Society Regn No. BOM 127/1963 GBBSD*
Public Trust Regn No. F-1166 (BOM)

April-June, 2016
Volume IX, Issue-2

NEOCHAP BULLETIN

AN OFFICIAL PUBLICATION OF IAP NEONATOLOGY CHAPTER

Theme : "Improving Quality of Neonatal Care"

CONTENTS

IAP NEOCON 2016

FIRST ANNOUNCEMENT

Dates : 20, 21, 22 & 23 October, 2016

Venue: Indian Institute of Coal Management (IICM), Ranchi

Hosts: IAP Neonatology Chapter,
Indian Academy of Pediatrics Ranchi, Central Coalfields Limited Ranchi

Central Coalfields Limited
A Miniratna Company

IAP Ranchi Branch

Scientific Highlights

Main attractions:

- Dr B B Jha Oration
- Guest Lectures
- Plenary Sessions and Symposia
- Presentation of Gold Medal and Award Papers
- Poster Presentations and Free Papers

Pre-conference workshops:

Invasive Ventilation: 2 days (20th and 21st oct) Ventilation – Basics and settings Surfactant therapy Pulmonary Graphics Patient Triggered Ventilation High Frequency Ventilation Nitric Oxide Therapy Workstations & Hands-on	**Non-invasive ventilation: 1 day (21st oct)** Physiological Basis, Art and Science of Non-Invasive Ventilation Nasal IMV CPAP HHHFNC Case Scenarios Workstations & Hands-on
Point of care USG and functional Echocardiography: 1 day (21st oct) ECHO –PDA, PPHN, Structure Brain USG – Intracerebral Bleeding & RI Chest USG – Pneumothorax, Pleural Effusion Abdominal USG – Ascities, Portal Vein Gas, NEC, Hydronephrosis, Bladder Assessment , Workstations & Hands-on	**Procedures in Neonatology: 1 day (21st oct)** Vascular Access-I –PICC, Managing Difficult Access, Use of Infrared Vein Viewer, Vascular Access-II – UVC, UAC, Central lines Therapeutic Hypothermia – Total Body Cooling (Tecotherm) and Mira Cradle Renal Replacement Therapy with emphasis on Peritoneal Dialysis

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EDITORIAL

Improvement in intact neonatal survival needs application of evidence-based preventive and therapeutic practices. Though we have existing evidence-based interventions both to prevent and to successfully manage major causes of newborn morbidity and mortality, their application in actual practice remains far below optimal. (1,2) This is especially true in countries like India where over last decade facility-based neonatal care has received a major boost in both public and private sector. Provision of infrastructure and staff for facility-based newborn care without an on-going monitoring of processes and health outcomes does not ensure that safe, efficient, effective, timely and patient-centered care is being delivered. This scope of improvement in our neonatal units leaves us with two jobs: the job of providing clinical care and the job of improving the systems and processes around us.(3) This issue of the bulletin of Neonatology Chapter of Indian Academy of Pediatrics highlights various aspects monitoring and improving the quality of care.

In the opening article of this issue Grover S and Kumar P present tools for monitoring quality of care in neonatal units. All neonatal units need to measure, plot and analyze certain indicators which give information about important outcomes (e.g. mortality, late-onset sepsis, air leaks, retinopathy of prematurity, intraventricular hemorrhage etc.) and processes (e.g. temperature at admission to unit, proportion of neonates who receive only human breast milk, proportion of eligible neonates screened for retinopathy of prematurity etc.) of the unit. This 'dashboard' of indicators can help us not only in monitoring the quality of care but also assist in choosing a target for improvement efforts.

Periodic perinatal meetings of neonatal and obstetric teams are commonly conducted in most of the hospitals. These meetings can be helpful in preventing deaths or near-misses if lessons are learnt from past mistakes. Classifying perinatal deaths following a uniform and standardized system and then detecting avoidable factors, missed opportunities and instances of substandard care should be integral part of perinatal meetings. Jain A and Behera B present detailed methodology of conducting a perinatal audit.

Each sick neonate hospital admitted in a hospital receives many medications during the hospital stay. Due to varying weight, gestation age and postnatal age dose and frequency of medications need to calculated on daily basis. This introduces a large scope of errors in calculating or administering the right dose of right drugs to right patients. In absence of computerized dose calculation and good pharmacy support, medication errors are likely to be very common in India. Jain S presents strategies to avoid medication errors in the neonatal units.

Among many tools for improving processes of care checklists have gained prominence. Checklists contain a list of crucial items which need to be completed to perform a procedure (e.g. inserting an intravenous line). Although the concept looks simple, checklists have proven effective in making commercial flights and surgeries safer across the world. There are many multi-step procedures in neonatal units which can be made safer (e.g. in making sure that asepsis is followed). Oleti T in his article introduces the examples of use of checklists in neonatal units.

Many improvement efforts need improving knowledge and skills of healthcare providers. Providing didactic lectures or issuing directions on how to do things are frequently ineffective in changing practices. Adult learning has to be participatory, self-directed and accompanied by immediate feedback. Simulation-based learning allows for training in a controlled environment with opportunities

for practice, assessment and debriefing. Sivanandan S and Sachdeva A present a strong case on how simulation can be used for learning and improving quality of care.

Science of healthcare improvement is relatively new for developing countries like India. However, there is an urgent need to focus on quality of health care and evolve a model of continuous improvement at our health facilities. I hope this issue of the bulletin would kindle an interest in readers to not only learn more about methods of quality improvement but also undertake small projects in their own workplaces.

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Tools for Monitoring Quality of Care in Neonatal Units

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Measurement and assessment of performance is an indispensable part of any system. It requires thorough analysis of the existing procedures and their outcomes in order to identify areas of potential problems or delays. It involves both prospective and retrospective reviews. It is aimed at measuring where you are, and devising ways to make things better. The quality of health care is measured in terms of *structure* or inputs, the material, human and intellectual resources needed to provide care; *processes*, the activities in which these resources are used to provide care; and *outcomes*, the results of the activities (1).

Measuring the quality of care in NICU

Nearly 50 years ago, Donabedian first proposed measuring the quality of health care by observing its structure, processes, and outcomes(2).The goals of measuring health care quality are to determine the effects of health care on desired outcomes and to assess the degree to which health care adheres to processes based on scientific evidence or agreed to by professional consensus and is consistent with patient preferences.

The rationale for measuring quality of care is the belief that good performance reflects good-quality practice, and that sharing experiences and comparing performance in a non-judgemental way among providers and organizations will encourage better performance.

Some recognized agencies and organizations like IHI (Institute for healthcare improvement) have endorsed the use of valid and reliable measures of quality and patient safety to improve health care in different settings and care processes (3). These measures are generally developed through a process including an assessment of the scientific strength of the evidence found in peer-reviewed literature, evaluating the validity and reliability of the measures and sources of data, determining how best to use the measure, and actually testing the measure (4,5).

How to measure quality of care?

Various methods have been described in the literature regarding the measurement of quality of care in various settings like out-patient department, hospital wards, intensive care units etc (2). However, no single method can be perfect because of the various dimensions of the practice of modern medicine. Another problem related to the measurement of quality of care is that there is no fixed definition of "quality". As such, the definition of quality maybe almost anything anyone wishes it to be, although it is, ordinarily, are flection of values and goals currently acceptable in the medical care system and in the larger society of which it is a part. In a given neonatal unit, there may be various sub-areas like delivery room, intensive care unit, well baby wards; each of which may be functionally unique and independent.

The relevant measures or benchmarks of quality may be different in each of these sub-areas of the same unit. Because quality of care is a vast and multi-faceted field, one may choose to focus on one particular theme or aspect before beginning to measure the quality of care in a given area / hospital / unit.

Approach to assessment: what to measure?

The outcomes of medical care interms of recovery, restoration of function, parents' satisfaction, caregivers' satisfaction etc. may be used. Many advantages are gained by using outcome as the criterion of quality in medical care. The validity of outcome as a dimension of quality isseldom questioned. Outcomes tendto be fairly concrete and, as such, seemingly amenable to more precise measurement. Some time saparticular outcome may be irrelevant, as when survival is chosen as a criterion of success in a situation which is not fatal but is likely to produce suboptimal health or crippling conditions, which may happen often in NICU (neonatal intensive care unit) graduates. Hence, judging a system's performance based solely on these *hard outcomes* like mortality has been questioned (5). Table 1 shows some examples of these measures.

Table 1: Examples of Measures of quality in a neonatal intensive care unit (NICU)

Category	Examples -Nurse: Patient ratio in NICU
Structure	-Doctor: Patient ratio in NICU -Assessments of residents' / nurses' skills in various aspects of neonatal care -Delay in procurement of laboratory results
Processes	-Number of babies with moderate to severe asphyxia receiving timely therapeutic hypothermia -Incidence of environmental hypothermia / hyperthermia -Timetaken while preparing a bed to receivea new admission -Hand hygiene compliance rates -Bedside availability of alcohol based hand rub -Number of mothers receiving antenatal counselling regarding breast feeding -Percentage of babies receiving exclusive breast feeds -Number of parents receiving pre-transfer and post-transfer counselling -Number of babies receiving antibiotics / antibiotic stewardship -Incidence of nasal trauma in babies receiving CPAP -Proportion of babies with respiratory distress receiving early CPAP -Proportion of eligible babies receiving probiotics (as per unit policy) -Number of non-isoimmunized babies with jaundicerequiring exchange transfusion
Outcomes	-Mortality (Gestational age / Birth weight specific) -Morbidity (Gestational age / Birth weight specific): Intraventricular haemorrhage (IVH), nosocomial sepsis, necrotizing enterocolitis (NEC), bronchopulmonary dysplasia (BPD), retinopathy of prematurity (ROP), neurological outcomes -Incidence of acute / chronic bilirubin encephalopathy amongst babies with jaundice

The various parameters explained above can be further categorized into sub-typesof "system level measures" as explained below.

How to measure the quality of care?
Measurement plays an important role in assessing the presence and extent of improvement. Key measures are required to assess progress toward the aim. An exercise that attempts to measure or reproduce all the minute details of a process is neither feasible nor effective, and carries the risk of quickly losing the engagement and energy of the key stakeholders. Hence, it is important to remain focused while measuring the quality of care.

What are "system level measures": They are a balanced set of measures which are **not** disease-specific or condition-specific (6). They provide the stakeholders with data which further helps to evaluate the performance of a system over time and serve as input for planning/ modifying the QI measures.

The various types of system level measures are:
1. Outcome Measures: These are used to measure the results at the level of patient. They help the stakeholders in answering some directly important questions like: how is the system performing, what is the result, how does the system impact the values of patients' health and well being? They usually relate to an overall system improvement or a clinical outcome (see table 1).

2. *Process Measures:* These measure the working of the system. They help us to understand if the parts / steps in the system performing as planned, and whether the team is on track in its efforts to improve the system. The estimates of quality that one obtains through this are less concrete and less final than those that derive from the measurement of outcome measures. They may, however, bemore relevant to the question at hand: whether medicine is being properlypractised (see table 1). They are more sensitive to change than the outcome measures. Process measures reflect how the improvements are done. Changes in the process measures eventually have an impact on the outcome measures.
3. *Balancing Measures:* These imply looking at a system from different directions / dimensions. They determine what happened to the system as we improved or tried to improve the outcome and process measures. They reflect unintended consequences of change to other parts of the system or other systems e.g. increase in re-admission rates while trying to reduce the average duration of NICU stay; increase in extubation failure rates while trying to decrease the duration of invasive ventilation in NICU, increased incidence of hyperthermia while trying to fulfil the aim of decreasing the incidence of hypothermia while shifting to NICU.

A project may need several measures to tell the full story, including balancing measures.

Properties of good "System level measures"
The system level measures should have the following essential qualities:

- Meaningful
- Provide us with information and ultimately, knowledge
- Important to all stakeholders
- Related to the project
- Can be operationalized
- Data can be obtained with existing resources
- Can be calculated easily

Operationalizing the "System level measures"
Once the system level measures have been appropriately identified and defined, the stake holders must define the following before operationalizing them for QI purposes

- What are we measuring?
- Why are we measuring it?
- How much data is needed (sample size)?
- How it will be measured (numerator,

denominator, definitions, sampling)?
- How long will it be measured (project duration)?
- Where will the data come from (patient population, inclusion and exclusion criteria)?
- Who will collect the data?
- How frequently will the data be collected?
- Who will analyse the data?
- What methods will be used to collect and analyze the data?

Data collection: Measuring and interpreting the quality of care /

Data collection is the most important aspect of any QI project. Many units across the globe evaluate their performance at regular intervals in the form of monthly or annual audits, and analyse the data for self-evaluation, as well comparisons with other standard units across the region / world.

Measurement of the processes and outcomes plays an important role while judging the quality of care being delivered. Key measures are required to assess progress toward the aim. Specific measures can be used for learning during PDSA (Plan – Do – Study – Act) cycles.

The following important points need to be understood about any data collection process.

- Provide key stakeholders with a clear picture of the structure and functions of the current system including its strengths and limitations
- Highlight the key risks and areas of concern
- Collect useful data, not perfect data
- The purpose of the data is learning, not evaluation
- Keep all data collection simple, yet clinically relevant
- Measurement is important, but not at the cost of disruption of pre-existing services
- Collect and make use of baseline data before starting improvement work
- The final goal of any such process is improvement, and ***not*** measurement
- Measurement is meant to help us decide if the change is leading to an improvement.

How to use the data to measure the quality of care being delivered

Once the planned data is collected, plotting of serial results on a line diagram and comparing them with the pre-existing standards or data from the same or different hospitals / neonatal intensive care units within the same region can be done. Plotting data over time is a simple and effective way to determine whether the changes you are making are leading to improvement ("Measurement–Improvement – Measurement" cycle) (Figure 1).

Figure 1: The "Measurement – Improvement – Measurement" cycle

Using data to measure the quality of care and to drive improvement

Overall performance of the system over a period of time can be done through benchmarking of the important outcome measures.

Benchmarking in health care is defined as the continual and collaborative discipline of measuring and comparing the results of key work processes with those of the best performers in evaluating organizational performance. There are two types of benchmarking that can be used to evaluate quality performance.

Internal benchmarking is used to identify best practices within an organization, to compare best practices within the organization, and to compare current practice over time e.g. comparing the incidence of nosocomial infections within the same unit over a period of time (Figure 2). The information and data can be plotted on a control chart with statistically derived upper and lower control limits. However, using only internal benchmarking does not necessarily represent the best practices elsewhere.

Competitive or external benchmarking involves using comparative data between organizations to judge performance and identify improvements that have proven to be successful in other organizations.

Benchmarking can stimulate healthy competition, as well as help members of a practice reflect more effectively on their own performance (7).

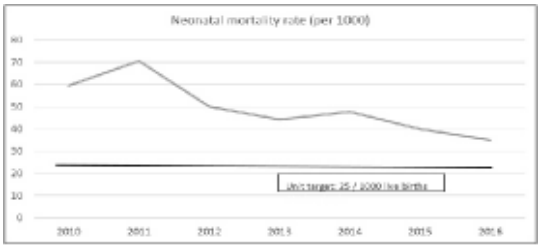

Figure 2: Internal benchmarking: Graph depicting the serial neonatal mortality rates in a tertiary care neonatal unit and the target neonatal mortality rate for the same unit.

The other ways of objectively expressing the quality of care are mentioned below.

Run Charts and Control charts:
One of the traditionally used methods to understand the quality of care being delivered and to understand the process of improvement is to plot the data using the run charts. They are one of the most commonly used tools to represent and analyse the processes and outcomes over a period of time.
Uses of run charts and control charts

- Monitor the quality of care over a period of time
- Monitor process variation
- Differentiate between variation due to common causes versus special causes
- Evaluate past performance
- Monitor current performance
- Determine if we are improving or deteriorating
- Determine if we are holding the gains

We can annotate the run charts with changes. With the help of this, the *effective changes* (changes which contributed to improvement) and *ineffective changes*can be identified. (as shown in figure 3).

A *control chart* is somewhat similar to the run chart, but it has additional *control limits* which help us to statistically understand the process variations. Minor variations ("common cause variations") are a part and parcel of any process and are not statistically significant. There is a certain set of rules i.e. "API (Associates for Process Improvement) Rules for detecting Special Cause", which can be applied to the control charts to interpret if any variations are "special cause variations" and can hence, help us understand that which processes are effective or ineffective. These are as follows:

1. A single point outside the control limits
2. Eight or more consecutive points above or below the centre line
3. Six (or more) consecutive points increasing (trend up) or decreasing (trend down)
4. Two out of the three consecutive points

near the control limit (outer one-third) (even if the points are on the opposite sides of the centre line).

5. Fifteen consecutive points close to the centre line (inner one-third).

The *common cause variations* indicate a stable process. The *special cause variations* suggest that either the process is unstable, or is showing improvement or worsening (depending upon the location or trend of the data points).

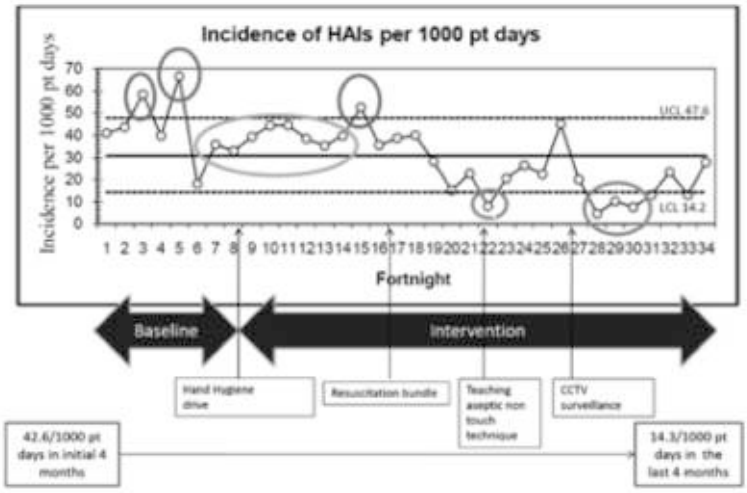

Table 2: Quality measures related to compliance to aseptic techniques in an neonatal intensive care unit

Evaluation issue / Quality parameter to be measures	**Sub-Questions**	**Methods / Indicators of quality of care**
Adherance to asepsis protocols in neonatal ICU	-Hand hygiene compliance -Compliance to aseptic non-touch techniques (ANTT) while blood sampling or inserting peripheral vascular lines -Compliance to central line insertion bundle -Rates of nosocomial infection	-Bedside availability of alcohol based hand rub -Bedside availability of gloves -Assessing the technique of hand hygiene of the nursing staff / doctors -Audits of hand hygiene compliance -Audits of adherence to ANTT / "Central line insertion" bundle -Incidence of screen positive / culture positive sepsis

Overall, measuring the quality of care being delivered is the most important part of any healthcare system. This must be followed by collaborative learning and the dissemination of information in order to provide good quality health care services.

Key messages:

1. Measuring the quality of care being delivered to the patients is an integral part of any health care system evaluation.
2. Measuring the quality of health care involves objective assessment and measurement of outcome measures, process measures, and balancing measures.
3. Planned collection of useful and clinically relevant data by using validated and pilot tested tools is very important.
4. Analyzing the data and representing the information through tools like run charts or control charts is an effective way of measuring and interpreting the quality of care being delivered to the patients.

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Perinatal Audit

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Perinatal mortality is an important indicator of quality of perinatal care. A perinatal audit is a serious systematic study or investigation into the possible potential determinants, their mechanisms of causation and scope of avoidability with regard to the perinatal and neonatal deaths. This logical exercise helps to improve the quality of care through systematic assessment of current practice against a defined standard with proven advantages. It educates the perinatal care providers of the deficiencies/successes in their practice.(1)An example is The Maternal and Perinatal Death Inquiry and Response (MAPEDIR) process conducted in selected districts of four states in India (Rajasthan, Orissa, Bihar, and Jharkhand) by use of standardized questionnaire for key informant interviews, participant observation checklist, analysis of verbal autopsy questionnaire and maternal death reports. This has been able to identify sociocultural, economic and health care systems related determinants of maternal deaths. (2)Perinatal audit is best and most commonly performed by the treating clinicians themselves. The clinicians look in retrospect at their own practice and derive out how to improve it so that the outcomes may be optimal. This is followed by advancing the derived knowledge and education in a systematic way at all levels of perinatalcare. Audit is a mandate if one wants to change the practice, to meet the constantly rising expectations. Simple audits that address clinically relevant questions can pay heavy dividends in changing the practice, improving the care and saving lives.(3)Hence, a perinatal audit may go a long way in improving the quality of perinatal care and chances of survival of pregnant women and their newborn babies.

Most centers now consider all stillbirths and early neonatal deaths after 22 weeks of gestation or weighing 1000 grams for the calculation of Perinatal Mortality Rate (PMR).

The perinatal audit like any other audit is a process of continuous improvement, and therefore the 'audit cycle' should repeat itself endlessly. The stages of the cycle are represented in the Figure 1

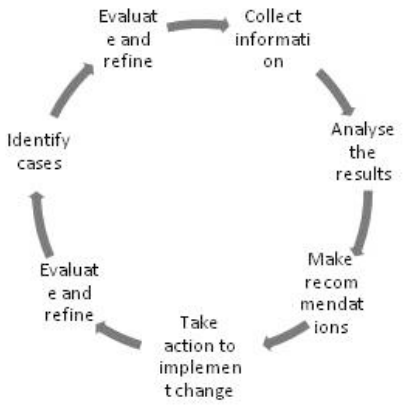

Figure 1: Audit Process of continues improvement

Types of Perinatal Audit(4)

The focus of the perinatal audit determines the type of the perinatal audit that is to be undertaken. Even though, the general principles of all the audits are the same. The objectives may differ in different types of audit. The following are some of the examples of types of perinatal audits

1. Outcome audit - Record all deliveries and perinatal deaths and estimate PMR.
2. Sentinel event audit (Critical incident audit) - case review of perinatal deaths, identify avoidable factors and make

recommendations.

3. Topic audit (Criteria based audit)- done to monitor implementation of a recommendation.

Classifying Perinatal Deaths in a Perinatal audit(5)

Classification of perinatal death in an audit helps to delineate major obstetrical or neonatal factors associated with perinatal death, thus guiding to take appropriate actions to reduce perinatal death. The Wigglesworth is the oldest classification system used. Various classification systems have evolved since than vizCODAC, PSANZ-PDC, ReCoDe , Aberdeen, and Tulip . TheCODAC and ReCoDe classifications are provided in appendix II and III respectively. A sample case history with the classification is also illustrated.

An effective perinatal audit process includes the following crucial activities:

Review of each perinatal and maternal death within 24 hours of the death:

Every perinatal and maternal death should be reviewed within 24 hrs. The team involved in the management of the mother and the baby should be consulted and efforts be made to ensure the accurate and complete record of information and a preliminary assessment of the primary cause of death, the final cause of death and preventable factors is determined. As a rule the earlier the records are completed after an event the better is their quality.

A preparatory review meeting:

A summary should be prepared that highlights the salient and relevant points learnt from the immediate review (see above) for the presentation at a formal perinatologymeet for discussion. The perinatal statistics for the month are to be reviewed monthly and interpreted and key indicators should also be analyzed. Each maternal and perinatal death is studied in detail to determine the primary and final causes of death and detect preventable factors (missed opportunities/ lapses / delays / system failures). Suggestions to ascertain how to improve future management against each case should be formulated. Preventable factors generally may be classified as;

(1) Health worker related: where doctor or midwife had a direct influence on the perinatal death; e.g.- if baby is not timely attended at delivery and the team is not trained in neonatal resuscitation.

(2) Administration related: where the responsibility of the health authority was not available;
e.g.- if the health authority fails to provide timely and adequate drugs, infrastructure, proper nurse to patient ratio, etc.

(3) Patient related: un-booked pregnancy, late admissions, delay in consent for the operative delivery, delay in arranging the blood, concealed medical history.

(4) Clinical management related: e.g. not providing timely antenatal steroids to mothers, not timely administering surfactant to premature babies, etc.

Monthly Perinatal Review Meeting (PRM):

This meeting is done with all the members (Doctors / Nursing staff / others) of the Obstetrics and the Neonatology team at least once a month. Here one should review the perinatal statistics, preventable factors for the month under review and determine the corrective action. One or two perinatal deaths should be selected for detailed presentation at the PRM. Cases which contains factors that are directly/indirectly preventable by the service, has educational value or the issue has not been reviewed recently. Detailed discussion of the obstetric topics, the protocols of management should be reviewed to decide whether any up-dating is necessary. Discussion of the statistics should probe all preventable factors and plan corrective action in the care patient has received. Issues like quality counselling and adequate follow-up also should be discussed and instituted.

Quarterly or 6-monthly epidemiological analysis of perinatal and maternal deaths

These meetings should focus on summarizing the (1) primary causes of maternal and perinatal deaths (2) The final causes of

maternal and perinatal deaths (3) The preventable causes of these deaths. The status may be compared with the national level statistics and statistics of the model referral hospitals.

Apart from internal audit, external audit at the national level has the advantage of superior knowledge, experience of experts and their valuable suggestions. Audit process must be used to identify suboptimal care and preventable factors and in evolving strategies and guidelines.

Sample Perinatal Death Audit form:

The structured documentation and a strict enquiry into the sequence of events is the most import step in the perinatal audit. The quality and the outcome of the perinatal audit depends on the availability of information at all stages starting from the antenatal events to the early neonatal course in the neonatal intensive care unit. A sample perinatal audit form is attached as annexure I. Based on such a perinatal audit form, one can assign the cause and the factors governing a perinatal death, the various classifications aid in this process (Annexure II, and III).

The final desired outcome of a perinatal audit is to formulate targeted recommendations, implementation of the new recommendations and to assess the changes as an ongoing process. This will reduce the perinatal mortality rate contributed by the preventable perinatal deaths.

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ANNEXURE 1

PERINATAL DEATH AUDIT FORM

Date of Audit……Health Facility (Name): ……Type of Facility: ……

TYPE OF PERINATAL DEATH:

Still Birth: ☐Antepartum ☐Intrapartum ☐Time of fetal death not known

Early Neonatal Death: ☐

MATERNAL DETAILS

CRNO. (Mother): …… Mother's name ……CRNo. (Newborn)……

Address:……

Date and time of baby's birth: Date: …… Time:……

Date and time of baby's death (neonatal): Date: …… Time ……..

Marital status: Unmarried / Married / Widowed/ Divorced /Separated

Education: …… Mother's occupation……

Mother's height:……cms , **Weight:……**kg , **Age** ……Yrs

Mother's previous obstetric history: G……**P……A……L……**

Details of previous pregnancies *(list in order from first pregnancy)*

DOB	Place of Birth	Gestational Age/ Sex	Birth Weight	Pregnancy outcome	Complications	Imp Investigations

Spontaneous conception, fertility treatment or assisted conception in this pregnancy?
Antenatal care: 1. Yes 2. No If yes how many times: ……., Gestation at first ANC……
Place of Visit:……..
Tetanus Toxoid: 1. TT1 2. TT2 .
HIV test : Positive / Negative If HIV positive: 1. On ARVs 2. Not on ARVs, Syphilis test:

Conditions in present pregnancy:
1. Antepartum Hemorrhage 2. Hypertension 3. Pre-labour rupture of membranes. 4. Diabetes 5. Anemia 6. UTI7. Malaria 8. Trauma-accidental 9. Trauma –gender based violence. 10. Multiple pregnancy 11. pPROM 12. Prolonged rupture of membranes 13. Cholestasis of pregnancy**.**
14**.** Confirmed maternal infection…….. 15. Others ……

Calculated gestation of pregnancy at birth: Completed Weeks……., Type:1. Singleton 2. Twin
Is mother a smoker? Yes/ No
Suspected fetal growth restriction during pregnancy: Yes/No, if Yes than onset ……..Wks
Antenatal procedures: Yes/No , Nature of Procedure ……
Antenatal Scans: First trimester screening scan: ……
Anomaly scan at ⩽ 20 gestation……

DELIVERY (PERIPARTUM) DETAILS
Place of birth : Home / Hospital / Referred from Primary center **, Date of delivery……..**On admission, were there fetal sounds present? Yes/No/Not assessed

Fetal monitoring during labour: Yes/No/ Unknown
Intermittent auscultation: FHR……., BBV……
CTG : Pattern (Worst) during examination : ……
Was partograph used? 1. Yes 2. No 3. Unknown, Was it used correctly? 1. Yes 2. No

Antenatal Steroids:
Drug……Doses:……Timing (in relation to birth)……
Mode of Delivery: 1. Vaginal Delivery 2. Caesarean Section 3. Vacuum or Forceps 4. Others ……
Indication for Instrumental /or Caesarean section: ……
Time between decisions for Cesarean section /instrumental and actual delivery of the baby:
1. Less than 30 minutes 2. 30 minutes - 1 hour 3. Greater than 1 hour
Did vaginal delivery occur in spite of decision to do caesarean section?? 1. Yes 2. No

Anesthesia for operative delivery : General / Spinal/ Epidural
Complications in labour: Yes/ No / Unknown
APH / Meconium liquor / Fetal bradycardia/ Non-reassuring CTG/ Cord entanglement/ prolapse
Shoulder dystocia / Failure to progress/dystocia / Other : ……

Duration of labour:
a) First stage: hours minutes *or* Unknown
b) Second stage: hours minutes *or* Unknown

Placental examination:
Placenta weight: gm **or** Unknown/ Gross Examination ……
Was placenta sent for Histopathology ……

Umbilical cord notable features:
Normal / True knot / Cord round neck / Cord round limbs or body / Marginal/ Velamentous insertion / Abnormal cord length short long (…….cms) / Meconium stained / SUA

NEONATAL (AT BIRTH) DETAILS:
Apgar score : 1 min…..5min…….10min……/ Don't know. Resuscitation done: Yes/No

Resuscitation: Done by: 1. Doctor 2. Nurse 3. Trainee (doctor/ nurse)
If 'Yes' 1. Stimulation 2. Suction 3. Oxygen given 4. Bag and Mask 5. Endotracheal & PPV 6.CPR 7. Medication. Cord gases at birth**:** Yes (Ph ……..BE……..) / No Unknown

Weight of the baby:…….gms. Sex: Boy/ Girl
Type of Perinatal Death: Fresh Still Birth / Macerated still Birth / Early Neonatal Death

Baby's examination after birth (live and stillborn babies):
Length……**cm .** OFC ……..External abnormalities noted……

NEONATAL (EARLY NEONATAL) DETAILS:

If baby admitted to hospital, provide details of further treatments
Reason for admission :Difficult feeding (baby)/ Difficult breast feeding (mother)/ Jaundice/ Anaemia / Difficult breathing / Hypoglycemia/ Septicemia/ Hypothermia/ Bulging fontanelle/ Fever/ Convulsions/ Bleeding / Other conditions specify:……

Summary of significant neonatal events:……
……

Probable cause of Early Neonatal death: Tick all applicable (tick)
Septicemia/ Birth Asphyxia / Trauma/ Congenital Anomaly / Extreme Prematurity / Others (Specify)
Most important single cause : ……

MATERNAL OUTCOME:

Maternal outcome:
- Alive and generally well
- Alive but with serious morbidity (e.g. admitted to ICU, hysterectomy, stroke).
- Dead

PERINATAL AUDIT DETAILS:
Avoidable factors/missed opportunities/substandard care.

1. Delay to seek health care	
2. Delay to reach the health facility	
3. Delay to provide care	
4. Absence of critical human resources	
5. Lack of resuscitation equipment	
6. Lack of supplies and drugs including blood	
7. Misdiagnosis	
8. Inappropriate intervention	
9. Poor documentation	
10. Others	

Comments on avoidable factors and missed opportunities:

……

……

SUGGESTED ACTION (SINGLE MOST IMPORTANT WITH HIGH IMPACT):

Actions taken to address the avoidable problems

……

……

CONFIRMATION OF DETAILS :

The form was completed by: Name: ----------Tel: ----------

Email: ---------- Date: ----------Signature: ----------

ANNEXURE II

Categories of the primary causes of death (COD) and associated conditions (AC); CODAC

0. Infectious causes of death (abbrev: Infection) Deaths caused by infections affecting the mother, neonate or intrauterine structures and compartments directly are coded here by the causative agents as the primary COD. This includes lethal effects of infection by leading to congenital anomalies, by causing direct failure of the placenta or vital fetal/neonatal/maternal organs, or by initiating pre-viable preterm labor.

1. Conditions, diseases and events specific to neonatal life (abbrev: Neonatal) Neonatal deaths caused by conditions or events specific to neonatal life are coded in this category as primary COD. Other COD and AC for neonatal deaths may be coded in any other relevant category.

2. Mechanics and events of parturition or its complications (abbrev: Intrapartum) Deaths occurring after onset of labor (intrapartum or neonatal) and where the most significant causal mechanisms were initiated by the onset, progress or complication of labor, are coded in this category as primary COD. Cases in which pre-existing conditions had reduced fetal survival potential to such an extent that mortality in normal and otherwise uncomplicated labor is significant (proportion > 0.05) if undelivered, should be coded with that condition as the primary COD with Intrapartum in a subsequent position.

3. Congenital anomalies, chromosomal anomalies and structural malformations (abbrev: Congenital anomaly) Deaths caused by congenital and chromosomal anomalies and structural fetal malformations, including effects of amniotic banding, are coded here as primary COD. Malformations of the placenta and cord are coded in those categories, with the exception of amniotic banding which are all coded here, irrespective of structures affected. Disruptions/deformations due to maternal uterine malformations are coded in Maternal.

4. Fetal conditions, diseases and events (abbrev: Fetal) Deaths caused by any fetal condition, disease or event (except Congenital anomaly) are coded here as primary COD. This includes those caused by placental transfer of toxins, or maternal antibodies against fetal tissues (as in alloimmunization) that does not constitute a maternal disease. The effects of maternal antibodies against her own tissues (as in anti-cardiolipin syndrome causing placental thrombosis or SS-A/SS-B antibodies causing fetal arrhythmias), should however be coded in Maternal.

5. Cord conditions, diseases and events (abbrev: Cord) Deaths caused by any condition, disease or event affecting the umbilical cord and its insertion are coded here as primary COD. If the same process has been shown to be present and equally significant in the fetal compartment, the primary COD should be coded there, if applicable.

6. Conditions, diseases and events of the placenta and membranes (abbrev: Placenta) Deaths caused by any condition, disease or event affecting the placenta and membranes are coded here as main COD. If the same process has been shown to be present and equally significant in the fetal or cord compartment, the primary COD should be coded there, if applicable.

7. Maternal conditions, diseases and events (abbrev: Maternal) Deaths caused by any maternal condition, disease or event, of a sufficient degree to significantly increase the risk of perinatal death are coded here as primary COD. If the same process has been shown to be present and equally significant in the fetal, cord or placental compartment, the primary COD should be coded there, if applicable. This category includes conditions that was unrelated to of pregnancy (as in maternal cancer), was incompatible with a viable pregnancy (as in Ehler-Danlos syndrome), was exacerbated by the normal physiology of pregnancy (as in anti-phospholipid syndrome), or was caused by uncertain mechanisms of pregnancy, and yet poses serious threats to maternal and fetal health (as in acute fatty liver of pregnancy). In exceptional cases, the category may include maternal pathology provoked by non-lethal pathophysiology of pregnancy (as in acute onset pregnancy-induced hypertensive crisis with apparently minimal placental pathology). Symptoms (as hypertension) caused by intrauterine pathologies (as placental insufficiencies) should not be coded as a COD, but may be coded in subsequent positions.

8. Unknown, unexplained and unclassifiable causes of death (abbrev: Unknown) Neonatal, antepartum, and deaths with unknown timing, in which no definite or probable COD has been found are coded in this category as the primary COD. Otherwise unclassifiable cases are also coded here. This category only exists for causes of death, and is replaced by Associated perinatal for AC.

9. Terminations of pregnancy (abbrev: Termination). All deaths caused by termination of pregnancy are coded in this category as the primary COD. This is irrespective of the indication, timing of death, or whether termination was performed by health professionals or not. It includes augmentations of labor in cases of expected unavoidable death, and also cases in which

death did not occur before the completion of delivery. This category only exists for causes of death, and is replaced by Associated maternal for AC.

Categories specific to associated conditions:

8. Associated conditions and complications in the perinatal period (abbrev: Associated perinatal) AC and complications of pregnancy are coded here in the secondary or third position.

9. Associated maternal conditions and identified risk (abbrev: Associated maternal) AC and identified risk of the mother are coded here in the secondary or third position.

ANNEXURE III

Classification system according to relevant condition at death (ReCoDe)

Group A: Fetus 1. Lethal congenital anomaly 2. Infection 2.1 Chronic 2.2 Acute 3. Non-immune hydrops 4. Isoimmunisation 5. Fetomaternalhaemorrhage 6. Twin-twin transfusion 7. Fetal growth restriction*	**Group B: Umbilical cord** 1. Prolapse **2. Constricting loop or knot†** **3. Velamentous insertion** **4. Other**
Group C: Placenta 1. Abruptio 2. Praevia 3. Vasa praevia 4. Other "placental insufficiency"‡ 5. Other	**Group D: Amniotic fluid** 1. Chorioamnionitis 2. Oligohydramnios† 3. Polyhydramnios† 4. Other
Group E: Uterus 1. Rupture 2. Uterine anomalies 3. Other	**Group F: Mother** 1. Diabetes 2. Thyroid diseases 3. Essential hypertension 4. Hypertensive diseases in pregnancy 5. Lupus or antiphospholipid syndrome 6. Cholestasis 7. Drug misuse 8. Other
Group G: Intrapartum 1. Asphyxia 2. Birth trauma	**Group H: Trauma** 1. External 2. Iatrogenic
Group I: Unclassified 1. No relevant condition identified 2. No information available	

* < 10th customised weight for gestational age centile.
†If severe enough to be considered relevant.
‡Histological diagnosis.

Example – 23 yrs old primigravida, booked lady, at 35 weeks of gestation developed sudden onset of bleeding per vaginum and abdominal pain. At admission in emergency fetal heart sound was not audible, mother was in shock, gasping with profuse bleeding per vaginum. She was immediately intubated, given saline bolus, ionotropic support, whole blood transfusion and taken to OT and emergency LSCS was done under GA. Baby was delivered , was limp, no efforts and no heart sounds recordable. Immediate resuscitation was tried but could not be revived and so declared as fresh stillbirth.On placental examination large retroplacental clot was present.

According to ReCoDe classification- Group C-1 (Annexure III)

Avoiding Medication Errors in Neonatal Intensive Care Unit

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Background: Patient safety is priority of health care system and has drawn particular attention since the publication of report of "To Err is Human: Building a safer health system."Medical errors are a general term used to denote all errors that occur within the healthcare system. Since medication is the most common health-care intervention the errors arising out of its usage are potentially an avoidable cause of iatrogenic injuries in health care set up. In United States alone more than 7,000 deaths /year happens in and out of hospital due to medication errors. Errors of medication have been reported to be as high as 15% in neonates from India. [1] In a recent survey done on knowledge of medication errors from north, west and east regions India it was found that 72% of respondents had average or above average basic knowledge regarding medication errors whereas 94% respondents had knowledge regarding non-existence of reporting system for medication error in India. [2]

Definition: Medication error is defined by United States National Coordinating Council for Medication ErrorReporting and Prevention (NCC MERP) as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use. [3]

Six severity levels, as a consequence of medication errors have been identified by American Society of Hospital pharmaceuticals: ranging from Level 1- "No injury" to level 6 as "Mortality".[4] Safety of margin is very narrow in neonates and even small errors can cause consequences in form of increased hospital costs, increased need of monitoring, of diagnostic tests, and of drug administration to control their effects, delayed hospital discharge, temporary or permanent patient disability, and cost of lives, increase of insurance premiums and above all loss of patient trust in the healthcare system.

Why are newborns more vulnerable for errors?

- Different body composition and organ maturity, which affects the ability to metabolize and excrete drugs and reduces the capability to counteract the consequences arising from a medication error.
- Dosing by age and weight, age specific contraindications of medications, age-related formula, mathematical calculations represent opportunities for error.
- Absence of pharmaceutical products with dose forms appropriate for paediatrics, which implies manipulation of the drug. Off-label drugs that are used under different conditions from those approved on the product label that do not provide information on the use of the product in children.
- Limited communication capacity. Children cannot identify and avoid errors that they might experience; they are dependent on their parents or caregivers.

Contributory factors of medication errors in neonates

Error-producing factors

1. Environmental – busy ward, interruptions

2. Team – lack of supervision
3. Individual – limited knowledge, fatigue, sleep deprivations, unavoidable imperfections in cognitive process (memory, attention, reasoning)
4. Task – repetitious, poor medication chart design
5. Mechanical- Poor devices, lack of devices

Latent factors

1. Organizational processes – workload, handwritten prescriptions, Nurse: Patient, Doctor: Patient ratio inadequate
2. Management decisions – staffing levels, shift duties, culture of lack of support for interns
3. Workplace design factor: Lack of reporting system, stacking of high alert medicines or look alike medicine together, and medication not stored in ready-to-use form
4. Medication design factors: Medications with similar names, e. g phytonadione 1 mg and 10 mg are very similar looking, labelling too small to read

Tools to identify errors [5-8]

	Various tools for error detection	Limitations
1.	Audit: Medical record review and prospective by Audit team blinded to interventions	Time consuming
2.	Patient satisfaction questionnaire	Biased and limited opinion
3.	Audit of morbidity and mortality	Time consuming, lacks real time assessment
4.	Self-reporting of Incidents	No such structured system exist in our country, fear of punitive action
5.	Event Surveillance program	Harm might have already happened
6.	Learning from verbal autopsy	Effective but limited tool
7.	Trigger tools	Effective tool but miss out lots of errors
8.	Fish-bone analysis (Cause and effect analysis)	Effective tool
9.	Automated Detection of Medication Administration Errors	Better than trigger tool or self reporting

What should be done if error is detected?

Transparency and open disclosure can reduce risk to institution; but there is some fear among the health care team regarding the disclosure. There should be clear law of the country, state and institutions on compensation issues. As per last amendment of drug and cosmetic act in 2013 it is essential to report any unexpected event and serious adverse event in a clinical trial. There is a checklist for submission of serious adverse events (SAE) to Central drug standard control organization but there is no structured format of incident or error reporting, auditing and feedback from various centres. Confidentiality and anonymity should be maintained for patient and reporting personnel and reporting should be non –punitive.

The Harvard Framework for disclosure includes seven steps: preparation; initiating a conversation; presenting the facts; active listening; acknowledging what has been said; concluding the conversation; and documenting

the conversation.

Interventions to decrease medication error

Decreasing medication preparation error

- Using standardized protocols (with diagram for steps of preparation)
- Optimize environmental conditions (less noise, well illuminated room)
- Different syringe for loading drug and diluents
- Syringe size should be according to volume to be loaded (as dead space allowed is 0.07-0.20 ml for various volume of syringe)
- Avoid using bottle/ bags of diluents
- Mix reconstituted medicines for at least 30-60s
- Avoid volumes with decimals wherever possible
- Label medicine after preparation
- Use three way valves to ensure health care safety

Above bundle had been shown to decrease calculation error to nil and accuracy rate error to 50% in NICU [9].

***Reducing antibiotic errors by accountingfor*: [10]**

- Prescribing errors: Over/under dose. 10% variance from prescribed dose
- Omission: not omitting once not indicated, eg inotropes tapered and omitted late
- Inappropriate route/schedule, > 30 minutes in case of emergency and 90 minutes for routine
- Inappropriate empiric antibiotic (susceptibility/ culture report not taken into account), patient details not reviewed
- Drug interactions and contraindications
- Administration rate: as per pharmacokinetics and pharmacodynamics: concentration based/ time based
- Cutting/grinding medicine/ dispersible tablets affects bioavailability, stability and compatibility (Let the drug be prepared in pharmacy)
- Shelf life of medicine after preparation
- Potential error: misspelled drugs, illegible order, leading decimal, tailoring zero, using abbreviations, first/loading dose

Look alike/sound alike medicine error reduction

- Avoid verbal order
- Careful reading of label
- Check the purpose of medication on prescribing order
- Use BOLD face/ colour difference
- Don't stack such medicines in close proximity

Preventing Patient misidentification

- Use ID bands
- Use standardized format of information on ID bands (name and date of birth)

Dealing with Concentrated electrolyte solution

- Limit the supply
- Use infusion pumps (smart pumps with alarm for deviation from programmed dose)
- Put high risk warning labels

Preventing Tubes and catheters wrong connections (Such errors are common with central lines/ TPN)

- Tubing and devices not to be touched by non-clinical staff, patient's family
- Separate label / different colour lines for (arterial/ venous/ peritoneal dialysis catheter/ intra-arterial blood pressure monitoring, oxygen and suction)
- Trace all lines from origin to connection port before making connections or reconnections, administering solutions, medications or other products

Reducing prescribing errors

- Use 7 R system
  - Right drug
  - Right route
  - Right time
  - Right dose
  - Right patient
  - Right documentation
  - Right of a staff member to question a medication order
- Double checking of prescriptions
- Reading the label on ampoule before loading the medicine
- Avoid verbal order: if verbal order is needed in emergency situation use complete prescription (name of drug, dose, its dilution factor), further sister should close the loop by

saying she is giving prescribed oral drug in a dilution factor.

- Pre-formatted medical order sheet. [11]
- Double checking of prescriptions
- Reading the label on ampoule before loading the medicine
- Avoid verbal order: if verbal order is needed in emergency situation use complete prescription (name of drug, dose, its dilution factor), further sister should close the loop by saying she is giving prescribed oral drug in a dilution factor.
- Pre-formatted medical order sheet. [11]

Start date, time	Signature	Drug	Dose (mg/kg/dose)	Dose interval	Route	Infusion time (in minutes)	Stop time, date,signature
		Drug 1					
		Drug 2					
		Drug 3					

- Use drug formulary to check dose
- Use electronic calculator for calculations/MS excel sheets/Apps/ computerized algorithm

***Multifaceted education intervention to decrease medical preparation and administration errors*[12]**

- Group discussion
- Video-based
- Power point presentations
- WHO patient safety curriculum
- E-learning modules
- Simulation based

Building Good communication system

One of the tools used is SEUGE (Set the stage, Elicit information, Give information, Understand patient perspective, End the counter)

Others

- Use CPOE –CDS (Computerized provider order entry with clinical decision support) although recent reports of new errors introduction by CPOE system has been seen
- Colour coded pre-filled syringe[13]
- Automated system with smart infusion pump to detect rate difference as small as 0.1 ml between ordering and administering especially for inotropes, opioids, vasopressers[8]
- Enlisting high risk medications

An international group of experts defined 14 medications and 4 class of medication as high risk for pediatricpatients; newborn till 18 years of age. [14]

<u>High alert medicines</u>

Gentamycin	Dopamine
Digoxin	Tacrolimus
Norepinephrine	Phenytoin
Potassium	Insulin
Amiodarone	Morphine
Epinephrine	Heparin
Propofol	Fentanyl

<u>Classes of high alert medicine</u>

Chemo-therapeutic drugs
Immunosuppressive drugs
Lipid/Total parental nutrition
Opioids

Conclusion: Medication error are preventable iatrogenic injuries which can be reduced by multi-faceted approach dealing with human factors, environmental factors, establishing learning system and patient safety organisation programs involving family of patient.

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Use of Checklists in Neonatal Intensive Care Units

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With improvements in technology and personal expertise, the survival rates are getting better in neonatal intensive care units (NICUs). However, the improvement in just survival rates may not be enough and preventing long-term morbidities among the survivors is equally important. The quality of care and exposure to different short-term morbidities during neonatal period may impact the growth of developing brain and other vital tissues.

Checklist is a tool which contains a list of items required, things to be done, or points to be considered while doing a process or before starting a treatment. Checklists are used readily available reminders which can help in reducing errorsdue to human memory lacunae and inattention. Use of checklists gained popularity first in the aviation industry. Later checklistswere introduced in different industries and organisations. In medical profession, they have been tried in many high-risk areas. Checkliststry to bridge the gap in existing knowledge and practices. In 2009, Haynes et al. reported that by using these pre- and post-surgical checklists, in-hospital mortality rate reduced by half while complications related to surgery fell by one-third.[1]This study was done as a part of "Safe Surgery Saves Lives program" conducted in collaboration with World Health Organisation (WHO) and these results encouraged many clinicians to apply the checklists in different fields of medicine. It has been shown that checklists show their effect by multi-layered protection effect (Swiss-cheese model).[2]

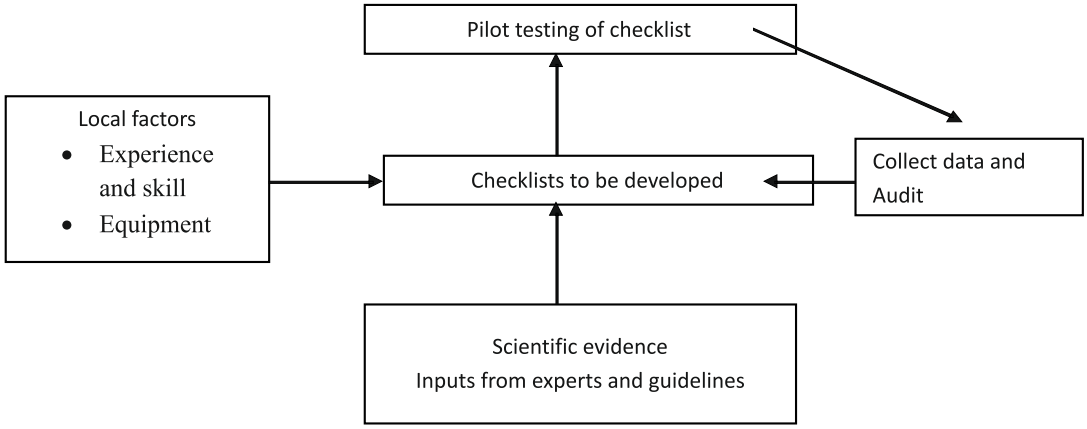
How to make a checklist? [3,4]

- Determine the need for checklist
  - The checklists should define in which context it is to be used. Before, preparing the checklist, one should go through the available peer-reviewed literature and the evidence on the quality points and prevention of errors should be adapted to local needs.
- Identify the personnel and situations where it should be used
  - Identify teams who will use it like nurses, doctors and other para-medics
  - List the instruments required for the implementation
  - Identify and define the area and process where it should be used
- Develop content based on evidence, inputs from multi disciplinary team, looking at the current practices in the unit and conducting an expert review where needed
- Design of the checklist
  - The structure of checkpoints should be in the standard flow of patient care
  - Use clear equally spaced word with good font size to make check lists
  - The capitals, images and colours should be used where it is appropriate (red: to indicate emergency or error prone areas).
  - Should also consider the clinical state of mind
- Pilot test to look at the validity
- Review the results with appropriate team
- Take permissions from the concerned authorities before implementation
- Develop a training programme for the personnel
- Run a small test to look at the benefits and compliance
- Review the content of checklist regularly based on available evidence

How to use checklists?

- The person who is doing the process should be aware of the potential complications and difficulties that can occur at each step of the

process
- He/she should read it before starting the procedure
- An independent person should fill the compliance of check list components and give the summary at the end of the process
- Take the signature of independent observer and the other personnel involved in it at the end of the process



Flow diagram showing process in developing checklist and its implementation

Advantages of checklists
- Improvement in mortality related to process or treatment
- Reduction in the process/treatment related complications like nosocomial infections, errors in drug dosage and complications related to medical therapies, mishaps occurring during catheter insertions and other routine procedures
- Improvementin the quality of care

Disadvantages of checklist
- Checklists fatigue
  - o Too many or too lengthy checklists may burden the process
- Checklists may complicate the implementation of process and decrease reliability
- Too strict implementation may undermine the clinical judgement

The routinely used checklists in NICU are
1. Checklists to prevent central line associated blood stream infections
   a. Include insertion and monitoring checklists for peripherally inserted central catheters (PICC) and umbilical vascular catheters
2. Infection control audit checklist
3. Checklist during endotracheal intubation
4. Checklists during suctioning of end otracheal tube
5. Checklist to prevent ventilator associated pneumonia (VAP) for neonates on respiratory support
6. Checklists for transportation
7. Checklist during exchange transfusion
8. Peri-operative checklists for neonates undergoing surgery
9. Checklist for neonatal resuscitation and management during golden hour

Examples for checklists
Central line associated blood stream infection (CLABSI)checklist:

Name: Sex: Hospital ID:

Date of birth: Gestation: CGA:

Birthweight: Catheter days:

Is the central venous catheter indicated (ask yourself daily): YES / NO

	YES	NO	NA
DURING INSERTION			
Central line insertion kit ready			
Vein identified and measurements done before the procedure			
Upper limb veins preferred			
Hand hygiene ensured			
Clinician / Nurse wears cap, mask, sterile gown and gloves			
Skin disinfected as per local protocol			
Number of pricks minimized			
Hemostasis ensured before dressing			
Transparent dressing used			
Catheter tip positioned properly and checked			
Access ports covered with sterile pads			
Access ports placed away from diaper area			
MAINTENANCE & HANDLING OF CATHETER			
Hand hygiene before accessing the catheter			
Sterile gloves used before access			
Catheter entry site checked for inflammation / swelling			
Replace dressings that are wet, soiled, or dislodged			
Perform dressing changes under aseptic technique using clean or sterile gloves			
Scrub the hub with antiseptic as per local policy			
Flushing done under aseptic precaution			
Central catheter used only for infusions			

This is one of the commonly used checklists in NICU. In the above checklist, you can appreciate the incorporation of error prone and safety points and other important steps.

Evidence on checklists in neonatal intensive care units

Sculman et al. in their study have looked at the effect of state wide adaption of CLABSI checklists and bundles in a before and after study design. [5] In this study, CLABSI rates were decreased by 67%state-wide (risk ratio: 0.33 [95% confidence interval: 0.27– 0.41]; P: .0005). California Perinatal Quality Care Collaborative (CPQCC) initiative has used evidence based intervention bundles and checklists in the delivery room to improve the quality of care. Implementation of a CPQCC

initiative has shown that the risk of hypothermia has reduced from 39% to 21%, delivery room intubation from 53% to 40% and surfactant administration from 37% to 20%.[6] This quality initiative has also looked at the implementation of nosocomial infection prevention tool kit to reduce the late-onset infections among very low birth weight infants (VLBW). Incidence of late-onset sepsis was reduced from 16.9 % in 2002 to 14.5% in 2006.[7]

Azab SF et al. have studied the effect of "VAP prevention bundle" in reducing VAP in their NICU. The bundle included simultaneous implementation of measures to prevent infections forall patients which are aided often by checklists. The rate of VAP was significantly reduced from 36.4 VAP episodes/1000 mechanical ventilation days (MV days) to 23 VAP/1000 MV days (RR 0.565, 95 % confidence interval 0.408-0.782, p=0.0006) after VAP prevention bundle implementation. There was also a significant reduction in MV days, trend toward decrease in mortality and reduction of NICU stay.[8]

Summary

Careful design and judicious use of checklists in clinical care settings can reduce healthcare-related complications. In neonatal practice, central venous line insertion and endotracheal suctionare two examples where use of checklists can be most useful.

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Use of Simulation for Learning and Improving Quality of Care

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Simulation can be defined as the imitation of the operation of a real-world process or a system over time(1). According to David Gaba, a pioneer in the field, "Simulation is a technique–not a technology – to replace or amplify real experiences with guided experiences that evoke or replicate substantial aspects of the real world in a fully interactive manner"(2). Simulation is used in many fields; for example, in military, flight, marine systems, industry and engineering to train people and facilitate team work. The history of simulation dates back to sixth century when the game of chess was used as an exercise for military training. The first simulator in the modern era was the was built in 1928, by Edwin Link who made a flight trainer to provide a safe and less expensive way for learning flying. In the medical field, Resusci Annie was one of the earliest manikins to be made to teach resuscitation skills to trainees. The various domains in which simulation is used by healthcare professionals include teaching and learning, clinical care and patient safety, team building exercises and assessment of clinical skills or performance.

Simulation in teaching and learning

The various methods employed in medical school curriculum include lectures, problem-based learning, inpatient and outpatient based clinical experience and self learning modules using multimedia or computers. Many clinical skills need to be practiced again and again to achieve competency. However, limited number of patient encounters and a concern about patient safety results in trainees not getting enough opportunity to develop clinical skills.

Simulation based education method allows for training in a controlled environment, with ample opportunities for deliberate practice and assessment. In addition, it can be scheduled as per convenience and not as a competing activity with patient care routines.

A simulation based education program should usually complement an existing educational curriculum. Simulation based mastery learning is a step ahead in simulation based education where the goal is to ensure that all learners accomplish all educational objectives with little or no variation in outcome (3). The time required to achieve the mastery standard will vary between learners. Studies have reported that simulation based mastery learning not only improves procedural performance and successful task completion but also better patient care outcomes like lesser patient discomfort, shorter procedure time, less complication rates and lesser cost(4).

The simulators or simulation exercises for trainees include:

- Role Plays
- Standardized patients
- Partial Task Trainers
- Complex task trainers
- Integrated simulators
- Full Mission Simulation

In Role play the learners act out an event or situation. Role play is most commonly used to teach communication skills to trainees(5). The cost of this type of simulation is relatively low. Despite its low fidelity, it can reap substantial

benefits in team training and change in attitude. E.g. A mother complains of decreased milk output and feeding difficulties in the postnatal period. She needs to be talked to identify her problems and providedcounseling. A simple "role-play" can be done for residents and nurses and then these health care professionals can practice reverse role play which shall help them practice counseling.

Standardized or simulated patients on the other hand are actors who are trained to simulate a disease symptom. Standardized patients can help a student to conduct physical assessment, take history and communicate bad news etc. A standardized patient encounter enhances the fidelity and helpscreate a valuable learning simulation, the disadvantages being only recurring cost and scheduling of the actors.

Partial task trainers or simple part task trainers try to replicate an anatomical body part in its normal state or representing a disease. These models are most commonly used to train basic psychomotor skills, such as intubation, intravenous cannulation or venepuncture. Advantages include simplicity, low cost, standardization and portability. Disadvantages include a lower level of realism and limited task purpose of the trainer. A common scenario includes the procedure of umbilical venous cannulation which needs to be taught to pediatric residents. A cut cord of variable length fixed with plasticine to the end of a mineral water bottle can serve the purpose. The student can do deliberate practice many times until s/he is confident.

Some limitations of the simple trainer are overcome by more sophisticated part trainers. An example is the laparoscopic training box (Laptrainer) that facilitates the practice of laparoscopy for surgical trainees. Other examples include pelvi trainers for pelvic examination, the 'Harvey' cardiology simulator that combines a life size manikin and can simulate most cardiac disease at the touch of a button by varying blood pressure, pulses, heart sounds and murmurs. An improvised version of these complex trainers is the addition of haptic systems which can provide tactile feedback to the trainer for greater fidelity and better training.

Integrated simulators are part-task trainers or whole body manikins which respond to interventions done on them (like; administration of medication, intravenous fluids, oxygen, chest compression, chest tube placement etc) by displaying physiological responses (like heart rate, blood pressure, saturation, breathing movements, heart sounds etc) on monitors or computer screens. An example is the SimNewB manikin which has features like spontaneous breathing with different rates, differential air entry, respiratory sounds like grunting, varying heart rates, ECG monitoring, vascular access, umbilical vascular access, anatomically accurate airway with ability to insert LMA (laryngeal mask airway) and endotracheal tube. The model-driven simulators are even more sophisticated wherein the simulator automatically senses the interventions and displays appropriate physiological responses. Examples include, The METI Human Patient Simulator (HPS), PaediaSim and the MedSim Patient.

Full mission simulation brings the learner into a complex situation or task that usually involves a team. The scenario begins with a pre-brief, followed by the execution of the task and concludes with the instructor leading the review of the event in a debrief session. Debriefing is the formal reflective stage which aids the clarification of the simulation experience and helps in the integration of simulation experience with the previous knowledge. An example of a full mission simulation is neonatal resuscitation scenario. A small team of pediatric residents and nurses are exposed to a manikin in a delivery room like set-up smeared with green pea-soup like meconium. As they enter they are told that the baby is gasping. They are provided a real time status of baby's heart rate and respiratory

efforts. Their disbelief is suspended as they work together with real emotion and learned skill trying to resuscitate the baby beginning with initial steps or airway management. At the end of the sessions they sit together, reflect and debrief. Each trainee emerges with new cognitive, technical, and behavioral skills and they transfer these skills to the real environment in a seamless manner.

In addition to education, simulation based technologies have been increasingly used to assess competencies among trainees in various fields (6). A useful framework for the assessment of competence is the Miller's Pyramid (Figure 1). At the base of the pyramid is knowledge (knows; assessed by paper based or computer based simulation tests), followed by competence (knows how), performance (shows how; assessed by standardised patient based examination (SP-based examination) and the objective structured clinical examination (OSCE)), and action (does; assessed by Objective Structured Assessment of Technical Skill (OSATS) involves direct observation of residents performing a variety of structured operative tasks on either live animals or bench models(7)).

Comparison of simulation based teaching learning with traditional methods

The traditional teaching method followed in many medical schools consists of didactic lectures in class room or bed-side, small group discussions, simple exercises in the laboratory and observation of more experienced colleagues at the bedside. As the student progresses in training he is allowed to perform supervised and finally independent procedures on real human patients. In the 21st century there has been a paradigm shift in medical education to include simulation-based methods in teaching and learning. In the traditional method, the focus of training is on knowledge acquisition and the process is teacher centered. It does not take into account that each learner is different with varying strengths, weaknesses, and different pace of learning. The traditional method also assumes that at the end of a stipulated period of training all learners achieve the expected competencies. There are some pitfalls with this method; a) with duty hour restrictions a trainee may not be exposed to sufficient number of difficult scenarios to gain expertise b) there is little opportunity to learn and practice team-work and communication c) the opportunity to practice a procedure multiple times is limited d) learning from one's own mistakes in the real life scenario is dangerous as it places patients at risk. Simulation based method on the other hand leads to avoidance of risk to patients and learners can practice skills repeatedly and at their own pace. Simulation can be scheduled according to the convenience of learners and instructors and tasks and scenarios can be crafted simple or complex to suit a novice or an advanced learner. In addition, skill retention and transfer of training from simulation room to real situations is enhanced. Simulation can also be used in infrequent high-risk situations, for team training, for communication and inter-professional skills development.

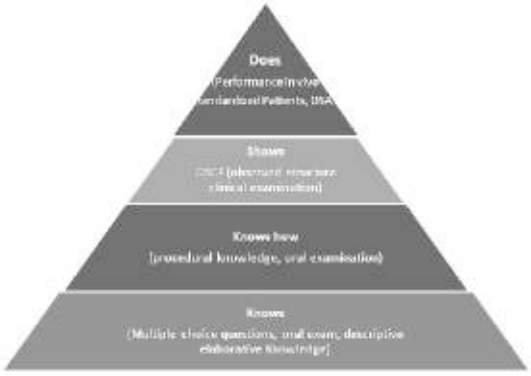

Figure 1: Miller's Pyramid

Simulation for improving quality of care and patient safety

Patient safety is a multi-dimensional concept and involves avoidance of and reporting of medical errors that can lead to adverse patient outcomes. Lessons learnt from disasters in other fields like nuclear power generation, air

and space travel etc have helped in understanding that errors are caused by multiple factors, not single factors in isolation: they include individual factors, workplace conditions and latent organizational factors. Simulation techniques are now increasingly used to improve patient safety. Beyond the impact on individual learning and overall team performance, simulation exercises also provide an opportunity to improve system performance. Medication errors are one of the most important causes of adverse events in hospital and are due to multiple causes including errors in prescription, errors in medication preparation and administration as well due to systems-related issues like improper labeling, environmental distractions, inadequate hand-off and miscommunication. Simulation exercises can be designed to address each one of these (8). For example, in the midst of a resuscitation scenario, a nurse is asked to administer adrenaline to a patient. The 5 rights of drug administration can be checked (right patient, right drug, right dose, right route and right documentation) and students can be taught to identify areas of potential errors. Simulation exercises also give an opportunity to stress the importance of effective communication and reporting of medication errors through simulated handoffs and simulated adverse drug reactions. It is also known that system improvements can reduce error rates and improve the quality of healthcare. Simulation puts patient safety first; it enables the training of tomorrow's practitioners without risking today's patients. Simulation provides an opportunity to reach proficiency on difficult and critical skills which are the basic need for a safe and reliable system performance (9). Feedback and learning about the consequence of one's decision which is an essential component of simulation completes the loop of learning process and gives simulation its compelling and engaging quality (10). The participants can recalibrate their performance.

About 10 years back, Agency for healthcare research and quality (AHRQ) initiated a grant program to advance knowledge of how simulation can improve patient safety across diverse health care disciplines, settings, and populations. Despite simulation's impressive growth and an expanding evidence base, health care simulation applications are at an early stage of development compared to other high-risk industries. The important challenge lies in the appropriate use of simulation based techniques in undergraduate and graduate medical and nursing education.

To summarize,simulation is not a substitute or a stand-alone method for medical education though some people still believe that simulation based method is the silver bullet to tackle the challenges in medical education and residency training. Simulation may not always be the best tool for all teaching/learning activities. For example, when teaching basic knowledge or theory, a formal face-face teaching is better than a simulation exercise. In addition, the facilitators needed for the conduct of simulation scenarios are senior experienced staff and hence their availability away from clinical care may be scarce

Although simulation is used to teach practical or technical skills in a safe and controlled environment, the road to clinical expertise happens only from repeated exposure to real patients in real clinical contexts and not from simulation environment alone. Others believe that simulation is possible only if high fidelity simulators are available. The truth is; while high-fidelity simulators are useful for learning complex skills requiring integration of cognitive and psychomotor skills, the low fidelity ones are most appropriate for deliberate practice of a specific task and for novice learners. Hence the lack of high fidelity manikin or virtual reality simulator is never an excuse to not having a simulation exercise.

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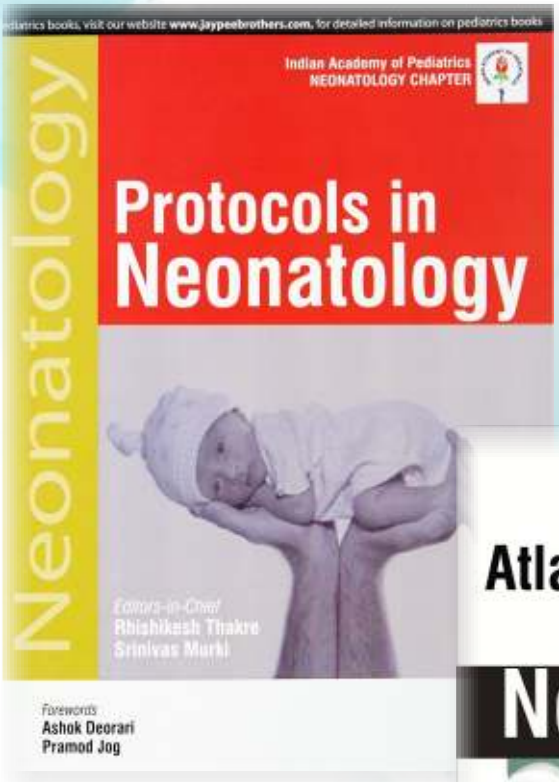

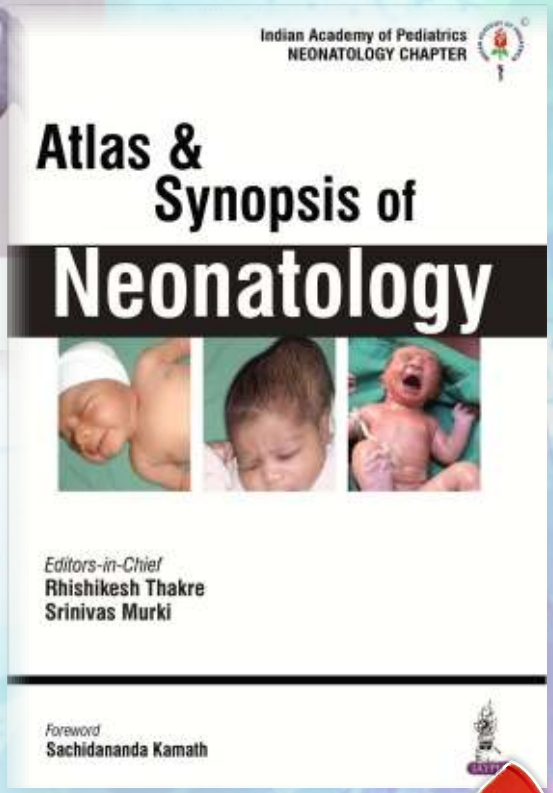

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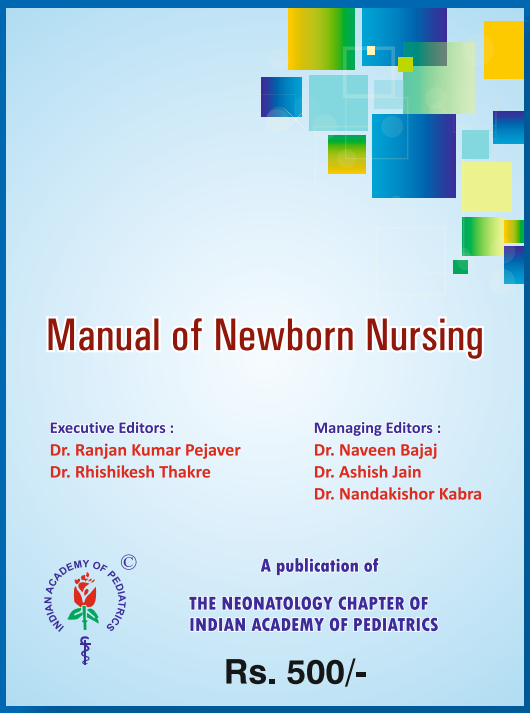

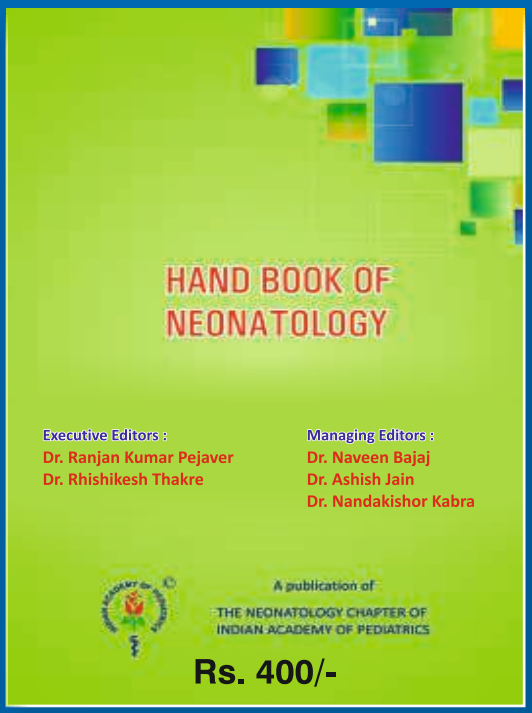

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