018 released a revised committee opinion to reinforce the importance of fourth trimester and to propose a new paradigm for postpartum care.

ACOG recommends that post-partum care should be an ongoing process, time of visit should be individualized.
women centered and follow up should be a full assessment of mood and emotional well-being, Sleep and fatigue, Infant care and feeding, Sexuality contraception, Birth spacing, Physical recovery from birth, health maintenance and chronic disease management. On May 18, 2018 ACOG recommends pain management approach tailored to patients.

Retrospective Risk identification.

Reporting of incidents that already happened helps in analysis, assessment and further action mode to prevent or reduce certain risk events, mostly obstetric emergencies/intrapartum events require reporting and further investigation

Any perceived risk events should be reported by filling a “Risk form” manually or electronically by dealing individual and staff should be motivated by feedback for reporting data on hospital database. Reported incidents should be linked to hospital or trust wide reporting system linked to NPSA.

Most maternity unit have a reporting incident the trigger list requiring reporting and further investigation.

RCOG suggested trigger list:

**Neonatal /Fetal incidents**
- Still birth >500gm.
- Apgar score <7 at 5min.
- Fetal laceration in C.S.
- Neonatal seizures.
- Undiagnosed congenital abnormality
- Neonatal death
- Birth trauma
- Cord pH <7.05 arterial or venous <7.1.
- Unexpected neonatal unit admission of term baby

**Maternal incidents**
- Maternal death
- Undiagnosed breech
- Shoulder dystocia
- Blood loss >1500ml
- Intensive care admission
- Venous thrombosis or Pulmonary embolism
- 3rd & 4th degree tear
- Return to theatre
- Eclampsia
- Hysterectomy/laparotomy
- Anesthetic complications
- Failed instrumental delivery in delivery room
- Uterine rupture

**Organizational incidents**
- Unavailability of health record
- Delay in responding to call for assistant
- Unplanned home birth
- Faulty equipment
- Conflict over case management.
- Potential service user complaint.
- Medication error
- Retained swab or instrument
- Violation of local protocol
- Hospital acquired infection

**Change in trend**

Risk team should have overall view on any change in trend to avoid certain risk incidents like 3rd degree tear (no full investigation is required) Maternity dash board is useful tool for monitoring these data.

**SIRIS (serious incidents requiring investigation)**

previously known as SUI (serious untoward incidents) focus on incidents which need more investigations

SIRIS include reference to an incident involving unexpected and avoidable death, serious harm to patient or staff or visitors

It involves incidents where the outcome requires lifesaving /major surgical/medical intervention/permanent harm/shortening life expectancy/prolonged pain or psychological harm.

**Complaints and Legal claims**

Information resulting from complaints and legal claims should be available and are dealt with by CRM team, information’s are collected from reports of ward manager, clinical manager, department head and consultants by filling an incident/accident form. Full investigation is further done by reporting body or system in place.

Staff should feel comfortable about reporting in a “blame free” atmosphere, Claims may be due to

- Clinical negligence
- Employer’s liability claims for compensation
- Public liability claim
- Property expenses & personal injury claims

In some instances, these claims need full investigation of risk events which may not have been reported through reporting system.
Clinical Audit

- Is an integral component of CRM specially to ensure that local guidelines are being adhered to and highlight potential risk areas?
- It is a proactive method.

For ex. continuous audit in a department on massive PPH may highlight trends in the management of such cases that can be addressed by the risk management team.

- It may be

(0) an annual audit program or
(1) in response to an incident

**Once risk has been identified, prioritization (by Risk Score) is done for further action**

Risk evaluation helps decide on the treatment and mode of treatment depending on the risk score and the risk appetite

**Analysis of risk events**

Goal of analysis is to determine:

- causes of risk
- factors that favor error
- the likelihood of occurrence
- their effect on safety of patient

**Prospective Analysis**

*Risks highlighted because of an emergency drill or a staff risk workshop*

A structured tool such as FMEA (Failure Mode Effect Analysis) adds to further analysis, Joint Commission and Accreditation of Hospitals Now Joint Commission implemented FMEA in 2011. It is a structured tool analyses the steps,

- In 2011 clinical audit strategy was developed and implemented to support robust and effective clinical audit activity.

Once the risk has been identified risk assessment is done for prioritization for further action. Prioritization of risk is given by Risk Score made of potential seriousness of the potential risk with likelihood of its occurring. Risk treatment or Risk mitigation looks at what can be done to minimize the risk event occurring again.

Risk assessment is the determination of quantitative or qualitative estimate of risk related to a well-defined situation and a recognized threat.

- It looks in detail & identifies what can go wrong at each step
- It analyzes the contributory factors of these steps going wrong
- It details existing control in place to prevent the risk
- It rates the risk and helps to decide which risks are unacceptable and need to be treated FMEA provides a conclusive clear action plan on how to implement any change to secure patient safety.

**Retrospective Analysis**

This is a research method after the outcome. It helps answer the “Why” (why did this happen to the patient currently)

The cause is established and then the Risk assessment happens (impact and likelihood) – this leads to the action plan A systemic approach is adopted - the RCA (Root Cause Analysis) approved by JC in 1997.
Root Cause Analysis (RCA)

RCA is time consuming but well accepted tool, it has been criticized for oversimplifying the process by assuming there is only one root cause. “System analysis” which is a broader examination of all the aspects of the health care system in question.

Steps of RCA are:

- Defining the problem
- Gathering and mapping of information
- Identifying service and delivery problems
- Identifying and generating recommendations & effective solutions
- Implementing and tracking solution along with report writing

Control Measures

The control of risk events is the process of learning lessons (through study of adverse outcomes) and sharing these findings among all members & staff (may be done at local departmental or national level). This is done to prevent/avoid recurrence.

Maternal death is the most serious incident in obstetrics. Health care associates must deal with the family, friends, relatives, public concerned, counseling should be done sympathetically, findings, causes, methods of prevention for future should be shared and discussed.

Aim of control measure is to prevent the recurrence, to minimize unacceptable risk level to an acceptable one. It is done by:

- Investigation by individual feedback, group discussion and staff motivation, should be done in a blame free atmosphere.
- Documentation should be legible, accountable and contemporaneous.
- Shared understanding between health care professionals creates a better work environment, good communication and teamwork mentality.
- Revalidation was started in 2012, deals with human error, RCOG recognized that the doctors often struggle with work life stress leading to mistakes due to heavy work load. This problem can be solved by counseling and debriefing. Monthly newsletters and interactive risk meetings are of help.

Institute of Health Care Improvement provides tools for use in the management of serious clinical adverse events. IDT (Incident Decision Tree) is an electronic interactive tool designed for NHS managers dealing with staffs who have been involved in an incident guides through a series of structured questions about the individuals’ actions, motives and behavior at the time of the incident. It encourages fair and consistent treatment across NHS, supports managers considering actions and alternatives. It aims to avoid hindsight and outcome bias. System analysis is a boarder examination of all aspects of health care system in question.

Treatment of Risk Events

Risk treatment looks at the measures to minimize the chance of recurrence. It focuses on minimization of risk factors, chances of recurrence and mitigation of damage already in place. RISK Score matrix is the tool which helps in prioritization and strategy decisions.

- It also looks at ways to limit the damage occurred
- Likelihood and severity of risk event give a combined score
- It is closely linked in with Risk control
Conclusion

Patient safety is our main concern with the outcome of a healthy mother & baby. Improvement in patient care rest not only on treatment but also on reduction in the adverse events done in a cost-effective manner, CRM program analyses the factors contributing to obstetric emergencies, and adverse outcome, boost staff morale and reduce the financial cost associated with adverse events.

CRM in Obstetrics is a multidisciplinary management. There is a need for a team of obstetrician, anesthetist, pediatrician, skilled midwives and junior staffs, hence there should be a team culture and good communication mentality. CRM is a rapidly evolving part of obstetric practice

WHO states that any health system should seek to make improvement in 6 areas of health care system, Effectiveness, efficacy, accessibility, acceptability, safety and equitability.

Safety is paramount in any clinical service and good training and supervision of trainees is essential to ensure patient safety. Skill & drill training to manage critical cases is an essential part. A robust RCA is fundamental to improve quality & patient care, FMEA the preventive process based on analysis cannot be separated from RCA. For quality improvement clinical audit is essential. Clinical audit monitors changes & improvement keeping the best practices in mind. CRM works in a systematic manner, by assessment, analysis, reporting in prospective as well as retrospective way,

high profile enquiries in several countries have helped to raise public awareness of safety issue and driven policy change in obstetrics. Systemic approach of CRM ensures patient safety improves standard of care to prevent medical error leading to adverse events, harm to patient, distress to family, friends, relatives, defamation of organizations, financial burden, litigation cost, psychological trauma to treating doctor and team. Advice from national colleges RCOG and ACOG helps in good clinical practice and improvement in all aspects of the best patient care and outcome, highlight the problems and their solution, different helping organizations are there to handle the problems faced and make solutions. CRM will reduce the adverse outcome, improvement in quality care and boost staff morale.
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38. Taylor-Adams S, Vincent C et al; Applying Human Factors methods to investigation and analysis of clinical adverse events; Safety science. 1999;31:143-159
