



Use of Antenatal Corticosteroids in Preterm Labour

(Under Specific Conditions by ANM)

OPERATIONAL GUIDELINES | June 2014



Child Health Division
Ministry of Health and Family Welfare
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Foreword

Globally, every 10th baby is born preterm and India contributes to a quarter of all preterm burden. Preterm birth is major risk for mortality and morbidity. Those who survive without proper intervention end up having long-term disabilities. A higher risk of adult chronic disease in those born preterm also leads to a major strain on families.

Effective interventions exist to reduce death and disability in premature babies, yet this care does not reach the poorest and most disadvantaged populations where the burden is highest. Globally evidence exists that deaths from preterm birth complications can be reduced by over three-quarters even without the availability of neonatal intensive care which as a routine is available in developed countries.

Use of Ante Natal Corticosteroid (ANCS) injection for women at risk of preterm delivery is the most effective intervention to reduce the risk of complications in preterm babies and is mentioned as the standard-of-care in all the related guidelines like BeMOC, CeMOC and Medical Curriculum. Yet, there was a need to bring this intervention into focus and also to empower ANMs to give a pre-referral dose of ANCS to a pregnant women going in to preterm labour to improve its access.

The current guideline regarding the use of Antenatal Corticosteroid by ANM in Preterm Labour is the immediate action needed to close this coverage gap. I do hope that the programme managers will use this guideline and all the states will implement this low cost yet effective intervention at all levels of health facility to reduce mortality and morbidity in Pre-term babies.

(Anuradha Gupta)



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Preface

Globally, preterm birth is a serious public health problem and a leading cause of perinatal death and disability. India carries the highest burden of the world's premature deliveries. Preterm birth, occurring more commonly in economically disadvantaged communities is further compounded by limited and expensive neonatal health-care services. However, three-quarters of premature babies in India could be saved with simple, feasible, cost-effective interventions, such as use of antenatal steroids, kangaroo mother care, proper temperature regulation at birth and simple infection prevention measures.

Under the existing health service infrastructure, it is feasible to implement the antenatal corticosteroid therapy. Skilled health-care providers available at primary health care unit can identify women in preterm labour and can also administer intramuscular injections. Effective antenatal screening for pre-eclampsia, providing information to pregnant women for birth preparedness and education of health-care providers would continue to contribute towards successful implementation of this intervention.

I sincerely hope that this guideline will enable the service providers and the managers to implement this intervention with great vigour.

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Acknowledgement

Timely obstetric and new-born care is the key strategy to reduce morbidity and mortality in newborns. Since the mother and newborn exist as dyad, the care provided to the mother during antenatal period has a significant bearing on the new-born survival. During past few years prematurity has emerged as one of the most complex health challenges. It has immense economic and health consequences, and deserves adequate preventive and management steps. Under the supervision of trained health workers, neonates above 32-34 weeks of gestation can be managed successfully in public health facilities. While use of injectable corticosteroid in pre-term labour to reduce morbidity and improve neonatal outcome is a well-accepted intervention there is a need to scale up its implementation at various levels of health facilities.

The Ministry of Health & Family Welfare, Govt. of India, in consultation with experts has taken a decision to empower ANMs to administer injectable Antenatal corticosteroids to the pregnant women in preterm labour at public health facilities and this Operational Guidelines for Use of Ante-natal corticosteroids by ANMs in preterm labour has been developed based on wide consultations and represents hard work of many individuals and institutions. The efforts of Dr. Vinod K. Paul and Dr. Ashok Deorari of AIIMS, New Delhi are gratefully acknowledged in developing this Operational Guideline.

Dr. P.K.Prabhakar, Deputy Commissioner, MOHFW coordinated the development of these guidelines and led the Team of CH Division and Experts from various Institutions and Development Partners.

I sincerely acknowledge the contributions of all the experts and contributors.

Dr. Ajay Khera

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List of Acronyms

ANCS Antenatal Corticosteroids

ANM Auxiliary Nurse Midwife

IVH Intra Ventricular Haemorrhage

PDA Patent Ductus Arteriosus

RDS Respiratory Distress Syndrome

SBA Skilled Birth Attendant

SNCU Special Newborn Care Unit

WHO World Health Organization

As per World Health Organization (WHO), a preterm baby is defined as a baby who is born alive before 37 weeks of pregnancy are completed. The rate of preterm birth ranges from 5-18% across 184 countries. India has the highest number of preterm births as well as neonatal deaths due to prematurity. Out of an estimated 2.6 crore live births in India each year, 35 lakh babies are born preterm, and out of these, 3.03 lakh babies (10% approximately) die due to complications of preterm births. Several survivors face a lifetime of disability, including learning, hearing and visual disabilities. Preterm birth is a risk factor in at least 50% of all neonatal deaths and is the second most common cause of death (after pneumonia) among children under the age of five.

Preterm newborns are classified on the basis of completed gestation period as:

- **Extremely Preterm – Less than 28 weeks**
- **Very Preterm – 28 to <32 weeks**
- **Late and Moderate Preterms – 32 to <37 weeks**

The relative proportion of these groups is 5%, 10% and 85%, respectively. The mortality rate among preterm newborns increases with decreasing gestational age. It may be noted that even the moderate and late preterm neonates have an increased mortality risk as compared to those born at term gestation.

Extremely preterm babies require neonatal intensive care for survival. Most of the other preterm babies have a good chance of healthy survival with special newborn care envisaged at sub district, district and medical college hospitals, coupled with facility based kangaroo mother care and home based newborn care.

Preterm babies have numerous challenges including difficulty in feeding maintaining body temperature and increased susceptibility to infections. Other serious complications which can develop are necrotizing enterocolitis (death of intestinal tissue) and intraventricular hemorrhage (bleeding into the brain). However, the most common cause of death among preterm babies less than 34 weeks is Respiratory Distress Syndrome (RDS). This is an acute lung

disease due to surfactant deficiency in the lungs which leads to atelectasis and subsequent failure of gas exchange. Fortunately, RDS can be largely prevented by administering injection Corticosteroids to the pregnant woman as soon as she is diagnosed with preterm labour.

Injection Corticosteroids (such as Dexamethasone or Betamethasone) when administered to the pregnant woman antenatally, cross the placenta and reach the foetal lung and stimulate surfactant synthesis and maturation of other systems. If this foetus is now delivered prematurely, s/he will have a low risk of developing RDS and, therefore, much higher chance of surviving with supportive care.

Evidence

Timely use of Antenatal Corticosteroids in a mother reporting with preterm labour before 34 weeks of gestation has the following clinical impacts in new borns who receive good supportive care:

- 34% reduction in Respiratory Distress Syndrome (RDS)
- 46% reduction in Intra Ventricular Haemorrhage (IVH)
- 54% reduction in Necrotising enterocolitis (NEC)
- 31% reduction in mortality

Studies have shown that near universal coverage of this intervention can reduce 40% of mortality amongst neonates. Also, it has been reported that use of Antenatal Corticosteroids leads to other benefits too like reduction in the incidence of PDA, reduction in systemic infections, decreased need for respiratory support and therefore, reduced length of hospital stay, low rate of intensive care admissions and finally reduced cost of care.

The Cochrane reviews have shown that a single course of corticosteroid therapy for preterm birth does not appear to be associated with any significant short-term maternal or foetal adverse effects. Antenatal steroids do not increase the risk of maternal infection. Antenatal Corticosteroids are widely recommended by obstetric societies.

Antenatal Corticosteroid therapy has maximal effect if the fetus is delivered 24 hours after the last dose and up to 7 days thereafter. Partial effect is evident within a few hours before birth and is worth it. Thus, even if the delivery occurs in the course of treatment regimen, there are clinically important benefits. There are, therefore, good reasons to initiate Antenatal Corticosteroids as soon as preterm labour is diagnosed.

Long-term follow-up of survivors from randomised trials of antenatal corticosteroid therapy through childhood to adulthood (up to 20 years of age) shows no definite adverse effects.

Purpose and Scope of Guideline

The purpose of this guideline is to:

1. Guide the health programme manager and the service providers working at health facilities.
2. Empower Auxillary Nurse Midwives (ANMs) on the appropriate use of Antenatal Corticosteroid therapy to pregnant women in preterm labour.
3. Outline the steps for optimal implementation and scale up of this intervention.

Recommendation

Government of India recommends the following for the administration of Antenatal Corticosteroid in preterm labour:

Single course of injection of Dexamethasone to be administered to women with preterm labour (between 24 and 34 weeks of gestation) at all levels of health facilities in the public as well as the private sector.

1. To empower Auxiliary Nurse Midwives (ANMs) to administer intramuscular injection Dexamethasone, as a pre-referral dose to a pregnant woman in preterm labour (between 24 and 34 weeks of gestation) and appropriate referral to health facility utilising the free referral transport. In case the referral is delayed, refused, or referral is not possible, ANM may complete the full course of treatment (4 doses 12 hours apart).
2. Appropriate and timely in-utero referral of pregnant women in preterm labour to facilities with provision of caesarean section and special care newborn units (e.g. District Hospitals/Medical Colleges) to promote adequate and quality care.
3. To recommend that as far as possible, all elective caesarean section or induction of labour in uncomplicated deliveries should be done at or after 39 weeks of gestation to ensure that the baby is mature and of normal weight.

Reduction in the morbidity and mortality in a preterm baby in addition to use of injection corticosteroid in pregnant women shall also be facilitated by

1. Ensuring Skilled attendance at birth
2. Better Access to EMoC services
3. Provision of Kangaroo Mother Care and support for feeding
4. Ensuring protocols for Infection prevention and management
5. Special care newborn unit at district hospital
6. Adequate referral linkages to a tertiary care unit where ventilator support may be easily available in case of need.

Why Injection Dexamethasone is Recommended

Dexamethasone sodium phosphate and Betamethasone acetate + phosphate are the only two efficacious and safe corticosteroids to be used during antenatal period. Both these drugs are identical in biologic activity and readily cross the placenta.

Dexamethasone: It is listed in the WHO essential medicines list, is inexpensive and widely available in facilities for multiple indications.

Betamethasone: In India, the salt Betamethasone acetate + phosphate, which requires only two doses at 12 hourly interval, is not available. The available salt in India is Betamethasone phosphate which is short acting and requires more frequent administration as compared to the former. Hence, the dosage schedule of Betamethasone phosphate is similar to that of the Dexamethasone and has no added advantage over Dexamethasone. Further, Betamethasone is more costly and less stable than Dexamethasone at high temperatures. However, in individual cases where Inj. Dexamethasone is not available the service provider may use Inj. Betamethasone phosphate to give the advantage of corticosteroids to the newborn.

Dexamethasone is thus a more appropriate option and recommended.

- Administration of Antenatal Corticosteroid (Dexamethasone) constitutes an integral part of standard treatment in preterm labour
- Oral Preparations of steroids are not to be used
- Repeated courses/more frequent doses are not useful. Multiple courses in fact could have harmful neuro-developmental effects in the baby
- ANCs have a role even if surfactant replacement is available

Preparation and Dosage of Dexamethasone

Preparation



Injection
Dexamethasone Sodium
Phosphate is available in
4 mg per ml strength.

Table 1: Dose and Route of Administration of
Injection Dexamethasone

Dose	6 mg each
No. of Injections	4
Interval between injections	12 hours
Route of administration	Deep Intramuscular
Site of administration	Preferably antero lateral aspect of thigh
Complete course	Four doses (equivalent to 24 mg total)
Logistics	2 ml disposable syringes and 22/23 gauge needles
Storage	No need to refrigerate

The 6 mg dose would require 1.5 ml of the preparation provided each ml has 4 mg of Dexamethasone.

Table 2: Indications and Contraindications for using Corticosteroids in Antenatal Period

Indications	Contraindications
<ol style="list-style-type: none"> 1. True preterm labour 2. Following conditions that lead to imminent delivery: <ul style="list-style-type: none"> • Antepartum haemorrhage • Preterm premature rupture of membrane • Severe pre-eclampsia 	<p>Frank chorioamnionitis is an absolute contraindication for using antenatal corticosteroids. Following signs and symptoms in the mother suggests Frank amnionitis:</p> <ol style="list-style-type: none"> 1. History of fever and lower abdominal pain 2. On examination: Foul smelling vaginal discharge, tachycardia and uterine tenderness 3. Fetal tachycardia

Maternal diabetes, pre-eclampsia and hypertension are NOT contraindications for using injection corticosteroid in pregnant women. Dexamethasone can be administered if otherwise indicated with a careful watch on blood sugar and blood pressure [If chorioamnionitis is suspected, consider delivering the baby].

Role of Antenatal Care in Implementation

A system of quality and effective Ante Natal Care (ANC) during pregnancy to detect complications and management at an early stage plays a critical role in the prevention and management of preterm births.

Early registration of every pregnancy within 12 weeks, followed by regular antenatal care visits till term should be ensured. Information to pregnant women would need to focus on early reporting to a health facility at the first signs of pregnancy complications such as preterm uterine contractions, premature rupture of membranes and symptoms of pre-eclampsia or any other complication.

The pregnant woman and her family should be counseled by ANM/ASHA for birth preparedness, danger signs and to opt for institutional delivery.

Role of ANM

This guideline enables ANM to give the pre-referral dose to pregnant women with preterm labour between 24 to 34 weeks of gestation. To avoid the misuse/overuse of the drug without compromising with the benefit the ANM needs to correctly assess gestational age and true labour pains in case any pregnant woman reports with labour pains. ANM will assess the gestation age as per SBA guidelines and true labour pains as elaborated in Table 3. In case the drug is to be given, safe injection practices for administrating injections should be followed.

Table 3: Assessing True Labour Pains

True Labour Pain	False Labour Pain
1. Begins irregularly but becomes regular and predictable	1. Begins irregularly and remains irregular
2. Felt first in the lower back and sweeps around the abdomen in a wave pattern	2. Felt first abdominally and remains confined to the abdomen and groin
3. Continues no matter what the woman's level of activity	3. Often disappears with ambulation or sleep
4. Increases in duration, frequency and intensity with the passage of time	4. Does not increase in duration, frequency or intensity with the passage of time
5. Accompanied by 'show' (blood-stained mucus discharge)	5. 'Show' absent

Once the ANM confirms the diagnosis of true preterm labour between 24 and 34 weeks she will follow the instructions given in the box below:

1. If the mother is in true labour give recommended prerenal dose of steroids as given in the flow chart*
2. Refer the pregnant women to higher centre where neonatal resuscitation facilities exist under Janani Shishu Sureksha Kayakaram (JSSK) Scheme
3. In case the referral is not possible complete the course of antenatal steroid and contact the nearest health facility
4. In case the delivery is imminent prepare for delivery and resuscitation of the baby
5. Refer neonate to the nearest SNCU after appropriate stabilization with a duly filled Referral slip. Ensure that the temperature of the newborn is maintained during transportation

It is to be always remembered that use of Antenatal Corticosteroid is only a part of comprehensive management protocol of preterm labour

*Flow chart as provided in the guideline on page 11

As per BemOC training manual MoHFW, GoI if the medical officer at a referral facility plans to delay the labour to have adequate response of Antenatal Corticosteroid, should follow as below:

1. If possible delay labour for at least 24 hours for Dexamethasone to have effect or for a period in which the fetus gets maximum benefit of antenatal steroids (within 7 days).
2. Tocolysis (Delaying the labour) is to be done if gestation is more than 24 weeks upto 34 weeks after excluding risk factors like frank infection, pre-eclampsia and diabetes.
3. Labour is allowed to progress in conditions where delay in delivery may worsen the maternal medical status.

Care during Referral of Pregnant Woman or Newborn

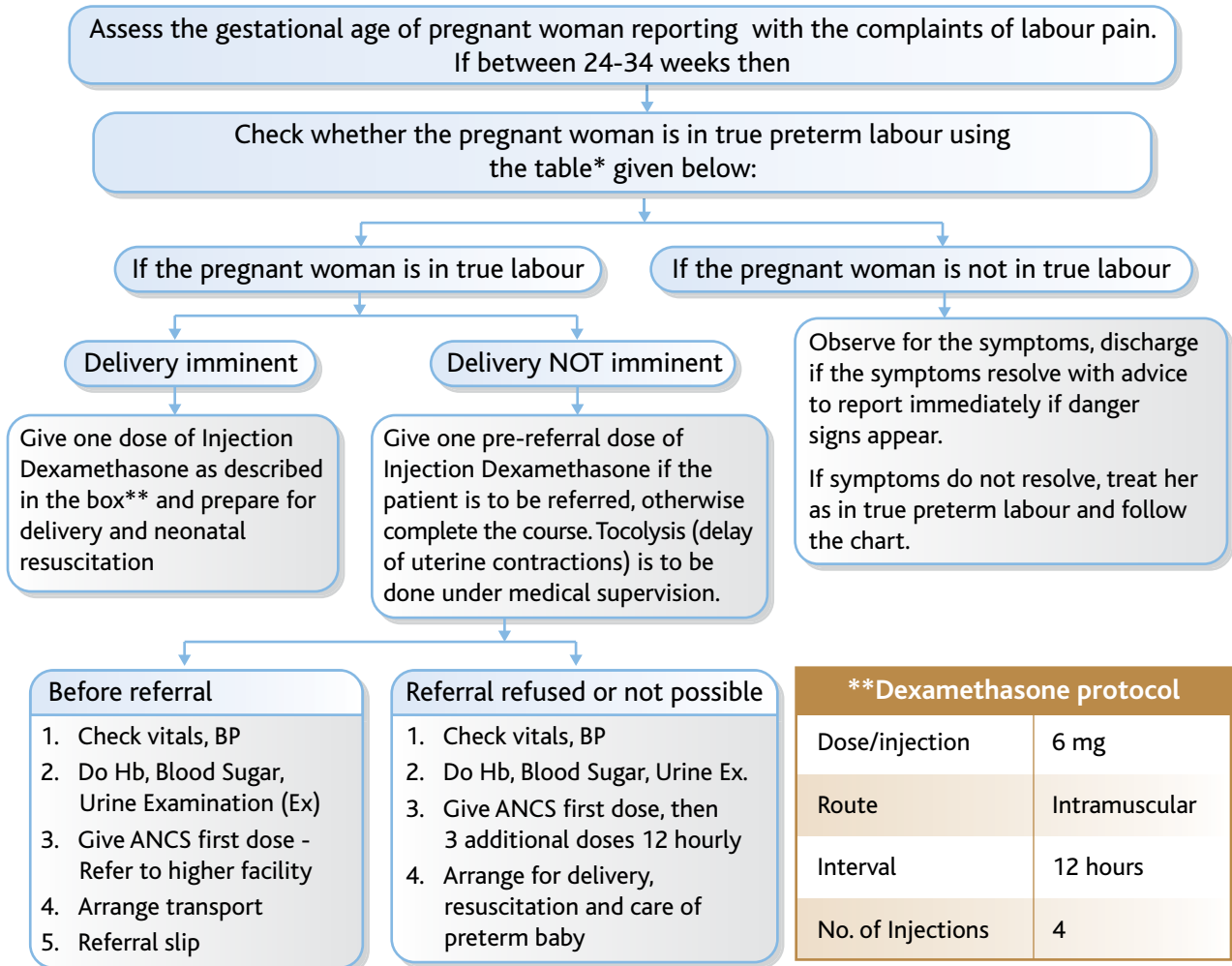
Referral of pregnant woman or preterm newborn becomes a critical activity under the management of preterm labour. Under Janani Shishu Suraksha Karyakaram (JSSK) zero expense treatment and referral is provided at all public health facilities to all sick infants up to 1 year of age and the mother even during antenatal period. The service provider must ensure all findings related to maternal morbidities are mentioned on the case sheet or on the referral slip if the patient is being referred to a higher facility. Recording of Blood Pressure and Urine sugar on the referral slip before giving the referral shot of ANCS should be considered as a mandatory activity. While referring a preterm newborn the service provider must ensure the full documentation both in the case sheet and referral slip. The provider also requires to be aware of the following important aspects of referral:

- Provide relevant, immediate information regarding referral to parents/relatives in simple and practical language which may require repetition for the parents to understand.
- While taking the consent before referring, poor prognosis/adverse events etc. related to patient needs to be documented in the case sheet.
- Preferably a nurse/ANM/Doctor/ASHA should accompany the baby in the vehicle to facilitate transfer. Mother or any other relative should accompany the baby.

The ambulance (102/108) should have the following requirements if using transport incubator:

- Secure fixation for the transport incubator, oxygen and air tanks, monitoring equipment etc.
- Independent power source and necessary adapters for power source to supplement equipment batteries to ensure uninterrupted operation of the equipment.
- Equipments needed for thermal control, maintaining the airway, resuscitation, oxygen therapy, CPAP/mechanical ventilation, administration of IV fluids and monitoring should be available and be in working order. Availability of all essential medicines should be ensured.

Flow Chart for Antenatal Corticosteroid (ANCS) Administration {24-34 Weeks Gestational Age}



Contraindication for use of ANCS is Frank Chorioamnionitis

*Symptoms of True and False Labour Pain

TRUE Labour Pain	FALSE Labour Pain
1. Begins irregularly but becomes regular and predictable	1. Begins irregularly and remains irregular
2. Felt first in the lower back and sweeps around to the abdomen in a wave pattern	2. Felt first abdominally and remains confined to the abdomen and groin
3. Continues no matter what the woman's level of activity	3. Often disappears with ambulation or sleep
4. Increases in duration, frequency and intensity with the passage of time	4. Does not increase in duration, frequency or intensity with the passage of time
5. Accompanied by 'show' (blood-stained mucus discharge)	5. Show absent
6. Associated with cervical effacement and cervical dilatation	6. Does not associate cervical effacement and cervical dilatation

Key Messages

1. Role of antenatal corticosteroids in reducing morbidity and mortality in preterm births is well established
2. ANMs will give the pre-referral dose and refer the case at a higher facility for appropriate care
3. A single course comprising of four doses of Injection Dexamethasone to be given to all pregnant women going into preterm labour (24-34 weeks gestation)
4. Dose: Injection Dexamethasone 6 mg intramuscular repeated every 12 hours x 4 doses
5. Chorioamnionitis is an absolute contraindication to administer antenatal corticosteroids
6. Repeat course of antenatal steroids is not recommended
7. Monitoring and implementation of activities related to use of ANCS
8. Quality antenatal care, skilled attendance at birth, Kangaroo mother care for preterm and low birth weight babies will continue to contribute towards reducing the morbidity and mortality.

Action Plan for Implementation

State Level Activities

Communication from the state to the district should be issued to ensure the dissemination of these guidelines and if required, printing in the local language should be done.

1. State level orientation for all the stakeholders including private partners regarding the guidelines for use of Antenatal Corticosteroids to be organized.
2. Capacity building at the district level to be ensured so that the officials and ANMs are oriented towards the guidelines for giving Dexamethasone to pregnant women with preterm labour and make arrangements for referral under JSSK scheme to an appropriate facility.
3. Complete SBA training of ANMs and NSSK training the doctors in the delivery room with special focus on how to diagnose preterm labour, indications and contraindications for use of antenatal corticosteroids to avoid misuse/overuse of the medicine. Safe injection practices to be a part of the training and capacity building.
4. Ensure Injection Dexamethasone is listed in the essential drug list and is available at the facilities. The states must ensure regular procurement and availability of Injection Dexamethasone at all delivery points including sub-centres.
5. Ensure strict monitoring by the state nominated Maternal/Child Health/RCH officer to oversee the progress of the initiative by regular reporting and record keeping at all delivery points.
6. District wise data to be compiled quarterly and shared with Gol.

Ensure support of Professional bodies like FOGSI, IAP, IMA and NNF to ensure dissemination and increase awareness of the members in their regular meetings for use of ANCS for management of preterm labour. The services of the members/trainers may be utilized for Capacity building/Mentoring at the facilities if needed.

To amplify the useful effect of antenatal corticosteroid ensure skilled care at birth and appropriate care of preterm and low birth weight babies in KMC wards and SNCUs. Also strengthen the availability of effective referral linkages to tertiary level neonatal care units with SNCUs so that the critical care/ventilator support required by a preterm is available when needed.

District Level Activities

District Hospitals/Medical Colleges

Facility in-charges and or I/C of Obstetrics and Gynaecology Department to orient and take overall responsibility to ensure appropriate use of the ANCS for management of preterm labour. Ensure emphasizing on the key messages of the guidelines during teaching and trainings.

District Level Facilities under CMHO

1. CMHO/district training officers/RCHO to disseminate the guidelines and impart key messages from this guideline in the relevant trainings/meetings for service providers at delivery points at all levels.
2. CMHO will orient the block level medical officers, especially SBA trainers who in turn will orient the ANMs in the weekly review meetings.
3. During these meetings a feedback on the usage of the drug will also be taken once it gets implemented. Regular monitoring of supplies to avoid any stock out situations and corrective actions to be taken if such a situation arises.
4. CMHO/RCHO/Maternal/Child and District Training Officers to include the key actions from this guideline in the supportive supervision and monitoring visits to the delivery points at all levels.

Orientation

All the related trainings for medical officers/staff nurses/ANMs must incorporate the key messages and actions from the guidelines regarding use of Antenatal Corticosteroid. During SBA training to ANMs, special mention of these guidelines should be made as this empowers ANMs to give a pre-referral dose of antenatal corticosteroid. During these trainings the trainer, besides orienting the ANMs towards the guidelines while referring to the management of preterm labour, must highlight the indications, contraindications and doses.

Similarly during BemOC and CemOC trainings, use of ANCS in the management of preterm labour is to be emphasized and to orient the students the new guidelines are to be linked to the pre-service curriculum. The state and the districts within, must ensure that all the high caseload delivery points – especially Medical Colleges, District Hospitals and Sub District Hospitals are oriented towards these guidelines first as they will be catering to a large population and will also be serving as training centres. Safe injection practices and bio medical waste management are to be an integral part of the teaching.

Standard Flow Chart given along with guidelines should be made available to all service providers at all delivery points including labour room at a visible display point.

Logistics

The states to ensure the supplies of Injection Dexamethasone at all the delivery points up to the sub-centre level. The drug does not require refrigeration and can be easily stored at room temperature. This drug is listed in the essential Drug List and also in the ANM Kit of essential drugs. Therefore, ensuring availability at all health centres should not be difficult. The supply of drug is to be estimated for 10% of all the deliveries conducted at the delivery point. Ensure regular monitoring of stocks to provide timely feedback to districts to avoid stock out situations. The message to ensure availability in the drug tray of the labour room should be communicated.

Record Keeping and Reporting

The service provider of all the delivery points at all levels of public or private health facility will maintain the records for use of ANCS in the delivery registers, case sheets of the patients and the referral slips. Record keeping of ANCS administration will be done appropriately and validated from delivery room registers, case sheets, discharge tickets, referral registers. This information will be finally transferred into MCTS.

The key indicators described below should be compiled at the district level on monthly basis to measure the effective implementation of the guideline. Data will be compiled at the state level quarterly and reviewed before sharing at the national level.

Monitoring

Following indicators are to be monitored at the state level and compiled quarterly:

1. **% of pregnant women diagnosed with preterm labour (>24 weeks up to 34 weeks) receiving any dose of ANCS***

$$= \frac{\text{Number of pregnant women with preterm labour (>24 weeks up to 34 weeks) given ANCS}}{\text{Total number of preterm pregnant women identified with preterm labour (>24 weeks up to 34 weeks)}} \times 100$$

2. **% of pregnant women with preterm labour receiving full course of ANCS***

$$= \frac{\text{Number of pregnant women with preterm labour given ANCS full course}}{\text{Total number of preterm pregnant women identified with preterm labour}} \times 100$$

3. **% of newborns delivered up to 34 weeks requiring SNCU admissions****

$$= \frac{\text{Number of newborns delivered up to 34 weeks requiring SNCU admission}}{\text{Number of total newborns delivered up to 34 weeks}} \times 100$$

4. **Proportion of SNCU admissions up to 34 weeks receiving ANCS****

$$= \frac{\text{Number of newborns up to 34 weeks admitted to SNCUs whose mothers were treated with at least one dose of ANCS}}{\text{Total number of preterm admissions up to 34 weeks in SNCUs}} \times 100$$

Data Source:

* Indicators 1 & 2: Facility records

** Indicators 3 & 4: SNCU Records and SNCU online records

Evaluation

Since it is a new programmatic approach, comprehensive and strict monitoring of implementation has to be in place. A system of reporting and monitoring will have to be institutionalized.

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