





FOGSI - ICOG

Good Clinical Practice Recommendations GCPR

Neonatal Resuscitation



Convenor – Chinmayee Ratha Co-Convenor – Haresh Doshi Mentors – Hrishikesh D Pai, Madhuri Patel, Laxmi Shrikhande Advisors – Sanjay Gupte, Hema Divakar National Co-ordinators – CN Purandare, Rishma Dhillon Pai, Nandita Palshetkar, Jaydeep Tank Co-ordinator – Surekha Tayade

PERINATOLOGY COMMITTEE

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Perinatology Committee

Fogsi Good Clinical Practice Recommendations

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LEVEL OF EVIDENCE

COR indicates the strength the writing group assigns the recommendation, and the LOE is assigned based on the quality of the scientific evidence

Class 1, strong recommendation for which the potential benefit greatly outweights the risk

Class 2a, moderate recommendation for which beneft most likely outweights the risk

Class 2b, weak recommendation for whcih it's unknown whether beneft will outweight the risk

Class 3, no benefit, moderate recommendation signifying that there is equal likelihood of benefit and risk; and

Class 3, harm, strong recommendation for which the risk outweighs the potential benefit

Level A are derived from high-quality evidence from more than 1 randomized clinical trial, or RCT; meta-analyses of high-quality RCTs; one or more RCTs corroborated by high-quality registry study

Level B-R (randomized) are derived from modrate-quality evidence from 1 or more RCTs; meta-analyses of modrate-quality RCTs

Level B-NR (nonrandomized) are derived from modrate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies meta-analyses of such studies

Level C-LD (limited data) are derived from randomized or nonrandomized observational or registry studies with limitations of design or execution meta-analyses of such studies; physiological or mechanistic studies in human subjects

Level C-EO (expert opinion) are derived from consensus of expert opinion based on clinical experience

COR and LOE are determined independently (any COR may be paired with any LOE)

A recommendation with LOE C does not imply that the recommendation is weak

INTRODUCTION

The perinatal period is an important and critical phase in neonatal health accounting for one-third of neonatal deaths and stillbirths; and of this, two-thirds happens in the first week. Simple, cost-effective and evidence-based interventional methods are available to prevent and reduce neonatal asphyxia, the major contributor to this neonatal mortality. The neonatal mortality rate (NMR) and maternal mortality ratio (MMR) are important parameters to estimate any country's progress in the field of health. India, a signatory to the Sustainable Development Goals (SDGs), is bound to provide the state-of-the-art and yet affordable healthcare to each and every citizen and reduce the neonatal and maternal mortality and morbidity. The present NMR rate is 19–22 per 1000 live birth and our government plans to achieve single digit figure by 2030, which is more ambitious than the SDGs. About 70% of all these deaths are seen in the first 24 hours. Perinatal asphyxia (a preventable event) remains an important cause of neonatal morbidity and contributes to 20% mortality and neonatal resuscitation is the most important tool to reduce that. About 90% of all newborns do not need any assistance to take the first breath, 10% need some help, and 1% of these need drug treatment and intubation on occasions. Neonatal resuscitation remains an important tool to prevent perinatal asphyxia in these 10% neonates. The 90 % healthy babies along with these neonates prevented from dying by proper resuscitative efforts will directly improve the health indicators of the country and contribute to our nation's economic progress also. Hence, the statement - HEALTHY NEWBORNS, HEALTHY NATION.

Sequelae of Birth Asphyxia

Low Apgar scores at 1 and 5 minutes are not predictive; but infants with low scores that persist at 15–20 minutes have a 50% chance of developing cerebral palsy if they survive. Moderate-to-severe encephalopathy carries 50–75% risk of death or disability. Widespread organ injury is seen in perinatal asphyxia, the long-term neurologic sequelae of which are cerebral palsy with or without associated cognitive deficits and epilepsy if other causes for the same have been ruled out. To tackle all these issues, the important principles of GOLDEN MINUTE AND GOLDEN HOUR have been recommended.

First Golden Minute/Golden Hour

The Golden Minute of neonatal life is defined as the first 60 seconds of postnatal life in both preterm and term neonates during which the complex but natural transition from intra- to extra-uterine life occurs. The first Golden Minute after birth has been identified as a critical window for establishing ventilation in a newborn and also for interventions with impact on

the immediate and long-term survival of the newborn. In addition to cardiopulmonary resuscitation, thermal regulation is also included in the Golden Minute. The first "GOLDEN HOUR "after birth is similarly important as it allows for ventilation, temperature control with skin-to-skin contact (SSC) and delayed cord clamping (DCC) for extra blood to be transferred to the neonate. Early breastfeeding within 15–20 minutes is also sought to be established if the baby is active and healthy and breathing normally. For a limp/nonactive neonate, attention is provided by a Neonatal Resuscitation Program (NRP) trained neonatologist/ obstetrician. For limp babies, efforts have to be started to establish breathing and ventilation by resuscitation; and in the following pages, the entire process in detail has been described.

DEFINITION OF NEONATAL RESUSCITATION

Most of the babies do not need resuscitation as they are healthy, active, and breathing without any support; but for those who are limp and not breathing adequately, the aim of such resuscitative efforts is to take steps necessary to ventilate it and to protect the life of that baby. The "NEWBORN" period extends from birth to the end of resuscitation and stabilization in the delivery area. Neonatal resuscitation means to revive and restore life to such limp babies from the state of asphyxia.

AIMS AND OBJECTIVES OF NEONATAL RESUSCITATION

Aims

- The aim of neonatal resuscitation is to help each and every baby take the first breath of life freely and effectively. To that
 effect, the Good Clinical Practice Recommendation (GCPR) aims to empower each and every birth care provider to do
 that emphatically.
- To train and provide guidelines to all obstetricians and nursing staff/traditional birth attendants (TBAs) in a manner such that each and every delivery in the country will be attended by a NRP trained doctor/personnel. Through this visionary document, the Federation of Obstetric and Gynaecological Societies of India (FOGSI) wants to train all obstetricians/TBAs in the art and science of neonatal resuscitation and to update the knowledge of all those already well-versed in that field.

Objectives

- To give the best possible perinatal treatment to the woman giving birth and the neonate.
- Description of minimal care/facility to be arranged even in a resource-deficient setup.
- Basic arrangements in the labor room (radiant warmer, suction, neonatal resuscitation tray, and oxygen provision).
- Arrangements for training all personnel involved in delivery Doctors to TBAs.

NEONATAL RESUSCITATION

It is known that healthy babies' transition naturally and easily and for these babies, the promotion of mother-baby bonding and promoting early breastfeeding are very important apart from stabilizing the newborn's cardiovascular status and temperature. This is facilitated by delivering the neonate on the maternal abdomen, with SSC and DCC.

For babies, who may need resuscitation (high risk), it is important to anticipate which babies may need resuscitative efforts and be alert for such babies; but at the same time not become complacent while dealing with low-risk patients/ babies.

Key Measures

- Anticipation: Approximately 90% of all births are uneventful and the newborns do not need any resuscitation, but 10% need assistance to breathe and 1% of these may need intensive resuscitative efforts. And, these newborns, who need resuscitation, may end with major morbidity and occasionally mortality also and create medicolegal issues for the doctor. Anticipating, which babies may need extensive resuscitative efforts, is the key to giving good perinatal results. This can be achieved by a risk factor assessment as outlined below.
- Risk Factor Assessment [maternal risk factors hypertensive disorders of pregnancy (HDP), gestational diabetes mellitus (GDM), placenta previa, previous cesarean surgeries, and fetal risks such as fetal growth restriction (FGR), prematurity, multifocal pregnancies] - [Class of Recommendation (COR)-1, Level of Evidence (LOE) B-nonrandomized (NR)].

- Checklist for equipment in the labor room warmers, oxygen, resuscitation tray [COR-1, LOE C limited data (LD)].
- Preparation of a team with at least one person trained in neonatal resuscitation (COR-1, LOE B-NR).
- Counseling of patient and communication.
- Execution of steps for neonatal resuscitation as given in the flowchart and intervention as and when needed (COR-1, LOE C-LD).
- Call for help if needed.
- Documentation of all procedures.
- Team drills for the long-term training of all people involved in birthing.

Preparation: The labor room should be ready with warmers, oxygen, and dedicated "newborn care" area. The World Health Organization (WHO) CLEAN SIX - clean hands, mother, delivery surface, cord cutting, cord tying, and cord care standard should be strictly adhered to.

Place of Birth: The delivery place/labor room should fulfill the minimum criteria of a proper labor room and should have at ALL TIMES, provision for:

- Well-lighted room.
- Adequate ventilation.
- Minimum cleanliness and hygiene levels.
- Oxygen, suction, radiant warmer. Checklist for equipment (COR-1, LOE C-LD).
- Dedicated area for baby resuscitation.

NEWBORN CARE CORNER REQUIREMENTS IN LABOR ROOM

| Environment | Radiant warmer in a well-lit area which is draught free |
|---------------|---|
| Equipment | All equipment for resuscitation Infant weighing machine Clearly visible clock All supplies/medications checked regularly for their availability by a designated individual using an equipment checklist must |
| Asepsis | Hand washing facility (24 hours water supply with elbow operated taps and hand wash) Availability of gowns, gloves, masks |
| Documentation | Standard forms for documenting resuscitation |

EQUIPMENT OF NEONATAL RESUSCITATION

| | Term neonates |
|---------------------------------|--|
| Temperature maintenance | Radiant warmer Pair of clean prewarmed sheets Room thermometer |
| For airway clearance | Suction device set at 80–100 mmHg Suction catheters Mucous extractor Oropharyngeal airway |
| | Shoulder roll |
| For ventilation and oxygenation | T-piece resuscitator Face mask Flow meter Oxygen source Oxygen blender/oxygen air mix Pulse oximeter (with neonatal probe) Laryngoscope endotracheal tubes Feeding tube (size 8F) |
| Circulation | Syringes Needles (25, 21, and 18 gauge) Stethoscope Electronic cardiac monitor and leads |
| Drugs | Epinephrine (1:10000) Normal saline (0.9%) |

DETAILS OF INITIAL STEPS OF RESUSCITATION (Figs. 1 and 3)

- Communication: Communication protocols with predecided individual and team responsibility. Practice drills from time to time on long-term basis.
- Equipment: All necessary equipment should be there in good working condition and in clean condition. Warmer, resuscitation tray, ambubag, laryngoscope, pulse oximeter, oxygen, T piece. (COR-1, LOE C-LD).
- Execution and Documentation: The actual steps to be followed by the delivery team is important, and for the same, correct knowledge, precise actions, and anticipation is important. Call for help as and when needed is also very important.

NORMAL BABY (Figs. 2 and 3)

If the baby at birth is breathing or crying, then keep the baby on the mother's abdomen with intact umbilical cord and dry the baby with prewarmed sheets. Remove the wet sheets and keep the baby in skin-to-skin contact (SSC) to provide warmth. If the baby is crying, then there is no need for the suction of nose or mouth of the baby. Suction by mucus extractor is done only if secretions are obstructing the baby's breathing. Cut the cord after one minute of delivery. Keep baby in prone position on maternal chest and cover the baby and mother with blanket/quilt. Evaluate the baby and mother for color and breathing and initiate early breastfeeding. Baby is kept in SSC for at least one hour before shifting both to the postnatal ward.

Delayed Cord Clamping

For term healthy newborns, who do not need resuscitation, it is reasonable to delay cord clamping for longer than 30 seconds, up to 60 seconds (2b, c – ld).

For preterm infants, who do not require resuscitation, it is reasonable to delay cord clamping for longer than 30 seconds (2a, b – r).

For term and preterm infants, who need resuscitation, there is insufficient evidence to recommend early v/s late cord clamping (2b, C - E O).

Early cord clamping is to be considered when placental transfusion is unlikely to occur as in maternal hemorrhage [antepartum hemorrhage (APH)].

Immediate cord clamping should be done only when the newborn is fully limp, apneic, or breathing inadequately.

Skin-to-Skin Contact

Healthy babies, who do not need resuscitation, benefit by improved breastfeeding, temperature control, and glucose stability by SSC (2a, B – R).

Temperature Control

The temperature of any newborn to be maintained between 36.5 and 37.5° C and hypothermia should be prevented (1, C – EO).

This is best done by SSC, keeping the baby prone on maternal abdomen and covering both baby and mother with blanket/quilt. The presence and degree of hypothermia after birth is strongly associated with increased neonatal mortality and morbidity. Before shifting the baby to room with the mother, it is recommended to measure the temperature.

For newborns needing resuscitation, all these procedures are to be done with temperature control mechanisms in place with radiant warmers. In resource-poor settings, it is reasonable to place newborn in a clean food grade plastic bag up to the level of neck and swaddle them to prevent hypothermia (2b, C – LD).

Tactile Stimulation

Actively crying babies are cared for with SSC and do not need intervention such as routine tactile stimulation or suctioning (3, C – LD).

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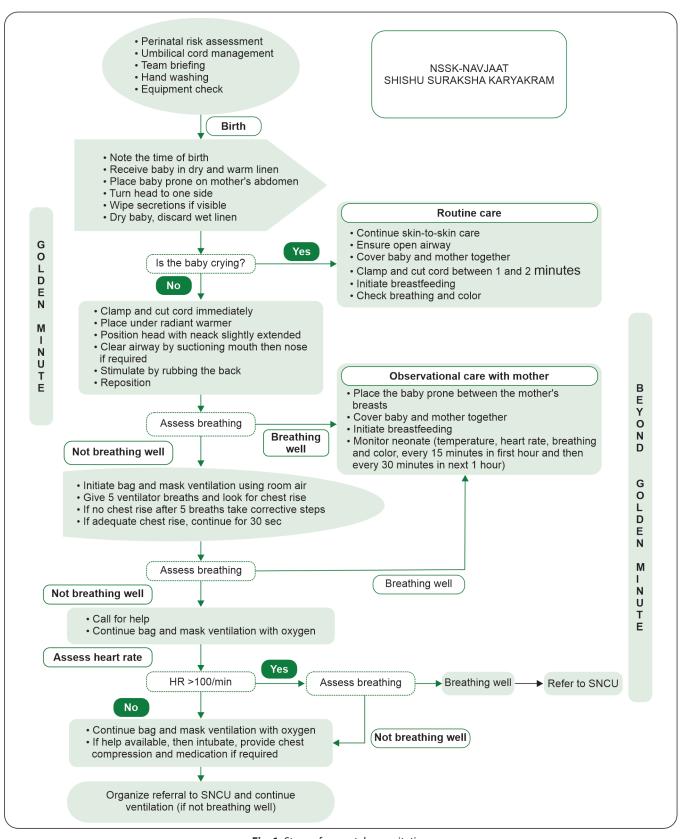
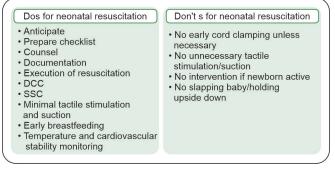


Fig. 1: Steps of neonatal resuscitation

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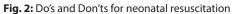




Fig. 3: Instruments, infrastructure and basic methods of newborn resuscitation

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DISTRESS BABY

Expected Asphyxiated Newborns [Ref: 2 – Navjaat Shishu Suraksha Karyakaram (NSSK); 3 – Indian Academy of Pediatrics (IAP); 4 – American Heart Association (AHA)]

- Resuscitation team on standby every birth to be attended by at least 1 person who can perform the initial steps of newborn resuscitation (COR-1, LOE – B NR).
- At least two people to stabilize and manage airway.
- Correct hypothermia by placing newborn under radiant warmer.
- Respiration Regular/Gasping/Apnea.
- Heart Rate: 100 bpm.
- Bag and mask.
- If no further response:
 - Head in slight extension,
 - Reapply mask for good respiration,
 - Suction mouth and/or pharynx,
 - Ventilate with mouth open, and
 - Intubation.

SPECIAL SITUATIONS (Fig. 4)

Preterm Babies

Preterm babies are at an increased risk of hypothermia and have immature lungs. Modifications in resuscitation that should be followed in preterm infants are:

- To prevent thermal stress, a servo controlled warmer must be used to manage preterm babies at birth. Environmental temperatures in delivery room should be maintained between 23°C and 25°C.
- Preterm infants <32 weeks, should be covered with a plastic sheet without drying and placed under the radiant warmer during resuscitation.



Fig. 4: Polyethylene cling wrap

- If positive pressure ventilation (PPV) is required for preterm babies, it is recommended a T-piece with face mask and positive-end expiratory pressure is used (PEEP).
- Initial oxygen concentration during PPV is between 21% and 30%.
- Labored breathing and heart rate more than 100 bpm warrants delivery room continuous positive airway pressure (CPAP).

Consent at Periviability Gestational Age

The level of medical care which can be provided to a newborn, especially at the extreme gestational age of 22–24 weeks can vary from the state-of-the-art to basics. But, the expectations of the patient and her family remain sky high; during such times, it is always better to counsel in a non-hurried quiet manner, in the language used by the patient. All documentation formalities should be completed with the notes of neonatologist too. A realistic account of the future scenario of the neonate after 2–5 years should be given along with the financial costs, which may be incurred by the family during treatment. Ultimately, it is the family which will decide upon treatment, we as the health care providers are supposed to make arrangements for the same and not take decision on behalf of the family.

Lower Segment Cesarean Section/Cesarean Section

At the time of admission to the hospital either for delivery/labor or for an elective cesarean section or for the induction of labor, the written informed consent should be taken, which has the signature and names of patient herself/her nearest of kin and the doctor, who has done all the counseling. It should state the purpose of admission, indication for the induction of labor, or indication for performing the cesarean section.

At any time of difficulty, if the patient refuses to give consent [decision of lower segment cesarean section (LSCS)/risk of vaginal delivery) for cephalopelvic disproportion (CPD) with fetal distress, it is okay to take the signature of a Third Party that the patient and family is refusing to give consent even though all possible risks have been explained.

Meconium-stained Amniotic Fluid

The management of newborn does not change if the newborn is born through meconium-stained amniotic fluid (MSAF). The current recommendations state that for non-vigorous newborns (with apnea or ineffective breathing efforts) delivered through MSAF, routine laryngoscopy with or without tracheal suctioning is not recommended.

Add Obstetricians "and" Nursing Staff

Which needs immediate resuscitation - which can be left alone - IDENTIFICATION?

Those babies who are alive, healthy, and crying immediately can and should be delivered on the maternal abdomen with SSC and DCC. At all given times, all babies should be delivered by obstetricians or trained TBAs. The babies who are limp/not crying or with irregular breathing should be handed over to neonatogists.

Initial steps by obstetricians: If the baby is active, then deliver on maternal abdomen with SSC and DCC.

In utero transfer for preterms: The neonatal outcomes of infants requiring neonatal intensive care unit (NICUI management is better for those transferred in utero rather than those transferred as neonates, especially those born at less than 30 weeks. Those "outborn" are at a significant risk of death/ *intraventricular hemorrhage* (IVH)/respiratory distress syndrome (RDS) and nosocomial infections.

ANOMALOUS BABIES

Correctable Anomaly

Although there should not arise a situation where a neonate is born and anomaly is diagnosed; but if it arises, proper diagnosis of the anomaly should be done, counseling should be done, its genetic implications should be discussed with the parents, and documentation should be completed. If an anomaly has been diagnosed, which can be corrected by surgery at a tertiary center, it is better to transfer in utero (e.g. some complex cardiac anomalies, open neural tube defect (ONTD), and gastroschisis, where the parents are willing to undertake treatment).

Anomaly Incompatible with Life

For anomalies, such as an encephaly, counseling of the patient and her family should be such that these neonates should not be resuscitated and documentation of their DNR (DO NOT RESUSCITATE) should be taken.

MEDICOLEGAL ISSUES

The ABCD of the "Medicolegal Part" of aspects of neonatal resuscitation:

- A Acumen (Clinical)
- B Behavior (Medical Treatment)
- C Communication
- D Documentation

If the steps mentioned till now have been followed diligently, medicolegal issues should not arise. Place of birth – as earlier.

Health care provider – obstetrician/TBA, trained in NRP equipment in labor room.

Counseling and Medicolegal Implications

Concerning neonatal resuscitation/perinatal morbidity or mortality. The fruits of intrapartum events and whether they are sweet or sour depend on the antenatal period. From the viewpoint of obstetrician, the following are important:

The antenatal visits, the check-ups done, investigations advised, follow-up, and counseling done all have implications on the way the intrapartum scenario develops. Hence, it is always wise to counsel well and document the fact that counseling has been done. The documentation of all Outpatient Department (OPD) papers should be available.

- Under ideal circumstances, all OPD papers should be with the hospital and the patient should have only the
 prescriptions of treatment being done.
- At the time of admission to the hospital either for delivery/labor or for an elective Cesarean section or for the induction of labor, the written informed consent should be taken, which has the signature and names of patient herself/her nearest of kin and the doctor, who has done all the counseling. It should state the purpose of admission, indication for the induction of labor, or indication for performing the cesarean section.
- India being a vast country with many languages, it is advisable that consent be taken in the native language of the
 patient apart from English/Hindi. At any time of difficulty, if the patient refuses to give consent (decision of LSCS/risk of
 vaginal delivery) for CPD with fetal distress, it is okay to take the signature of a Third Party that the patient and family is
 refusing to give consent even though all possible risks have been explained.
 - Documentation of all conversation happening between both parties (health care provider and patient) about the perinatal scenario should be done.
 - The date when called for next follow-up should be provided in a simple and easily understandable writing.
 - For any high-risk patient, if the visit is skipped, it is better to send a reminder by phone. The follow-up of high-risk patients is very important.
 - The OPD and Inpatient TRIAGE is better, so we know which patient needs more detailed check-up, notwithstanding the fact that knowing how unpredictable our field is any patient can suddenly throw surprises also.

Shifting Notes

If any newborn is shifted to a higher center, proper notes at the time of shifting, treatment already given, reason for shifting, and the condition of patient at the time of shifting should be mentioned on the paper. The heading should be "Shifting Notes" and it should be clearly mentioned. If there is a possibility that the patient may need multidisciplinary approach, and the procedure (delivery) is a planned one and not an emergency, it is better to manage such patients in tertiary care hospital (e.g. fetus with complex cardiac defects/diaphragmatic hernia), so that newborn is immediately shifted to NICU.

SUMMARY

These guidelines are made to equip all obstetricians and other TBAs to anticipate, predict, and prepare for not just normal births and babies, but to be able to resuscitate any newborn born with the varying degrees of birth asphyxia.

Evidence-based knowledge and training and sustained efforts at quality improvement will go a long way in improving neonatal mortality rates, as birth asphyxia is responsible for almost 80–90% of neonatal morbidity and mortality.

The FOGSI family wants to reduce MMR and NMR and bring both down to single digit figures and these guidelines empower you all toward those lofty goals.

SUGGESTED READING

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ANNEXURE-1

Bag and Mask – Parts and Functions

- Test the function of the bag and mask for ventilation.
- Selection of mask: For the mask to be of correct size, the rim should cover the tip of the chin and the nose but not the eye.
- Fit the mask onto the bag and deliver test breaths against the palm of the hand. You should feel pressure in the palm as the bag is squeezed.
- Form an airtight seal between the mask and the palm of the hand. Squeeze the bag enough for the pop off (pressure release) valve to open, which can be recognized by the hissing noise or valve movement as the air escapes through the valve.
- Check that the bag re-inflates quickly when you release it after squeezing the bag.

Disclaimer-These recommendations for "Neonatal Resuscitation" have been developed, to be of assistance to obstetricians, gynecologists, consulting physicians and general practitioners by providing guidance and recommendations for managing women with anemia and suffering from hemorrhagic conditions. The recommendations included here shouldn't be viewed as being exclusive of other concepts or as covering all legitimate strategies. The suggestions made here are not meant to dictate how a particular patient should be treated because they neither set a standard of care nor do they guarantee a particular result. To diagnose patients, choose dosages, and provide the best care possible while also taking the necessary safety precautions, clinicians must rely on their own experience and knowledge. The writers or contributors disclaim all responsibility for any harm and/or damage to people or property resulting from the use or operation of any techniques, goods, guidelines, or ideas presented in this content.